From:	Jones, Jennifer L
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To:	'Darcy Adin'; Freeman, Lisa; Joshua A Stern; Fries, Ryan C; B6
CC:	Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent:	4/20/2018 5:18:50 PM
Subject:	RE: hold-call with Dr. Adin re: DCM cases
Attachments:	02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-Network
	ProceduresOwners-12.22.2015.pdf
and potentially act o report a pet food rep <u>rucm182403.htm</u> . Th nttps://www.safetyre	r joining us on the call and providing the information about your cases. To help us catalogue these adverse events, please file an official consumer complaint. Instructions on how to port can be found at: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem he complaint can be submitted through the Safety Reporting Portal: eporting.hhs.gov. You can attach documents already created that compile your case data. data and may contact you for possible follow-up.
dispose of the anima dog, and mention th for potential follow-u	you have a dog with DCM on a grain free diet that dies or is euthanized, please do not al's body or any remaining food. Please submit an individual consumer complaint for that nat you have been instructed to submit the report by Vet-LIRN. We will review the complain up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network scribe how we operate. I also included a version for animal owners.
Please email or call Jen	me with any questions. Thank you again for your time and expertise,
lannifor lance DV/M	
Jennifer Jones, DVM Veterinary Medical Off Tel: 240-402-5421	ficer
U.S. FOOD & DRUG	
	mailto:dbadin@ncsu.edu]
	ril 19, 2018 11:00 AM
	sa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C</jstern@ucdavis.edu>
<rfries@illinois.edu></rfries@illinois.edu>	
C <mark>c:</mark> Rotstein, David Siobhan <siobhan.[< td=""><td>Jennifer.Jones@fda.hhs.gov> <david.rotstein@fda.hhs.gov>; Norris, Anne <anne.norris@fda.hhs.gov>; DeLancey, Delancey@fda.hhs.gov> -call with Dr. Adin re: DCM cases</anne.norris@fda.hhs.gov></david.rotstein@fda.hhs.gov></td></siobhan.[<>	Jennifer.Jones@fda.hhs.gov> <david.rotstein@fda.hhs.gov>; Norris, Anne <anne.norris@fda.hhs.gov>; DeLancey, Delancey@fda.hhs.gov> -call with Dr. Adin re: DCM cases</anne.norris@fda.hhs.gov></david.rotstein@fda.hhs.gov>
Dear Dr. Jones,	
We are all able to m	eet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and
	ng a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.
Ors. B6 Freeman	n, B6 Fries and Stern - the call details are in the forwarded email below.
Just a brief introduc	tion for the FDA group:
	В6
Dr. Lisa Freeman is	B6 a Professor of Clinical Nutrition at Tufts University, College of Vet Med

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

Thank you everyone for making time in your schedule! I am looking forward to this.

Sincerely, Darcy Adin

----- Forwarded message -----

From: **Jones, Jennifer** L < <u>Jennifer.Jones@fda.hhs.gov</u>>

Date: Thu, Apr 19, 2018 at 7:16 AM

Subject: hold-call with Dr. Adin re: DCM cases

To: "Rotstein, David" < <u>David.Rotstein@fda.hhs.gov</u>>, "Norris, Anne" < <u>Anne.Norris@fda.hhs.gov</u>>, "DeLancey,

Siobhan" < Siobhan. Delancey@fda.hhs.gov >, Darcy Adin < dbadin@ncsu.edu >

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Darcy B. Adin, DVM, DACVIM (Cardiology) Clinical Assistant Professor of Cardiology North Carolina State University NC State Veterinary Hospital 1060 William Moore Drive Raleigh, NC 27607 919-513-6032



Network Procedures for Veterinarians

1. Introduction

The purpose of this Network Procedure is to facilitate basic interactions between the Vet-LIRN Program Office (VPO) and veterinarians participating in Vet-LIRN case investigations. General procedures such as information flow, sample handling procedures, submission of reports and billing for services are discussed. The focus of most Vet-LIRN case investigations is on diagnostic samples, although occasionally animal food samples will also be submitted. Animal food testing conducted after receiving a consumer complaint is typically handled by FDA's Office of Regulatory Affairs (ORA) Laboratories or accredited laboratories.

- 1.1 In the case of Vet-LIRN investigations, the government is the client.
 - 1.1.1 The government is requesting assistance in its investigation, and is requesting tests or services to be performed by your clinic during this investigation.
 - 1.1.2 The government will pay for these services.
 - 1.1.3 The owner is helping with the government's investigation of a regulated product.
 - 1.1.4 The goal of the investigation is to determine if the product is at fault and why.
 - 1.1.5 The government's investigation may not provide a definitive diagnosis for the patient's illness.

2. Case Background - Consumer complaint

- 2.1 Vet-LIRN obtains information about the cases we investigate from 3 main sources,
 - 2.1.1 Consumer complaints (cc) obtained by FDA Consumer Complaint Coordinators by phone
 - 2.1.2 Electronic consumer complaint submissions through FDA's Food Safety Reporting Portal, and
 - 2.1.3 Vet-LIRN partner laboratories.

NOTE: Generally, the information received in a consumer complaint **is not** kept confidential. In most cases, only protected personal information (such as names and addresses) is withheld in an effort to prevent the complaint from being traced back to the individual who submitted it.



3. Communications

- 3.1 VPO will discuss the case with the referring veterinarian and or the owner.
- 3.2 VPO evaluates the case history and determines a need for follow up testing to determine if the food (or drug) is the cause of the illness or death.
- 3.3 VPO contacts the appropriate member laboratory(-ies) (chosen based on location and capabilities) and provides initial information
 - 3.3.1 In some cases only partial history is available
 - 3.3.2 Follow up information will be sent as it becomes available.
- 3.4 VPO proposes the tests to be conducted and prepares billing documents.
- 3.5 VPO makes arrangements with the veterinarian to obtain and ship samples.
 - 3.5.1 VPO receives test results and forwards the results to the veterinarian who will then communicate the results to the owner.

4. Case history

- 4.1 A complete medical history is essential,
 - 4.1.1 age, sex, breed, animal's ID/name,
 - 4.1.2 other animals affected,
 - 4.1.3 duration of problem, lesion distribution (diagrams or photos are welcome),
 - 4.1.4 treatment of problem (especially dose and duration of therapy) and response to treatment.
 - 4.1.5 concomitant drugs or dietary supplements administered (not used for treatment of the reaction, but administered for other reasons at the same time or within a short time of the problem occurrence).
- 4.2 Vet-LIRN Case Numbers:
 - 4.2.1 Include Vet-LIRN case number in all correspondence.
 - 4.2.2 E-mail: include the Vet-LIRN case number as the first part of the subject line. This will help archiving data for each case.
- 4.3 Electronic submission of medical records and laboratory results is preferred.
- 4.4 Histories can also be submitted by FAX to Vet-LIRN (301-210-4685).
- 4.5 Information about follow-up visits related to the investigation and additional laboratory reports should be provided as soon as possible. Phone calls are very useful for



discussing cases in depth, but should be followed up with the medical records and lab reports.

4.5.1 Due to time difference around the country, email communication is often the best way to assure information is transferred in a timely manner.

5. Services Requested by VPO

- 5.1 Services typically tests will fall into 3 categories:
 - 5.1.1 Office Examination
 - 5.1.2 Clinical laboratory samples
 - 5.1.3 Pathology

5.2 Office Examination:

- 5.2.1 To evaluate the current status of the patient.
- 5.2.2 To obtain samples from the patient for further analysis (blood, urine, feces).

5.3 Clinical Laboratory Samples:

- 5.3.1 VPO may ask for repeat analysis of new samples to be run either by the veterinary hospital, or by its usual testing laboratory.
- 5.3.2 Typical tests include clinical hematology, microbial cultures, urinalysis, and fecal examination.
- 5.3.3 Additional testing may be requested and the samples sent to a Vet-LIRN network laboratory.

5.4 Pathology:

- 5.4.1 Either submit the entire carcass or conduct a routine necropsy examination. Record your findings in detail and submit. Histopathology and microbiological cultures as appropriate.
 - 5.4.1.1 Describe all lesions location, color, size, texture.
 - 5.4.1.2 Culture lesions or intestinal contents as deemed appropriate based on the history.
 - 5.4.1.3 Save tissues for histopathology- be sure to use 10:1 formalin to tissue mass.
- 5.4.2 Histopathology tissues (preserve in 10% neutral buffered formalin 10:1 ratio fixative to tissue):



- 5.4.2.1 thyroid, thymus, lung, heart, liver, spleen, adrenal, kidney, pancreas, stomach, duodenum, jejunum, ileum, colon, urinary bladder, skeletal muscle, brain.
- 5.4.2.2 Request a duplicate set of H&E for submission to VPO for archiving.

5.5 Toxicology:

- 5.5.1 Freeze and hold tissues if there is any indication that a toxic substance may be involved:
 - 5.5.1.1 brain (for organophosphates and carbamates),
 - 5.5.1.2 eyes, liver, kidney, brain, stomach content, fat,
 - 5.5.1.3 if available, serum, EDTA blood, urine.
- 5.5.2 Following a review of histopathology, VPO may select tissues to be analyzed and request that tissues be sent to a Vet-LIRN laboratory.
- 5.5.3 When the case is closed by VPO, samples can be disposed of. When in doubt, please ask.
 - 5.5.3.1 The animal's remains can be disposed of following the laboratories' customary procedures.

6. Sample submissions

- 6.1 Normally, VPO prefers that the veterinarian, not the pet owner submit samples.
- 6.2 Arrangements for transport should be made with the VPO (see additional shipping instructions).
- 6.3 A Vet-LIRN Sample Submission Form, given by VPO to the veterinarian, should be provided to the veterinarian and should accompany all samples being sent to our Vet-LIRN laboratory, listing the recommended tests.
- 6.4 A Shipping Inventory Sheet, given by VPO to the veterinarian, should also be provided by VPO and should be submitted with all samples. This form will be filled out and faxed to the VPO (301-210-4685) by the receiving Vet-LIRN laboratory.
- 6.5 Vet-LIRN case numbers should be provided by the VPO and should be included on all samples and reports.
 - 6.5.1 Rarely, an owner will deliver a specimen or an animal for necropsy directly to the participating laboratory. Vet-LIRN should notify the lab to expect the owner if this happens and will provide appropriate forms.



7. Sample types that Vet-LIRN may request from the Veterinarian

- 7.1 Entire bodies (fresh or frozen)
- 7.2 Organs from necropsy (fresh, frozen or formalin fixed)
- 7.3 Clinical samples (serum, blood, urine, feces, biopsy samples, cultures)
- 7.4 Food samples (open bag products from home)

8. Reporting

- 8.1 All reports from Vet-LIRN testing labs are submitted to VPO.
- 8.2 VPO will forward reports to the veterinarian, who should discuss the results with the owner.
- 8.3 If appropriate, VPO will forward reports to the owner.

9. Communications with Owners

- 9.1 General:
 - 9.1.1 VPO usually will have contacted the owner to request permission and assistance in the investigation.
 - 9.1.2 Vet-LIRN's investigation is focused on determining if a regulated product is the cause of the animal's illness. The testing requested by Vet-LIRN may not provide a definitive diagnosis
 - 9.1.3 VPO will provide testing results to the veterinarian for communication to the owner. This ensures that:
 - 9.1.3.1 Owners can be counseled on the interpretation of the test results,
 - 9.1.3.2 Appropriate medical follow-up care based on test results can be recommended by the owner's veterinarian.



10. Billing

- 10.1 Vet-LIRN VPO can only pay for services which were requested and approved by VPO. Vet-LIRN cannot pay for treatment, or for diagnostic testing outside of the scope of the investigation.
- 10.2 Procurement and Billing Process: The following process needs to be followed in order to adhere to government regulations.
 - 10.2.1 The veterinarian must provide estimates so a Purchase Request can be prepared. Estimates should include items such as office visit(s), in-house diagnostic test costs, biopsy or pathology costs and additional charges such as potential shipping charges.
 - 10.2.2 A billing contact must be provided: include name, address, telephone + fax numbers, and email.
 - 10.2.3 Approved Purchase Request is required prior to beginning service.
 - 10.2.4 Additional services may only be initiated after authorized by Vet-LIRN, but must first be approved by VPO with an additional Purchase Request.
 - 10.2.5 Hospitals must provide an invoice to Vet-LIRN upon the completion of work before they can be paid. VPO is tax exempt. Taxes should be removed from all charges. The invoice must include the Vet-LIRN case number.



Network Procedures for Owners

The purpose of this Network Procedure is to help you, the owner, understand how the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) Program Office conducts case investigations (follow up to consumer complaints).

The following items are explained below:

- General Introduction
- Billing
- Step by Step Process
- Types of Services and Tests

1. General Introduction:

1.1. What is the goal of the case investigation?

The goal of the case investigation is to determine if the product is causing your pet's illness. Our case investigation MAY NOT provide a definitive diagnosis for your pet's illness, although we may rule out several other potential reasons for your pet's illness.

1.2. What is the focus of a case investigation?

Most case investigations focus on diagnostic samples (such as blood, urine or tissue from the pet), although we occasionally request and test pet food samples.

1.3. What is my veterinarian's role during the case investigation?

Your veterinarian helps our investigation into FDA- regulated products by providing information about your pet's medical history and by obtaining any diagnostic samples like blood, urine or tissue.

1.4. What will Vet-LIRN ask of me during a case investigation?

We may ask that your veterinarian perform certain tests or services or provide diagnostic samples to FDA or a Vet-LIRN cooperating laboratory.



1.5. Will Vet-LIRN pay for tests or services requested?

Yes, we will pay veterinarians or laboratories *for tests or services requested by Vet-LIRN* and approved through our government purchasing system. We cannot, however, reimburse owners for tests already performed or not specifically requested by Vet-LIRN. We recommend that you discuss with your veterinarian which tests and services will be billed to you and which will be covered by Vet-LIRN. For instance, Vet-LIRN may request that your veterinarian perform a urinalysis on your pet while he or she is hospitalized. Vet-LIRN will pay for the collection and testing of the sample, but would not cover the cost of your pet's stay in the hospital.

1.6. Is the information received in the consumer complaint confidential?

Generally, the information received in the consumer complaint is not kept confidential. In most cases, only protected personal information (such as names and addresses) is withheld in an effort to prevent the complaint from being traced back to the individual who submitted it.

2. Billing:

2.1. Will Vet-LIRN pay for bills related to the case investigation?

Vet-LIRN will cover the cost of services and testing that we specifically request. You should understand that Vet-LIRN *CANNOT* reimburse owners for any veterinary bills. Services *MUST* be pre-authorized and paid directly to the veterinarian.

2.2. Will Vet-LIRN pay for testing that was not requested by Vet-LIRN?

No, we will only pay for testing that we request and authorize.

2.3. Will Vet-LIRN pay for treatments or private cremation?

No, we cannot pay for treatment or cremation.



2.4. If I allow my veterinarian to submit my pet's body for testing, will I be able to have back his or her remains?

Each Vet-LIRN member laboratory has its own procedures for handling remains. Some Vet-LIRN member laboratories offer private cremation services for a fee payable directly to the laboratory. We advise you to discuss directly with the member laboratory the possibilities and costs for obtaining your pet's remains after examination are complete.

3. Step by Step Process:

Vet-LIRN will do the following during a case investigation:

- 3.1. Assign a case number which MUST be included in all correspondences
- 3.2. Discuss the case with you and your veterinarian
- 3.3. Request medical records from your veterinarian
- 3.4. Coordinate with your veterinarian and you to obtain and submit samples for testing
- 3.5. Provide results to your veterinarian who will discuss the results with you.

Vet-LIRN requests that:

- 3.6. Any follow-up veterinary visits related to the investigation are reported to Vet-LIRN
- 3.7. Additional laboratory reports are reported to Vet-LIRN by your veterinarian.

4. Types of Services and Tests:

4.1. What may a veterinary examination include once the case investigation is started?

A veterinary examination may include:

- an office visit and physical examination to assess your animals current health
- collection of clinical samples from your animal (blood, urine, feces).

4.2. Will your animal be tested more than once?



It is possible that Vet-LIRN may request additional tests or examinations depending on results from initial testing.

4.3. Will Vet-LIRN need to conduct a necropsy in the event of an animal death?

Yes, if you are willing, we may request that your veterinarian or another Vet-LIRN cooperating laboratory to conduct a necropsy to collect samples for testing. The samples collected may be tested right away or may be held for future testing or archiving. If the veterinarian completes the necropsy then the remains will be handled according the veterinarians normal procedures. If a Vet-LIRN cooperative laboratory completes the necropsy the remains are usually disposed of by that laboratory. Vet-LIRN cannot pay for private cremation. You are welcome to discuss normal procedures with the laboratory.

4.4. Will Vet-LIRN ask for a food sample?

Our main focus is on testing diagnostic tissue or fluid samples from the animal, but we may need to test the food. Please hold all food samples once the consumer complaint is submitted. If needed, we will make arrangements to collect the food.

4.5. What are some general tests that Vet-LIRN may request?

General tests that we may request include, but are not limited to:

- Hematology
- Microbial cultures
- Urinalysis
- Fecal examination
- Necropsy/Histology/Toxicology

4.6. Will I get results from Vet-LIRN requested tests?

Results of testing on your animal's diagnostic tissue or fluid samples will be forwarded to your veterinarian who will be asked to share the results with you.

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER> To: Rotstein, David: Jones, Jennifer L Sent: 4/30/2018 8:15:16 PM Subject: RE: DCM cases - proposed diet history Thanks – on my list for tomorrow morning to have a read – the day has flown by. The good news – they reinstalled SAS and JMP today, so baby steps... From: Rotstein, David Sent: Friday, April 27, 2018 9:00 PM To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> Subject: Fwd: DCM cases - proposed diet history Lee Anne, Thought you would be interested and could provide any comments/suggestions **From:** Freeman, Lisa <Lisa.Freeman@tufts.edu> **Date:** April 27, 2018 at 7:27:27 PM EDT To: Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >, Darcy Adin < dbadin@ncsu.edu >, Joshua A Stern <<u>istern@ucdavis.edu</u>>, Fries, Ryan C <<u>rfries@illinois.edu</u>>, B6 Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan Siobhan. Delancey@fda.hhs.gov>, Ceric, Olgica Solgica. Ceric@fda.hhs.gov> **Subject:** DCM cases - proposed diet history Hi everyone I'm attaching a proposed diet history form. I met with our cardiology group yesterday **B5** Please let me know if you have any comments -Our group also discussed a **B5** B5 Thanks Lisa Lisa M. Freeman, DVM, PhD, DACVN Professor **Cummings School of Veterinary Medicine** Friedman School of Nutrition Science and Policy Tufts Clinical and Translational Science Institute **Tufts University**

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]

Sent: Friday, April 20, 2018 3:50 PM

To: Darcy Adin <<u>dbadin@ncsu.edu</u>>; Freeman, Lisa <<u>Lisa.Freeman@tufts.edu</u>>; Joshua A Stern

<<u>jstern@ucdavis.edu</u>>; Fries, Ryan C <<u>rfries@illinois.edu</u>>;

B6

B6

Cc: Rotstein, David <<u>David Rotstein@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey,

Siobhan < Siobhan. Delancey@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >

Subject: RE: hold-call with Dr. Adin re: DCM cases

Importance: High

My apologies for the repeat email. After further internal discussion, in lieu of submitting Consumer Complaints, you can just email me a spreadsheet with the data.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Jones, Jennifer L

Sent: Friday, April 20, 2018 1:19 PM

To: 'Darcy Adin' dbadin@ncsu.edu; Freeman, Lisa lisa.freeman@tufts.edu; Joshua A Stern

<istern@ucdavis.edu; Fries, Ryan C : B6

Cc: Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey,

Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>

Subject: RE: hold-call with Dr. Adin re: DCM cases

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, please file an official consumer complaint. Instructions on how to report a pet food report can be found at: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm. The complaint can be submitted through the Safety Reporting Portal: https://www.safetyreporting.hhs.gov. You can attach documents already created that compile your case data. We will review the data and may contact you for possible follow-up.

In the meantime, if you have a dog with DCM on a grain free diet that dies or is euthanized, please do not dispose of the animal's body or any remaining food. Please submit an individual consumer complaint for that dog, and mention that you have been instructed to submit the report by Vet-LIRN. We will review the complaint for potential follow-up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network procedures that describe how we operate. I also included a version for animal owners.

Please email or call me with any questions. Thank you again for your time and expertise, Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, April 19, 2018 11:00 AM

To: Freeman, Lisa < lisa.freeman@tufts.edu>; Joshua A Stern < jstern@ucdavis.edu>; Fries, Ryan C

< <u>rfries@illinois.edu</u> >; B6
Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u> >; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u> >
Subject: Fwd: hold-call with Dr. Adin re: DCM cases
Dear Dr. Jones,
We are all able to meet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and
concerns surrounding a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.
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Drs. B6 , Freeman, B6 Fries and Stern - the call details are in the forwarded email below.
Just a brief introduction for the FDA group:
B6
Dr. Lisa Freeman is a Professor of Clinical Nutrition at Tufts University, College of Vet Med
B6
Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med
Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med
Thank you everyone for making time in your schedule! I am looking forward to this.
Sincerely,
Darcy Adin
Durcy 1xdiii
Forwarded message
From: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov > Date: Thu. Apr. 10, 2018 et 7:16 AM
Date: Thu, Apr 19, 2018 at 7:16 AM Subject: hold-call with Dr. Adin re: DCM cases
To: "Rotstein, David" < David.Rotstein@fda.hhs.gov >, "Norris, Anne" < Anne.Norris@fda.hhs.gov >, "DeLancey,
Siobhan" <siobhan.delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu></dbadin@ncsu.edu></siobhan.delancey@fda.hhs.gov>
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Meeting password: B6

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+1-877-465-7975 US Toll Free

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--

Darcy B. Adin, DVM, DACVIM (Cardiology) Clinical Assistant Professor of Cardiology North Carolina State University NC State Veterinary Hospital 1060 William Moore Drive Raleigh, NC 27607 919-513-6032

Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER> To: Rotstein, David; Jones, Jennifer L 5/1/2018 1:38:39 PM Sent: Subject: RE: DCM cases - proposed diet history Thanks – this is a great dietary history. My only comments: **B5** Thanks for the opportunity to comment! Lee Anne From: Rotstein, David Sent: Friday, April 27, 2018 9:00 PM To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> Subject: Fwd: DCM cases - proposed diet history Lee Anne, Thought you would be interested and could provide any comments/suggestions **From:** Freeman, Lisa <Lisa.Freeman@tufts.edu> **Date:** April 27, 2018 at 7:27:27 PM EDT To: Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >, Darcy Adin < dbadin@ncsu.edu >, Joshua A Stern <istern@ucdavis.edu>, Fries, Ryan C <rfries@illinois.edu>; B6 Cc: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>, Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >, Ceric, Olgica < Olgica. Ceric@fda.hhs.gov > Subject: DCM cases - proposed diet history Hi everyone I'm attaching a proposed diet history form. I met with our cardiology group yesterday Please let me know if you have any comments **B5**

B5

Our group also discussed

B5

B5

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]

Sent: Friday, April 20, 2018 3:50 PM

To: Darcy Adin dbadin@ncsu.edu; Freeman, Lisa Lisa.Freeman@tufts.edu; Joshua A Stern

size-up">size-up">s

B6

Cc: Rotstein, David < David.Rotstein@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; DeLancey,

Siobhan < Siobhan. Delancey@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >

Subject: RE: hold-call with Dr. Adin re: DCM cases

Importance: High

My apologies for the repeat email. After further internal discussion, in lieu of submitting Consumer Complaints, you can just email me a spreadsheet with the data.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Friday, April 20, 2018 1:19 PM

To: 'Darcy Adin' <dbadin@ncsu.edu>; Freeman, Lisa lisa.freeman@tufts.edu>; Joshua A Stern

<<u>istern@ucdavis.edu</u>>; Fries, Ryan C <<u>rfries@illinois.edu</u>>; B6

B6

Cc: Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey,

Siobhan < Siobhan. Delancey@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >

Subject: RE: hold-call with Dr. Adin re: DCM cases

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, please file an official consumer complaint. Instructions on how to report a pet food report can be found at: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm. The complaint can be submitted through the Safety Reporting Portal:

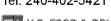
https://www.safetyreporting.hhs.gov. You can attach documents already created that compile your case data. We will review the data and may contact you for possible follow-up.

In the meantime, if you have a dog with DCM on a grain free diet that dies or is euthanized, please do not

dispose of the animal's body or any remaining food. Please submit an individual consumer complaint for that dog, and mention that you have been instructed to submit the report by Vet-LIRN. We will review the complaint for potential follow-up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network procedures that describe how we operate. I also included a version for animal owners.

Please email or call me with any questions. Thank you again for your time and expertise, Jen

Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421





From: Darcy Adin	<u>mailto:dbadir</u>	<u>n@ncsu.edu</u>
Sent: Thursday, Ap	oril 19, 2018 1	11:00 AM

To: Freeman, Lisa lisa.freeman@tufts.edu; Joshua A Stern lisa.freeman@tufts.edu; Fries, Ryan C

<rfries@illinois.edu>;

Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>

Cc: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey,

Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

We are all able to meet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and concerns surrounding a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.

Drs. **B6** Freeman, **B6** Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

B6

Dr. Lisa Freeman is a Professor of Clinical Nutrition at Tufts University, College of Vet Med

B6

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

Thank you everyone for making time in your schedule! I am looking forward to this.

Sincerely,

Darcy Adin

----- Forwarded message -----

From: **Jones, Jennifer L** < Jennifer. Jones@fda.hhs.gov>

Date: Thu, Apr 19, 2018 at 7:16 AM

Subject: hold-call with Dr. Adin re: DCM cases

To: "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey,

Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

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--

Darcy B. Adin, DVM, DACVIM (Cardiology) Clinical Assistant Professor of Cardiology North Carolina State University NC State Veterinary Hospital 1060 William Moore Drive Raleigh, NC 27607 919-513-6032

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

To: Jones, Jennifer L; Rotstein, David; Carey, Lauren

Sent: 5/7/2018 6:07:39 PM

Subject: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx **Attachments:** Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Ingredient listing by Atypical vs Typical Breed for Canine DCM

		Т	уріса	l vs Atypical		
	A	typical	7	「ypical		All
Ingredient	N	% of Total	N	% of Total	N	% of Total
Folic Acid	35	2.45%	4	0.28%	39	2.73%
Biotin	31	2.17%	4	0.28%	35	2.45%
Peas	31	2.17%	4	0.28%	35	2.45%
Pyridoxine hydrochloride	31	2.17%	4	0.28%	35	2.45%
Thiamine mononitrate	31	2.17%	4	0.28%	35	2.45%
Vitamin E Supplement	31	2.17%	4	0.28%	35	2.45%
Niacin supplement	31	2.17%	3	0.21%	34	2.38%
Vitamin B12 Supplement	29	2.03%	4	0.28%	33	2.31%
Vitamin D3 Supplement	29	2.03%	4	0.28%	33	2.31%
Natural Flavor	27	1.89%	4	0.28%	31	2.17%
Copper proteinate	26	1.82%	3	0.21%	29	2.03%
Manganese proteinate	26	1.82%	3	0.21%	29	2.03%
Flaxseed	26	1.82%	2	0.14%	28	1.96%
Calcium iodate	23	1.61%	4	0.28%	27	1.89%
Iron Proteinate	24	1.68%	3	0.21%	27	1.89%
Riboflavin Supplement	22	1.54%	4	0.28%	26	1.82%
Salt	22	1.54%	4	0.28%	26	1.82%
Calcium carbonate	20	1.40%	4	0.28%	24	1.68%
Choline chloride	20	1.40%	4	0.28%	24	1.68%
Zinc Proteinate	21	1.47%	3	0.21%	24	1.68%
Vitamin A Supplement	20	1.40%	3	0.21%	23	1.61%
Potassium Chloride	17	1.19%	4	0.28%	21	1.47%
Sodium Selenite	18	1.26%	3	0.21%	21	1.47%
Sunflower oil	20	1.40%	1	0.07%	21	1.47%
Calcium pantothenate	17	1.19%	1	0.07%	18	1.26%
Rosemary extract	16	1.12%	2	0.14%	18	1.26%
Chickpeas	16	1.12%	1	0.07%	17	1.19%
Green lentils	16	1.12%	1	0.07%	17	1.19%
Pea Protein	13	0.91%	4	0.28%	17	1.19%
Red lentils	16	1.12%	1	0.20%	17	1.19%
d-Calcium pantothenate	14	0.98%	3	0.07%	17	1.19%
	14	0.98%	1	0.21%	15	1.19%
Kangaroo Pea Fiber	13	0.98%	1	0.07%	14	0.98%
Probiotics	13	0.91%	1	0.07%	14	0.98%
100 S. School St. (1) S. (1) S	12	0.91%	1	0.07%	13	0.98%
Dicalcium Phosphate	10	0.70%	3		13	
Yucca schidigera extract	10		2	0.21%	12	0.91%
Alfalfa Meal		0.70%		0.14%		0.84%
Mixed Tocopherols	10	0.70%	2	0.14%	12	0.84%
Pea Flour	11	0.77%	1	0.07%	12	0.84%
Beta Carotene	11	0.77%	0	0.00%	11	0.77%
Betaine Hydrochloride	11	0.77%	0	0.00%	11	0.77%
Copper sulfate	8	0.56%	3	0.21%	11	0.77%
DL-methionine	11	0.77%	0	0.00%	11	0.77%
Ferrous sulfate	8	0.56%	3	0.21%	11	0.77%
Lactic acid	8	0.56%	3	0.21%	11	0.77%
Zinc Sulfate	10	0.70%	1	0.07%	11	0.77%
Sweet potatoes	8	0.56%	2	0.14%	10	0.70%
Taurine	7	0.49%	3	0.21%	10	0.70%

	_			al vs Atypical		
	-	/pical		Typical		All
Ingredient		% of Total		% of Total	N	% of Total
Cobalt proteinate	8	0.56%	1	0.07%	9	0.63%
Riboflavin supplement	9	0.63%		0.00%	9	0.63%
salt	9	0.63%	0	0.00%	9	0.63%
Apples	6	0.42%	2	0.14%	8	0.56%
Blueberries	7	0.49%	1	0.07%	8	0.56%
Carrots	8	0.56%	0	0.00%	8	0.56%
Manganese sulfate	7	0.49%	1	0.07%	8	0.56%
Potato	7	0.49%	1	0.07%	8	0.56%
Potassium Iodide	7	0.49%	0	0.00%	7	0.49%
Selenium yeast	6	0.42%	1	0.07%	7	0.49%
Vitamin A Acetate	7	0.49%	0	0.00%	7	0.49%
Cranberries	5	0.35%	1	0.07%	6	0.42%
Dried Tomato Pomace	4	0.28%	2	0.14%	6	0.42%
Kangaroo meal	5	0.35%	1	0.07%	6	0.42%
Manganese Oxide	4	0.28%	2	0.14%	6	0.42%
Salmon Oil	6	0.42%	0	0.00%	6	0.42%
Salmon meal	3	0.21%	3	0.21%	6	0.42%
Spinach	6	0.42%	0	0.00%	6	0.42%
Acetate	4	0.28%	1	0.07%	5	0.35%
Alfalfa	5	0.35%	0	0.00%	5	0.35%
Ascorbic acid	5	0.35%	0	0.00%	5	0.35%
Canola oil	4	0.28%	1	0.07%	5	0.35%
Lamb meal	5	0.35%	0	0.00%	5	0.35%
Lentils	5	0.35%	0	0.00%	5	0.35%
Parsley	4	0.28%	1	0.07%	5	0.35%
Vitamin A	4	0.28%	1	0.07%	5	0.35%
Zinc proteinate	5	0.35%	0	0.00%	5	0.35%
Beta-Carotene	2	0.14%	2	0.14%	4	0.28%
Cheese	4	0.28%	0	0.00%	4	0.28%
Dried Whole Egg	4	0.28%	0	0.00%	4	0.28%
Duck	4	0.28%	0	0.00%	4	0.28%
Duck meal	4	0.28%	0	0.00%	4	0.28%
Minerals	4	0.28%	0	0.00%	4	0.28%
Pumpkin	1	0.07%	3	0.21%	4	0.28%
Salmon	2	0.14%	2	0.14%	4	0.28%
Sorbic Acid	4	0.28%	0	0.00%	4	0.28%
Vitamins	4	0.28%	0	0.00%	4	0.28%
Celery	3	0.21%		0.00%	3	0.21%
Chicken fat	3	0.21%	0	0.00%	3	0.21%
Chicken meal	3	0.21%		0.00%	3	0.21%
Cobalt Amino Acid Complex	3	0.21%		0.00%	3	0.21%
	3			0.00%	3	0.21%
Copper Amino Acid Complex DL Methionine	2	0.21% 0.14%			3	
				0.07%		0.21%
Inositol	1	0.07%		0.14%	3	0.21%
Iron Amino Acid Complex	3	0.21%		0.00%	3	0.21%
L-Ascorbyl-2-Polyphosphate	1	0.07%		0.14%	3	0.21%
Lamb	3	0.21%		0.00%	3	0.21%
Lettuce	3	0.21%		0.00%	3	0.21%
Manganese Amino Acid Complex	3	0.21%	0	0.00%	3	0.21%
Menadione sodium bisulfite complex	1	0.07%		0.14%	3	0.21%
Poultry fat	1	0.07%	2	0.14%	3	0.21%

				al vs Atypical		
		typical		Typical	2.2	All
Ingredient	N	% of Total		% of Total	N	% of Total
Turkey meal	3	0.21%		0.00%	3	0.21%
Zinc Amino Acid Complex	3	0.21%		0.00%	3	0.21%
peas	3	0.21%		0.00%	3	0.21%
Beet Pulp	2	0.14%		0.00%	2	0.14%
Broccoli	2	0.14%		0.00%	2	0.14%
Brown Rice	1	0.07%	1	0.07%	2	0.14%
Caramel color	1	0.07%	1	0.07%	2	0.14%
Chicken Fat	2	0.14%	0	0.00%	2	0.14%
Chickory Root Extract	2	0.14%	0	0.00%	2	0.14%
Chicory root	1	0.07%	1	0.07%	2	0.14%
Citric acid	0	0.00%	2	0.14%	2	0.14%
Cobalt carbonate	2	0.14%	0	0.00%	2	0.14%
Copper Amino Acid Chelate	1	0.07%	1	0.07%	2	0.14%
Deboned Salmon	1	0.07%	1	0.07%	2	0.14%
Deboned chicken	2	0.14%	0	0.00%	2	0.14%
Dried Kelp	1	0.07%		0.07%	2	0.14%
Flaxseed oil	2	0.14%		0.00%	2	0.14%
Garbonzo bean	0	0.00%		0.14%	2	0.14%
Iron Amino Acid Chelate	1	0.07%		0.07%	2	0.14%
L-carnitine	1	0.07%		0.07%	2	0.14%
L-lysine	1	0.07%		0.07%	2	0.14%
Manganese Amino Acid Chelate	1	0.07%		0.07%	2	0.14%
Pomegranate	2	0.07%		0.00%	2	0.14%
Pork Fat	2	0.14%		0.00%	2	0.14%
Pork Liver	2	0.14%		0.00%	2	0.14%
Pork Liver Pork Meat Meal	2	0.14%		0.00%	2	0.14%
	2				2	
Rabbit		0.14%		0.00%		0.14%
Rabbit Meal	2	0.14%		0.00%	2	0.14%
Tomato pomace	2	0.14%		0.00%	2	0.14%
Tomatoes	2	0.14%		0.00%	2	0.14%
Venison	2	0.14%		0.00%	2	0.14%
Vitamin B12 Lactic Supplement	2	0.14%		0.00%	2	0.14%
Watercress	2	0.14%		0.00%	2	0.14%
Zinc Amino Acid Chelate	1	0.07%		0.07%	2	0.14%
Zinc Oxide	0	0.00%		0.14%	2	0.14%
Alfalfa sprouts	1	0.07%		0.00%	1	0.07%
Animal digest	1	0.07%		0.00%	1	0.07%
Animal fat	1	0.07%		0.00%	1	0.07%
Barley	1	0.07%	0	0.00%	1	0.07%
Barley grass	0	0.00%	1	0.07%	1	0.07%
Betaine	1	0.07%	0	0.00%	1	0.07%
Bison	1	0.07%	0	0.00%	1	0.07%
Brewers Rice	1	0.07%	0	0.00%	1	0.07%
Brewers Yeast	1	0.07%	0	0.00%	1	0.07%
Calcium Iodate	1	0.07%	0	0.00%	1	0.07%
Calcium phosphate	1	0.07%		0.00%	1	0.07%
Cauliflower	1	0.07%		0.00%	1	0.07%
Chicken	1	0.07%		0.00%	1	0.07%
Chicken cartilage	1	0.07%		0.00%	1	0.07%
Chicory Root	1	0.07%		0.00%	1	0.07%
Chicory root extract	1	0.07%		0.00%	1	0.07%
Critically root extract	1	0.0770	U	0.00/0	1	0.07/0

				al vs Atypical		A II
I	_	pical		Typical % of Total	NI	All % of Total
Ingredient	N	% of Total	N		N	
Cinnamon Cobalt Amino Acid Chelate		0.07%	15	0.00%	1	0.07%
2 Secretary Control of the Control o	1	0.07%	0	0.00%	1	0.07%
Corn gluten meal		0.07%	0	0.00%	-	0.07%
Deboned Beef	1	0.07%	0	0.00%	1	0.07%
Deboned Turkey	1	0.07%	0	0.00%	1	0.07%
Deboned buffalo	1	0.07%	0	0.00%	1	0.07%
Deboned duck	1	0.07%	0	0.00%	1	0.07%
Deflourinated Tricalcium Phosphate	1	0.07%	0	0.00%	1	0.07%
Dried Seaweed Meal	1	0.07%	0	0.00%	1	0.07%
Dried Yeast	0	0.00%	1	0.07%	1	0.07%
Dried kelp	1	0.07%	0	0.00%	1	0.07%
Duck fat	1	0.07%	0	0.00%	1	0.07%
Ergocalciferol	1	0.07%	0	0.00%	1	0.07%
Faba Beans	1	0.07%	0	0.00%	1	0.07%
Fennel	1	0.07%	0	0.00%	1	0.07%
Fish oil	0	0.00%	1	0.07%	1	0.07%
Garlic oil	1	0.07%	0	0.00%	1	0.07%
Glucosamine hydrochloride	1	0.07%	0	0.00%	1	0.07%
Glycerin	1	0.07%	0	0.00%	1	0.07%
Green tea extract	1	0.07%	0	0.00%	1	0.07%
Guar gum	1	0.07%	0	0.00%	1	0.07%
Inulin	1	0.07%	0	0.00%	1	0.07%
L-lysine monohydrochloride	1	0.07%	0	0.00%	1	0.07%
Manganous oxide	1	0.07%	0	0.00%	1	0.07%
Natural Chicken flavor	1	0.07%	0	0.00%	1	0.07%
Natural Pork flavor	1	0.07%	0	0.00%	1	0.07%
Nicotinic acid	0	0.00%	1	0.07%	1	0.07%
Oatmeal	0	0.00%	1	0.07%	1	0.07%
Oats	1	0.07%	0	0.00%	1	0.07%
Olive oil	1	0.07%	0	0.00%	1	0.07%
Papayas	1	0.07%	0	0.00%	1	0.07%
Pea flour	1	0.07%	0	0.00%	1	0.07%
Peppermint	1	0.07%	0	0.00%	1	0.07%
Pheasant	1	0.07%	0	0.00%	1	0.07%
Pork fat	1	0.07%	0	0.00%	1	0.07%
Pork liver	1	0.07%	0	0.00%	1	0.07%
Pork meal	1	0.07%	0	0.00%	1	0.07%
Potato protein	1	0.07%	0	0.00%	1	0.07%
Potato starch	0	0.00%	1	0.07%	1	0.07%
Poultry by-product meal	1	0.07%	0	0.00%	1	0.07%
Quail	1	0.07%	0	0.00%	1	0.07%
Quinoa	1	0.07%	0	0.00%	1	0.07%
Raspberries	1	0.07%	0	0.00%	1	0.07%
Rosemary oil	0	0.00%	1	0.07%	1	0.07%
Salmon Meal	1	0.07%	0	0.00%	1	0.07%
Salmon oil	1	0.07%	0	0.00%	1	0.07%
Soybean meal	1	0.07%	0	0.00%	1	0.07%
Spearmint extract	1	0.07%	0	0.00%	1	0.07%
Sulfur	1	0.07%	0	0.00%	1	0.07%
Tapioca	1	0.07%	0	0.00%	1	0.07%
Tomato powder	1	0.07%	0	0.00%	1	0.07%
Tomato powdel	-	0.0770	U	0.0070		0.0770

			Typica	ıl vs Atypical		
	Α	typical		ГурісаІ		All
Ingredient	N	% of Total	N	% of Total	N	% of Total
Turkey	1	0.07%	0	0.00%	1	0.07%
Turmeric	0	0.00%	1	0.07%	1	0.07%
Vitamin D Supplement	1	0.07%	0	0.00%	1	0.07%
Water for Processing	1	0.07%	0	0.00%	1	0.07%
Whole Grain Corn	1	0.07%	0	0.00%	1	0.07%
Whole Grain Wheat	1	0.07%	0	0.00%	1	0.07%
Wild boar	1	0.07%	0	0.00%	1	0.07%
Yellow squash	1	0.07%	0	0.00%	1	0.07%
Zinc oxide	1	0.07%	0	0.00%	1	0.07%
Zucchini	1	0.07%	0	0.00%	1	0.07%
alfalfa	1	0.07%	0	0.00%	1	0.07%
potatoes	1	0.07%	0	0.00%	1	0.07%
unknown	1	0.07%	0	0.00%	1	0.07%
L-Ascorbyl-2-Polyphosphate	0	0.00%	1	0.07%	1	0.07%
All	1243	86.98%	186	13.02%	1429	100.00%

¹ row has been excluded.

Document properties

Author: Palmer, Lee Anne Template: Normal.dotm

Page count: 2

Paragraph count: 1525

Line count: 1529 Word count: 1739

Character count (spaces excluded): 6739 Character count (spaces included): 6956 From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren

Sent: 5/8/2018 11:09:29 AM

Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Thank you, Lee Anne! This is great. Here's the list of product I sent for comparison Cystine, Taurine, and Methionine Testing. Let me know if you want the full ingredients to do Odds Ratios, etc. As I mentioned yesterday at OSC council, I listed in the far right column the ingredients in common between the non-GF and GF diets if the ingredient was more frequent than 14 in the frequency chart you sent. A lot of the nonGF foods also contained peas (which was surprising), but they were much lower on the ingredient list...

<u>Case ID</u>	Product Name	<u>Type</u>	<u>Grains</u>
		-	
800.216-sub 2		Grains	brown rice, corn, barley
800.215-sub 5		Grains	rice, rye flour, brown rice barley
800.210-sub 1		Grains	corn gluten meal, rice, b
800.194-sub 1		Grains	brewers rice, corn gluter wheat flour
800.240-sub 1	B4	Grains	corn, sorghum
800.240-sub 2		Grains	corn, sorghum
800.240-sub 3		Grains	corn, sorghum, brewers
800.240-sub 4		Grains	corn, sorghum,
800.250-sub 1		Grain Free-No PFRs	Grain FREE

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Monday, May 07, 2018 2:42 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Lee Anne.

It was all very helpful!

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT





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	pical vs Typical Breed for Canine DCM.docx
B5 ,	B5 Sorry about that, was answering the question you didn't ask!
- B B	
_auren < <u>Lauren.Carey@fda.hhs.gov</u> >	oical vs Typical Breed for Canine DCM.docx
_auren < <u>Lauren.Carey@fda.hhs.gov</u> > Subject: RE: Ingredient listing by Atyp	

From: Rotstein, David

Sent: Monday, May 7, 2018 2:19 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Lee Anne,

B5

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT











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From: Palmer, Lee Anne

Sent: Monday, May 07, 2018 2:16 PM

To: Rotstein, David < David.Rotstein@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; Carey,

Lauren < Lauren. Carey@fda.hhs.gov>

Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

B5

From: Rotstein, David

Sent: Monday, May 7, 2018 2:10 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

Carey, Lauren < Lauren. Carey@fda.hhs.gov>

Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Lee Anne.

Thank you.

I think

B5

Martine emailed me for an update.

Dave

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6 (BB)













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From: Palmer, Lee Anne

Sent: Monday, May 07, 2018 2:08 PM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Carey,

Lauren <Lauren.Carey@fda.hhs.gov>

Subject: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To: Rotstein, David; Palmer, Lee Anne; Hartogensis, Martine

CC: Burkholder, William; Carey, Lauren; Norris, Anne; DeLancey, Siobhan; Lovell, Randall A

Sent: 5/14/2018 11:09:04 AM

Subject: RE: DCM and meetign with Cardiac Care for Pets

I'll be interested to see	B5
B5	

Based on those results, Lee Anne's analysis, and thoughts from managament, Vet-LIRN could:

B5

<u>Case ID</u>	<u>Product Name</u>	<u>Type</u>	<u>Grains</u>
		-	
800.216-sub 2		Grains	brown rice, corn, barley
800.215-sub 5		Grains	rice, rye flour, brown rice barley
800.210-sub 1		Grains	corn gluten meal, rice, b
800.194-sub 1	D A	Grains	brewers rice, corn gluter wheat flour
800.240-sub 1	B4	Grains	corn, sorghum
800.240-sub 2		Grains	corn, sorghum
800.240-sub 3		Grains	corn, sorghum, brewers
800.240-sub 4		Grains	corn, sorghum,
800.250-sub 1		Grain Free-No PFRs	Grain FREE

Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421





From: Rotstein, David

Sent: Friday, May 11, 2018 6:06 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William. Surkholder@fda.hhs.gov>; Carey, Lauren < Lauren. Carey@fda.hhs.gov>; Norris, Anne < Anne. Norris@fda.hhs.gov>; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>; Lovell, Randall A < Randall. Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne and Jen,

which is the day CVCA is available. I made you both alternate hosts.

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6





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From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>;

Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic. **B5**



From: Palmer, Lee Anne < <u>Lee Anne Palmer@fda.hhs.gov</u>>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David < David. Rotstein@fda.hhs.gov>, Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>,

Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>,

Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >, Lovell,

Randall A < Randall.Lovell@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there –	B5
B5	

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne



From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne < <u>Lee Anne Palmer@fda.hhs.gov</u>>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>, Rotstein, David < David.Rotstein@fda.hhs.gov>,

Jones, Jennifer L < Jennifer. Jones @fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>,

Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

I want to confirm it, then will send it along – could be Friday before I get this in shape to sena...not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer,

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

Sent: Wednesday, May 09, 2018 2:06 PM To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov> Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets Good Afternoon. I spoke with **B6** Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point. Just some basic information: As a side note, there is a facebook page dedicated to this issue: https://www.facebook.com/groups/1952593284998859/about/ David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place **B6** U.S. FOOD & DRUG ADMINISTRATION This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov. From: Hartogensis, Martine Sent: Tuesday, May 08, 2018 10:58 AM To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Rotstein, David < David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov> Subject: RE: DCM **B6** Thank you Jen and Dave! Very interesting and sounds like you all are on it! **B6 B6**

From: Rotstein, David

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>

Subject: RE: DCM

Martine,



Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6











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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

Subject: RE: DCM



Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

Subject: Re: DCM

Martine

Lee Anne will likely		B5_		
В	5			
-				
Vet-LIRN is looking into		B5		
- bratatatatatatata	B5	07077777777777777777777777777777777777	JT17171717171717171717171	
There's a way to go on this moving	g forward.			

Dave

From: Hartogensis, Martine Martine.Hartogensis@fda.hhs.gov

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-

MHARTOGE>

To: Rotstein, David; Burkholder, William; Palmer, Lee Anne; Jones, Jennifer L; DeLancey, Siobhan CC:

Carey, Lauren; Norris, Anne; Lovell, Randall A; Reimschuessel, Renate; Ceric, Olgica; Nemser,

Sarah; Conway, Charlotte; Edwards, David; Atkinson, Krisztina Z; Hodges, April

5/21/2018 11:50:08 AM Sent:

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent, thank you!

Martine

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

В5

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

> **B6** BB)













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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan

< Siobhan. Delancey@fda.hhs.gov>; Rotstein, David < David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren < Lauren. Carey@fda.hhs.gov >; Norris, Anne < Anne. Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica

<<u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah <<u>Sarah.Nemser@fda.hhs.gov</u>>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z < Krisztina. Atkinson@fda.hhs.gov> Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets Thanks Bill and your concerns are noted! **B**5 Thank you all for your help and dedication to this fascinating issue! Martine From: Burkholder, William Sent: Friday, May 18, 2018 5:04 PM **To:** Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Hartogensis, Martine < Martine < Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov> Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z < Krisztina. Atkinson@fda.hhs.gov> Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets **B5 B5** At this point I think

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Hartogensis, Martine

< <u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets



Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David

<<u>David.Rotstein@fda.hhs.g</u>ov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421





From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>;

Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel,

Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 6:42 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; DeLancey, Siobhan

< <u>Siobhan.Delancey@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >; Palmer, Lee Anne

<<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!	One question though	do we see any	issues	B5
R5				

Thanks in advance!

Martine

From: DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David

<<u>David.Rotstein@fda.hhs.gov</u>>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>,

Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>, Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>, Reimschuessel,

Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>, Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>, Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, **B5**

From: Palmer, Lee Anne < <u>Lee Anne. Palmer@fda.hhs.gov</u>>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan < Siobhan Delancey@fda.hhs.gov >, Hartogensis, Martine

< <u>Martine.Hartogensis@fda.hhs.gov</u>>, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>, Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>,

Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel,

Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>, Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>, Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >;

Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel,

Renate < Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to **B6** talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne < Lee Anne. Palmer @fda.hhs.gov >

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>,

Rotstein, David < David. Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren Carey@fda.hhs.gov</u>>,

Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>, DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>, Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>, Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>, Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>, Nemser, Sarah <<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >; Palmer,

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov> Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets Excellent work Jen!! Just a few questions. On slide 6 (or the spreadsheet) DCM? Martine From: Jones, Jennifer L Sent: Thursday, May 17, 2018 11:29 AM Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov > Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell, Randall A < Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov>; Nemser, Sarah < Sarah. Nemser@fda.hhs.gov> Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets We ₫ Please see the PPT for the rationale/summary Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 🖫 U.S. FOOD & DRUG From: Rotstein, David **Sent:** Monday, May 14, 2018 10:22 AM To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A < Randall.Lovell@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets **B5**

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

From: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >
Date: May 14, 2018 at 9:09:17 AM EDT To Polymon Los Anno Clos Anno Polymon Ofde his coxy Potatoin Dovid Povid Potatoin Ofde his coxy Long.
To: Palmer, Lee Anne < <u>Lee Anne Palmer@fda.hhs.gov</u> >, Rotstein, David < <u>David Rotstein@fda.hhs.gov</u> >, Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William william.Burkholder@fda.hhs.gov">william.Burkholder@fda.hhs.gov , Carey, Lauren Lauren.Carey@fda.hhs.gov >,
Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >, DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u> >, Lovell,
Randall A < Randall Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets
B5
Martine
From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u> >; Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u> >;
Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> >
Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >;
Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u> >; Lovell, Randall A <randall.lovell@fda.hhs.gov></randall.lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets
Cusjour (CE. Bom and moongh with Carallac Caro for Fold
From what I've read, it can be a B5
B5
From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM To: Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine
Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <jennifer.jones@fda.hhs.gov></jennifer.jones@fda.hhs.gov>
Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>;
Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u> >; Lovell,
Randall A < Randall.Lovell@fda.hhs.gov >
Subject: RE: DCM and meetign with Cardiac Care for Pets
Lee Anne,
This is fantastic.
This is fantastic. B5
B5
B5
B5 B5
B5
B5 B5
B5 B5

From: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>, Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>,

Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>

 $\textbf{Cc:} \ Burkholder, William < \underline{William.Burkholder@fda.hhs.gov} >, \ Carey, \ Lauren < \underline{Lauren.Carey@fda.hhs.gov} >, \ Carey, \ Lauren < \underline{Lauren.Carey@fda.hhs.gov} >, \ Carey, \ Lauren < \underline{Lauren.Carey.gov} >, \ Carey. \ C$

Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >, Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there –	B5	
	B5	
	B5	

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne



From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne < <u>Lee Anne. Palmer@fda.hhs.gov</u>>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>;

Norris, Anne < Anne. Norris@fda.hhs.gov>; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne < <u>Lee Anne. Palmer@fda.hhs.gov</u> >		
Date: May 9, 2018 at 4:09:18 PM EDT		
$\textbf{To:} \ \ \text{Hartogensis, Martine} \leq \underline{\text{Martine.Hartogensis}} \underline{\text{@fda.hhs.gov}} >, \ \text{Rotstein, David} \leq \underline{\text{David.Rotstein}} \underline{\text{@fda.hhs.gov}} > \underline{\text{Rotstein, David}} \leq \underline{\text{Rotstein, David}} \leq \underline{\text{Pavid.Rotstein}} \underline{\text{@fda.hhs.gov}} > \underline{\text{Rotstein, David}} \leq \underline{\text{Pavid.Rotstein}} \underline{\text{@fda.hhs.gov}} > \underline{\text{Rotstein, David}} \leq \underline{\text{Pavid.Rotstein}} \underline{\text{@fda.hhs.gov}} > \underline{\text{Pavid.Rotstein}} \underline{\text{@fda.hhs.gov}} > \underline{\text{Pavid.Rotstein}} = \underline{\text{Pavid.Rotstein}} \underline{\text{@fda.hhs.gov}} > \underline{\text{Pavid.Rotstein}} = \underline{\text{Pavid.Rotstein}} \underline{\text{Pavid.Rotstein}} = \underline{\text{Pavid.Rotstein}} = \underline{\text{Pavid.Rotstein}} \underline{\text{Pavid.Rotstein}} = \underline{\text{Pavid.Rotstein}}$		
Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> >		
Cc: Burkholder, William < William Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren.Carey@fda.hhs.gov >,		
Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >		
Subject: RE: DCM and meetign with Cardiac Care for Pets		
B5		
Estimated it along – could be Friday before I get this in shape to sendnot to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!		
From: Hartogensis, Martine Sent: Wednesday, May 9, 2018 2:17 PM To: Rotstein, David < David.Rotstein@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; DeLancey, Siobhan < Subject: RE: DCM and meetign with Cardiac Care for Pets">DCM and meetign with Cardiac Care for Pets		
Awesome, thank you Dave!		
Martine		
From: Rotstein, David Sent: Wednesday, May 09, 2018 2:06 PM To: Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov> Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>; Norris, Anne < Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets		
Good Afternoon,		
I spoke with B6 Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.		
Just some basic information:		
B5		
As a side note, there is a facebook page dedicated to this issue:		
https://www.facebook.com/groups/1952593284998859/about/		

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison





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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Palmer,

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

B6 Thank you Jen and Dave! Very interesting and sounds like you all are on it!

Keep us posted!

Thanks again!

Martine

Hi Martine.

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>

Subject: RE: DCM

Martine,



Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6

(BB)













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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David < David.Rotstein@fda.hhs.gov >; Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >

Subject: RE: DCM

B5

B5

Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To: Carey, Lauren; Jones, Jennifer L; Palmer, Lee Anne; Hartogensis, Martine; DeLancey, Siobhan CC:

Burkholder, William; Norris, Anne; Lovell, Randall A; Reimschuessel, Renate; Ceric, Olgica;

Nemser, Sarah

Sent: 5/21/2018 11:41:45 AM

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, **B5**

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6





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From: Carey, Lauren

Sent: Monday, May 21, 2018 7:39 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>;

Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Norris, Anne < Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>;

Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As an FYI, this formulation type is so popular Amazon jumped on board.

https://www.petfoodindustry.com/articles/7209-amazon-wag-dog-foods-nutrient-content-analyzedrated?eid=418335734&bid=2101343

https://www.amazon.com/WAG-Added-Grain-Lentil-Recipe/dp/B078VV67DT

INGREDIENTS: BEEF, BEEF MEAL, LENTILS, PEA PROTEIN, PEAS, EGG PRODUCT, CHICKEN FAT (PRESERVED WITH MIXED TOCOPHEROLS), BREWERS YEAST, WILD BOAR, POTATO PROTEIN, DRIED PLAIN BEET PULP, FLAXSEED, NATURAL FLAVOR, SALT, CHOLINE CHLORIDE, DRIED CHICORY ROOT, YUCCA SCHIDIGERA EXTRACT, DRIED LACTOBACILLUS PLANTARUM FERMENTATION PRODUCT, DRIED BACILLUS SUBTILIS FERMENTATION PRODUCT, DRIED LACTOBACILLUS ACIDOPHILUS FERMENTATION PRODUCT, DRIED ENTEROCOCCUS FAECIUM FERMENTATION PRODUCT, DRIED BIFIDOBACTERIUM ANIMALIS FERMENTATION PRODUCT, VITAMIN E SUPPLEMENT, IRON PROTEINATE, ZINC PROTEINATE, COPPER PROTEINATE, FERROUS SULFATE, ZINC SULFATE, COPPER SULFATE, POTASSIUM IODIDE, THIAMINE MONONITRATE (SOURCE OF VITAMIN B1), MANGANESE PROTEINATE, MANGANOUS OXIDE, ASCORBIC ACID (PRESERVATIVE), VITAMIN A SUPPLEMENT, BIOTIN, NIACIN, CALCIUM PANTOTHENATE, MANGANESE SULFATE, SODIUM SELENITE, PYRIDOXINE HYDROCHLORIDE (SOURCE OF VITAMIN B6), VITAMIN B12 SUPPLEMENT, RIBOFLAVIN (VITAMIN B2), VITAMIN D3 SUPPLEMENT, FOLIC ACID.



From: Jones, Jennifer L

Sent: Friday, May 18, 2018 3:31 PM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, you're correct Lee Anne.	B5
В4	

Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421



From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 3:29 PM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 3:24 PM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Rotstein, David

< David. Rotstein@fda.hhs.gov >

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

	I just got a call from Dr. Fascetti with UC Davis-She runs the amino acid laboratory and B5)
	B5	
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Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421

U.S. FOOD & DRUG

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 3:10 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Jones, Jennifer L

<<u>Jennifer.Jones@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

In terms of # reported to us - I would look at (in terms of reports directly to FDA CVM) the top 2 primarily. Dave could do much better with contact info.



There are a variety of others – among those reported to	s, several have 1 report	t per brand, but all	grain-free
B4. B5			

From: Hartogensis, Martine

Sent: Friday, May 18, 2018 2:53 PM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov > Cc: Burkholder, William < William. Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren. Carey@fda.hhs.gov >; Norris, Anne < Anne. Norris@fda.hhs.gov >; Lovell, Randall A < Randall. Lovell@fda.hhs.gov >; Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah. Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, thank you to everyone on the call.

Anne and I are working on the advisory. In meantime, I thi	nk we
B5 Dave do you have that or any suggestions on	how to find contact names/numbers?

Martie

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks, suppose	B5	}, I
	B5	
I also cleaned up and did this one out!	B5	hanks – hope we can figure

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan

<<u>Siobhan.Delancey@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Rotstein, David

<<u>David.Rotstein@fda.hhs.gov</u>>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>;

Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel,

Renate < Renate.Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 6:42 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; DeLancey, Siobhan

<<u>Siobhan.Delancey@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

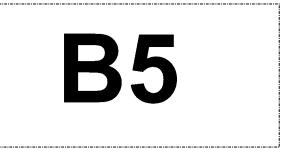
Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>;

Carab Namaar@fila bha mars
< <u>Sarah.Nemser@fda.hhs.gov</u> >
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
B5
Jennifer Jones, DVM
Veterinary Medical Officer Tel: 240-402-5421
U.S. FOOD & DRUG
From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u> >; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u> >; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> >; Rotstein, David
< <u>David.Rotstein@fda.hhs.gov</u> >, 30fles, 36fliller E < <u>seriller.sories@fda.hhs.gov</u> >, Notstein, <i>David</i>
Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u> >; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u> >;
Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u> >; Reimschuessel,
Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u> >; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u> >; Nemser, Sarah <sarah.nemser@fda.hhs.gov></sarah.nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
Yes, excellent work! One question thoughdo we see B5
Thanks in advance!
Martine
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Date: May 17, 2018 at 2:27:35 PM EDT
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >, Hartogensis, Martine
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >, Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >, Rotstein, David
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >, Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >, Rotstein, David < David. Rotstein@fda.hhs.gov >
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >, Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >, Rotstein, David < David. Rotstein@fda.hhs.gov > Cc: Burkholder, William < William. Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren. Carey@fda.hhs.gov >,
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >, Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >, Rotstein, David < David. Rotstein@fda.hhs.gov > Cc: Burkholder, William < William. Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren. Carey@fda.hhs.gov >, Norris, Anne < Anne. Norris@fda.hhs.gov >, Lovell, Randall A < Randall. Lovell@fda.hhs.gov >, Reimschuessel,
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov">LeeAnne.Palmer@fda.hhs.gov , Hartogensis, Martine Lennifer L Lennifer.Jones@fda.hhs.gov">Lennifer.Jones@fda.hhs.gov, Rotstein, David Leonifer.Jones@fda.hhs.gov, Rotstein, David Leonifer.Jones@fda.hhs.gov, Carey, Lauren Lauren.Carey@fda.hhs.gov, Reimschuessel, Ronate Reimschuessel, Ronate Reimschuessel, Ronate Reimschuessel, Ronate Roris@fda.hhs.gov, Ceric, Olgica Olgica.Ceric@fda.hhs.gov, Nemser, Sarah
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov">LeeAnne.Palmer@fda.hhs.gov , Hartogensis, Martine Martine.Hartogensis@fda.hhs.gov">LeeAnne.Palmer@fda.hhs.gov , Jones, Jennifer L Jennifer.Jones@fda.hhs.gov">LeeAnne.Jones@fda.hhs.gov , Rotstein, David Lauren Lauren.Carey@fda.hhs.gov">Lauren.Carey@fda.hhs.gov, Norris, Anne Anne.Norris@fda.hhs.gov, Lovell, Randall A Reimschuessel, Renate Reimschuessel, Renate.Reimschuessel@fda.hhs.gov, Ceric, Olgica Olgica.Ceric@fda.hhs.gov, Nemser, Sarah Sarah.Nemser@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov">LeeAnne.Palmer@fda.hhs.gov , Hartogensis, Martine Martine.Hartogensis@fda.hhs.gov">LeeAnne.Palmer@fda.hhs.gov , Jones, Jennifer L Jennifer.Jones@fda.hhs.gov">LeeAnne.Jones@fda.hhs.gov , Rotstein, David Lauren Lauren.Carey@fda.hhs.gov">Lauren.Carey@fda.hhs.gov, Norris, Anne Anne.Norris@fda.hhs.gov, Lovell, Randall A Reimschuessel, Renate Reimschuessel, Renate.Reimschuessel@fda.hhs.gov, Ceric, Olgica Olgica.Ceric@fda.hhs.gov, Nemser, Sarah Sarah.Nemser@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov">LeeAnne.Palmer@fda.hhs.gov , Hartogensis, Martine Martine.Hartogensis@fda.hhs.gov , Jones, Jennifer L Jennifer.Jones@fda.hhs.gov , Rotstein, David Lovelda.hhs.gov , Carey, Lauren Lauren.Carey@fda.hhs.gov , Norris, Anne Martine.Martine.Hartogensis, Martine Lovelda.hhs.gov, Rotstein, David Lovelda.hhs.gov, Carey, Lauren Lauren.Carey@fda.hhs.gov, Reimschuessel, Renate Reimschuessel, Renate <a< td=""></a<>
From: DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov > Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >, Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >, Rotstein, David < David.Rotstein@fda.hhs.gov > Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren.Carey@fda.hhs.gov >, Norris, Anne < Anne.Norris@fda.hhs.gov >, Lovell, Randall A < Randall.Lovell@fda.hhs.gov >, Reimschuessel, Renate < Reimschuessel@fda.hhs.gov >, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >, Nemser, Sarah < Sarah.Nemser@fda.hhs.gov > Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

From: Palmer, Lee Anne < <u>Lee Anne Palmer@fda.hhs.gov</u>>

To: DeLancey, Siobhan Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov> **Cc:** Burkholder, William < <u>William Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren Carey@fda.hhs.gov</u>>, Norris, Anne <Anne. Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov> **Subject:** RE: 800.267-DCM and meetign with Cardiac Care for Pets Hah! Perfect timing! We're all heading down the same path... From: DeLancey, Siobhan Sent: Thursday, May 17, 2018 2:13 PM To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov> Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne < Anne.Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov> Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets As luck would have it, I'm at CE today listening to **B6** talk about nutrition and cardiomyopathies. See attached slide. **From:** Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov> **Date:** May 17, 2018 at 2:06:04 PM EDT **To:** Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>, Rotstein, David < David. Rotstein@fda.hhs.gov> **Cc:** Burkholder, William "William.Burkholder@fda.hhs.gov" Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan , Lovell, Randall A < Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >, Nemser, Sarah < Sarah.Nemser@fda.hhs.gov > **Subject:** RE: 800,267-DCM and meetign with Cardiac Care for Pets HI there – is the slide set for tomorrow's meeting? Great work!

Date: May 17, 2018 at 2:14:48 PM EDT



B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >; Palmer,

Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>;

Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah. Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

Just a few questions.

DCM?

One other quest

issue?

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>;

Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

Cc: Burkholder, William < William. Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren. Carey@fda.hhs.gov >; Norris, Anne < Anne. Norris@fda.hhs.gov >; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >; Lovell, Randall A < Randall. Lovell@fda.hhs.gov >; Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah. Nemser@fda.hhs.gov > Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

We	B5
	B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Rotstein, David

Sent: Monday, May 14, 2018 10:22 AM

To: Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov">Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov> Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >, Rotstein, David < David.Rotstein@fda.hhs.gov >, Jones, Lee Grand Control of the Lee Control

Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>, Norris, Anne < Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov>, Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>;

Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Cc: Burkholder, William < William. Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren. Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A < Randall.Lovell@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets From what I've read, it can be a From: Rotstein. David Sent: Friday, May 11, 2018 4:14 PM To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell, Randall A < Randall.Lovell@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets Lee Anne, **B5** This is fantastic **B5 From:** Palmer, Lee Anne < <u>Lee Anne. Palmer@fda.hhs.gov</u>> **Date:** May 11, 2018 at 4:06:05 PM EDT **To:** Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>, Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov> **Cc:** Burkholder, William , Carey, Lauren < Lauren.Carey@fda.hhs.gov, Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan Delancey@fda.hhs.gov >, Lovell, Randall A < Randall.Lovell@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets Hi there

B5



I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne



From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Hartogensis, Martine

< Martine. Hartogensis@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >;

Norris, Anne < Anne. Norris@fda.hhs.gov >; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>, Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>,

Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>,

Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5 I want to confirm it, then will send it along – could be Friday before I get this in shape to send...not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 PM

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Palmer,

Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >;

Norris, Anne < Anne. Norris@fda.hhs.gov >; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>;

Norris, Anne < Anne. Norris@fda.hhs.gov>; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with B6 Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set me meeting up from that point.

Just some basic information:



As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B5













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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Rotstein, David < David.Rotstein@fda.hhs.gov>; Palmer,

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>

Subject: RE: DCM

Martine,

B5

B5
Looping in Jen.
Thanks for the update!
dave
David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6
DA U.S. FOOD & DRUG
This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov .
From: Hartogensis, Martine Sent: Tuesday, May 08, 2018 9:00 AM To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u> >; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u> > Subject: RE: DCM
B5
Martine
From: Rotstein, David Sent: Monday, May 07, 2018 1:13 PM To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov > Subject: Re: DCM
Martine
Lee Anne will likely discuss at B5
B5
Vet-LIRN is looking into B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-

MHARTOGE>

To: Palmer, Lee Anne; Jones, Jennifer L; DeLancey, Siobhan; Rotstein, David

CC: Burkholder, William; Carey, Lauren; Norris, Anne; Lovell, Randall A; Reimschuessel, Renate;

Ceric, Olgica; Nemser, Sarah

Sent: 5/18/2018 7:13:53 PM

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, **B5**

Martine

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 3:10 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William. Surkholder@fda.hhs.gov>; Carey, Lauren < Lauren. Carey@fda.hhs.gov>; Norris, Anne < Anne. Norris@fda.hhs.gov>; Lovell, Randall A < Randall. Lovell@fda.hhs.gov>; Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov>; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov>; Nemser, Sarah < Sarah. Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

In terms of # reported to us - I would look at (in terms of reports directly to FDA CVM) the top 2 primarily. Dave could do much better with contact info.

B4, B5

From: Hartogensis, Martine

Sent: Friday, May 18, 2018 2:53 PM

To: Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov > Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, thank you to everyone on the call.

B5

Martie

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine

< <u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Rotstein, David

<<u>David.Rotstein@fda.hhs.gov</u>>

 $\begin{tabular}{ll} \textbf{Cc:} & \textbf{Burkholder, William.} & \textbf{Surkholder@fda.hhs.gov.} \\ \textbf{Carey, Lauren} & < \underline{\textbf{Lauren.Carey@fda.hhs.gov.}} \\ \textbf{Norris, Anne} & < \underline{\textbf{Anne.Norris@fda.hhs.gov.}} \\ \textbf{Enate} & < \underline{\textbf{Reinschuessel@fda.hhs.gov.}} \\ \textbf{Ceric, Olgica} & < \underline{\textbf{Olgica.Ceric@fda.hhs.gov.}} \\ \textbf{Norris, Anne} & < \underline{\textbf{Norris, Anne.Norris@fda.hhs.gov.}} \\ \textbf{Norris, Anne.} & < \underline{\textbf{Norris, Anne.Norris@fda.hhs.gov.}} \\ \textbf{Norris.} & < \underline{\textbf{Norris.}} \\ \textbf{Norris.} & < \underline{\textbf{Norris.}} \\ \textbf{Norris.} \\ \textbf{Norr$

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; DeLancey, Siobhan

 $<\underline{Siobhan.Delancey@fda.hhs.gov}>;\ Palmer,\ Lee\ Anne\ <\underline{LeeAnne.Palmer@fda.hhs.gov}>;\ Rotstein,\ David =\underline{Construction}$

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah < <u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>;

Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>;

 $Norris, Anne < \underline{Anne.Norris@fda.hhs.gov} > ; Lovell, Randall A < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Lovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Rovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Rovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Rovell@fda.hhs.gov} > ; Reimschuessel, Anne < \underline{Randall.Rovell@f$

Renate < Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting. Martine From: Jones, Jennifer L **Sent:** Friday, May 18, 2018 6:42 AM To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov> Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov> Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets **B5** CVCA is not a part of Vet-LIRN. Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 U.S. FOOD & DRUG

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate < Renate . Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica . Ceric@fda.hhs.gov >; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work! One question though...do we see

they part of VET-LIRN?	•	<u> </u>	
Thanks in advance!			
Martine			

B5

From: DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne < <u>Lee Anne. Palmer@fda.hhs.gov</u>>, Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>, Norris, Anne < Anne. Norris@fda.hhs.gov>, Lovell, Randall A < Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate < Renate. Reimschuessel @fda.hhs.gov>, Ceric, Olgica < Olgica. Ceric @fda.hhs.gov>, Nemser, Sarah

with CVCA? Are

<sarah.nemser@fda.hhs.gov></sarah.nemser@fda.hhs.gov>					
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets					
B5					
PJ					
From: Palmer, Lee Anne < Lee Anne . Palmer@fda.hhs.gov > Date: May 17, 2018 at 2:14:48 PM EDT					
To: DeLancey, Siobhan < Siobhan Delancey@fda.hhs.gov >, Hartogensis, Martine					
$<\!\!\underline{Martine.Hartogensis@fda.hhs.gov}\!\!>\!, Jones, Jennifer L <\!\!\underline{Jennifer.Jones@fda.hhs.gov}\!\!>\!, Rotstein, David$					
<pre><david.rotstein@fda.hhs.gov></david.rotstein@fda.hhs.gov></pre>					
Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u> >, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u> >, Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >, Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u> >, Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u> >, Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u> >, Nemser, Sarah					
< <u>Sarah.Nemser@fda.hhs.gov</u> >					
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets					
Hah! Perfect timing! We're all heading down the same path					
From: DeLancey, Siobhan Sent: Thursday, May 17, 2018 2:13 PM To: Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >; Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov > Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel, Renate < Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov > Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets As luck would have it, I'm at CE today listening to B6 talk about nutrition and					
cardiomyopathies. See attached slide.					
From: Palmer, Lee Anne < Lee Anne . Palmer@fda.hhs.gov > Date: May 17, 2018 at 2:06:04 PM EDT To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >, Rotstein, David < David.Rotstein@fda.hhs.gov > Cc: Burkholder, William < William. Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren. Carey@fda.hhs.gov >, Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >, Lovell, Randall A < Randall. Lovell@fda.hhs.gov >, Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov >, Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >, Nemser, Sarah < Sarah. Nemser@fda.hhs.gov > Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets					
HI there – is the slide set for tomorrow's meeting? Great work! B5					
B5					



B5

B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Palmer,

Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>;

Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

Just a few questions. On slide 6 (or the spreadsheet),

B5

From: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne < <u>Lee Anne. Palmer@fda.hhs.gov</u>>, Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>, Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>, Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>, DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>, Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

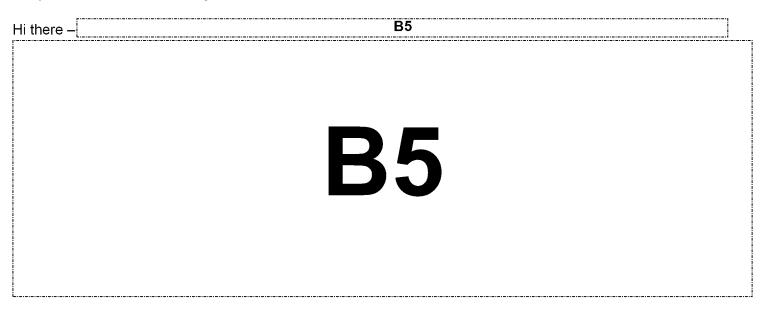
Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very inter	esting.	В5	Pave, do you have any idea
abou B	5	J	
Martine			
From: Palmer, L			
Sent: Friday, Ma	-		
		l.Rotstein@fda.hhs.gov>; Hartogensis, Martine	e < <u>Martine.Hartogensis@fda.hhs.gov</u> >;
·		<u>:Jones@fda.hhs.gov</u> > <u>Villiam.Burkholder@fda.hhs.gov</u> >;	ren <l auren="" carev@fda="" gov="" hhs="">:</l>
		@fda.hhs.gov>; DeLancey, Siobhan <siobhar< td=""><td></td></siobhar<>	
Randall A <rand< td=""><td></td><td>-</td><td><u>, (5), (3), (3), (1), (1), (1), (1), (1), (1), (1), (1</u></td></rand<>		-	<u>, (5), (3), (3), (1), (1), (1), (1), (1), (1), (1), (1</u>
Subject: RE: DC	M and m	eetign with Cardiac Care for Pets	
		be B5	
From what I've re	ead, it car	bei Bo	<u> </u>
p		B5	·
L		B9	
From: Rotstein,	David		
Sent: Friday, Ma		4:14 PM	
		<u>eAnne.Palmer@fda.hhs.gov</u> >; Hartogensis, M	
	_	.hhs.gov>; Jones, Jennifer L < <u>Jennifer.Jones@</u>	
	_	<u>Villiam.Burkholder@fda.hhs.gov</u> >; Carey, Laur	
Randall A <rand< td=""><td></td><td><u>@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhar</u></td><td>n.Delancey@tda.nns.gov>; Lovell,</td></rand<>		<u>@fda.hhs.gov</u> >; DeLancey, Siobhan < <u>Siobhar</u>	n.Delancey@tda.nns.gov>; Lovell,
		eetign with Cardiac Care for Pets	
Canjour (C. De	on and m	Cargar Mari Cararac Caro for 1 Cac	
Lee Anne,			
•	r		
This is fantastic.		B5	
r		;	·
<u> </u>	В	<u> </u>	
		B5	
		D J	
		<u></u>	
		B5	
F			
From: Palmer, L	ee Anne <	LeeAnne.Palmer@fda.hhs.gov>	
Date: May 11, 20		-	
•		d.Rotstein@fda.hhs.gov>, Hartogensis, Martin	ne < <u>Martine.Hartogensis@fda.hhs.gov</u> >,

 $Norris, Anne < \underline{Anne.Norris@fda.hhs.gov}>, DeLancey, Siobhan < \underline{Siobhan.Delancey@fda.hhs.gov}>, Lovell, Randall A < \underline{Randall.Lovell@fda.hhs.gov}>$

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren.Carey@fda.hhs.gov >,

Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>



I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne



From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Hartogensis, Martine

< Martine. Hartogensis@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >;

Norris, Anne < Anne. Norris@fda.hhs.gov>; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>, Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>,

Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Cc: Burkholder, William < <u>William Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren Carey@fda.hhs.gov</u>>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets **B5** I want to confirm it, then will send it along – could be Friday before I get this in shape to send... not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks! From: Hartogensis, Martine Sent: Wednesday, May 9, 2018 2:17 PM To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov> Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne. Norris@fda.hhs.gov>; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets Awesome, thank you Dave! Martine From: Rotstein, David Sent: Wednesday, May 09, 2018 2:06 PM To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov> Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne. Norris@fda.hhs.gov >; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov > Subject: RE: DCM and meetign with Cardiac Care for Pets Good Afternoon. Dardiac Care for Pets. He is going to look into times/dates with the cardiologists I spoke with **B6** there and we can set the meeting up from that point. Just some basic information: As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place







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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Rotstein, David < David.Rotstein@fda.hhs.gov>; Palmer,

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

B6

.....

Thanks again!

Keep us posted!

Martine

Hi Martine,

B5

I'm happy to share more info as needed. Jen

Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov >; Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >

Subject: RE: DCM



Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6











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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David < David.Rotstein@fda.hhs.gov >; Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >

Subject: RE: DCM



Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: Re: DCM Martine Lee Anne will likely discuss at But it does look like there is a **B**5 relationship between the increased DCM reports and grain free diets. Vet-LIRN is looking into **B5** There's a way to go on this moving forward. Dave **From:** Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>> **Date:** May 7, 2018 at 1:03:13 PM EDT **To:** Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>> Subject: DCM Hi Dave! Do you have any more details on the DCM and grain free diet issue?

Martine

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To: Burkholder, William Sent: 6/18/2018 12:01:06 PM

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Excellent! Thanks, Bill.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Burkholder, William

Sent: Sunday, June 17, 2018 8:49 PM

To: Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen,

First, thanks for compiling my literature reading list for the next few weeks (I am being serious in my thanks). Attached are the two documents you requested comment on with edits and comments in track changes. Keep or reject as you see fit. As always, thank you for the opportunity to comment.

Bill

From: Jones, Jennifer L

Sent: Monday, June 11, 2018 12:06 PM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Edwards, David <<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William < William.Burkholder@fda.hhs.gov >; DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov > Cc: Carey, Lauren < Lauren. Carey@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah. Nemser@fda.hhs.gov >; Conway, Charlotte < Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z < Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <<u>April.Hodges@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Good morning everyone,

Vet-LIRN created a procedure document that outlines a prospective case investigation for new complaints about DCM and consuming grain free products. We plan to **B5** However, we will be **B5** to В5

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,

Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Norris, Anne

Sent: Tuesday, May 22, 2018 9:24 AM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Rotstein, David < David. Rotstein@fda.hhs.gov >;

Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>; Reimschuessel, Renate

< <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Edwards, David < <u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine

< <u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; DeLancey,

Siobhan < Siobhan. Delancey@fda.hhs.gov>

 $\textbf{Cc:} \ \, \mathsf{Carey,} \ \, \mathsf{Lauren.} \\ \mathsf{Carey@fda.} \\ \mathsf{hhs.} \\ \mathsf{gov} > ; \ \, \mathsf{Lovell}, \ \, \mathsf{Randall.} \\ \mathsf{Lovell@fda.} \\ \mathsf{hhs.} \\ \mathsf{gov} > ; \ \, \mathsf{Ceric,} \\ \mathsf{Randall.} \\ \mathsf{Lovell@fda.} \\ \mathsf{hhs.} \\ \mathsf{gov} > ; \ \, \mathsf{Ceric,} \\ \mathsf{Randall.} \\ \mathsf{Lovell} \\ \mathsf{gov} > ; \\ \mathsf{Ceric,} \\ \mathsf{Randall.} \\ \mathsf{Rand$

Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >; Conway, Charlotte

 $<\!\!\underline{Charlotte.Conway@fda.hhs.gov}\!\!>; Atkinson, Krisztina Z <\!\!\underline{Krisztina.Atkinson@fda.hhs.gov}\!\!>; Hodges, April Conway@fda.hhs.gov$

April.Hodges@fda.hhs.gov

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining B5
B5

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 9:13 AM

To: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Edwards, David <<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>> Cc: Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah <<u>Sarah.Nemser@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z <<u>Krisztina.Atkinson@fda.hhs.gov</u>>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B4, B5

From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:49 AM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >;

Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate

<Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine

; Burkholder, William < William.Burkholder@fda.hhs.gov; DeLancey,

Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric,

Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

That should be fine. I apologize if we already discussed this,

B5

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 8:39 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <Villiam.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric,

<<u>April.Hodges@fda.hhs.gov</u>> **Subject**: RE: 800.267-DCM and meeting with Cardiac Care for Pets

If we go forward,	B5
B5	

Olgica < Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte < Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z < Krisztina.Atkinson@fda.hhs.gov>; Hodges, April

From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:37 AM

To: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>;

Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah <<u>Sarah.Nemser@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z <<u>Krisztina.Atkinson@fda.hhs.gov</u>>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne.

Agreed.

Part of this outreach is for us to directly contact firms.	B5	B5
B5		

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6 (BB)







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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Rotstein, David < David.Rotstein@fda.hhs.gov>;

Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William

<<u>William.Burkholder@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >; Conway, Charlotte < Charlotte.Conway@fda.hhs.gov >; Atkinson, Krisztina Z < Krisztina.Atkinson@fda.hhs.gov >; Hodges, April

< April. Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

We could update the advisory further as more information comes in.

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:31 AM

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Reimschuessel, Renate

<Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee

Anne < LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A

< <u>Randall.Lovell@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah

< Sarah. Nemser@fda.hhs.gov>; Conway, Charlotte < Charlotte. Conway@fda.hhs.gov>; Atkinson, Krisztina Z

< Krisztina. Atkinson@fda.hhs.gov>; Hodges, April < April. Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

В5

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:25 AM

To: Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov >; Edwards, David

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William

< <u>William.Burkholder@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

< Randall.Lovell@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah

< <u>Sarah.Nemser@fda.hhs.gov</u>>; Conway, Charlotte < <u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z



David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6 (BB)





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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David < <u>David.Edwards@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>;

Hartogensis, Martine < Martine < Martine.Hartogensis@fda.hhs.gov>; Burkholder, William

- < William.Burkholder@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne.Palmer@fda.hhs.gov >; Jones, Jennifer L
- <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

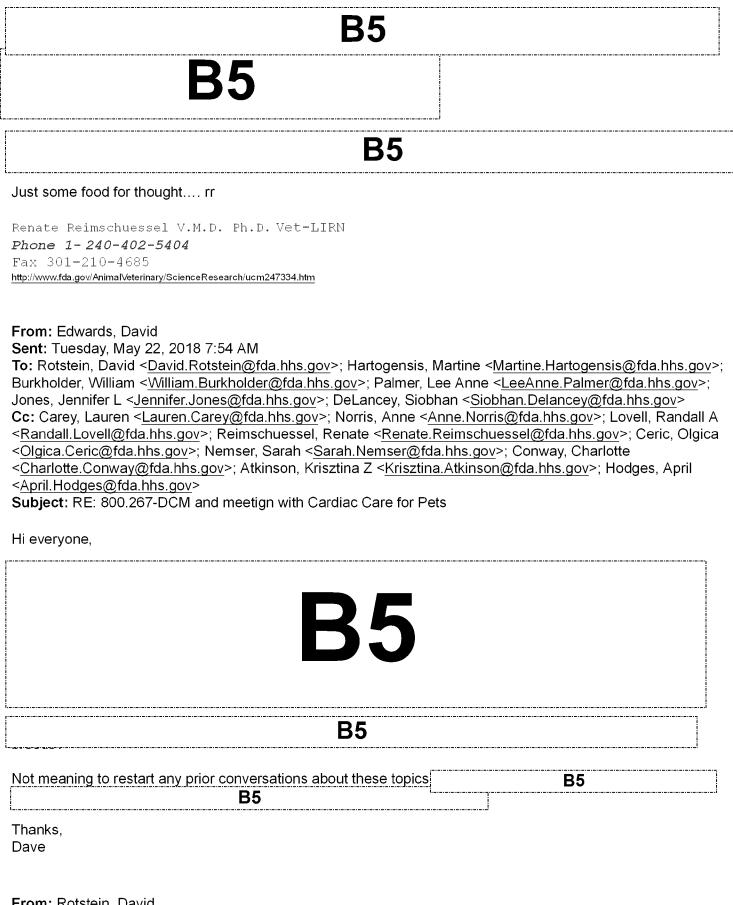
- <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah
- <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z
- <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

I agree with a careful approach to this investigation.

B5

B5



From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren < Lauren. Carey@fda.hhs.gov>; Norris, Anne < Anne. Norris@fda.hhs.gov>; Lovell, Randall A

< <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica

< Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, if I can get the complete list of products so that I don't miss any, we will reach out to the Divisions and provide a general summary of what is going on and then work with the Divisions on setting up calls.

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6 (BB)





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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William < William. Burkholder@fda.hhs.gov>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Rotstein, David < David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A

<Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!



Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A

< <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine

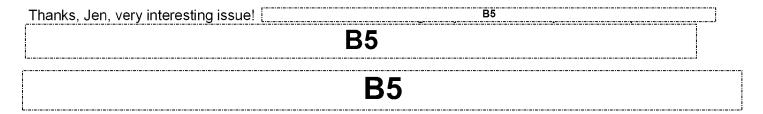
< Martine. Hartogensis@fda.hhs.gov>; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah

<<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets



Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>; DeLancey, Siobhan

<<u>Siobhan.Delancey@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel, Renate < Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>;

Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < Anne.Norris@fda.hhs.gov>; Lovell, Randall.Lovell@fda.hhs.gov>; Reimschuessel,

Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 6:42 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>;

Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u> >; Reimschuessel, Renate <renate.reimschuessel@fda.hhs.gov>; Ceric, Olgica <olgica.ceric@fda.hhs.gov>; Nemser, Sarah</olgica.ceric@fda.hhs.gov></renate.reimschuessel@fda.hhs.gov>
< <u>Sarah.Nemser@fda.hhs.gov</u> >
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
B5
Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421
From: Hartogensis, Martine Sent: Thursday, May 17, 2018 7:52 PM To: DeLancey, Siobhan <siobhan.delancey@fda.hhs.gov>; Palmer, Lee Anne <leeanne.palmer@fda.hhs.gov>; Jones, Jennifer L <jennifer.jones@fda.hhs.gov>; Rotstein, David <david.rotstein@fda.hhs.gov> Co: Burkholder, William <william.burkholder@fda.hhs.gov>; Carey, Lauren <lauren.carey@fda.hhs.gov>; Norris, Anne <anne.norris@fda.hhs.gov>; Lovell, Randall A <randall.lovell@fda.hhs.gov>; Reimschuessel, Renate <reimschuessel@fda.hhs.gov>; Ceric, Olgica <olgica.ceric@fda.hhs.gov>; Nemser, Sarah <sarah.nemser@fda.hhs.gov> Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets</sarah.nemser@fda.hhs.gov></olgica.ceric@fda.hhs.gov></reimschuessel@fda.hhs.gov></randall.lovell@fda.hhs.gov></anne.norris@fda.hhs.gov></lauren.carey@fda.hhs.gov></william.burkholder@fda.hhs.gov></david.rotstein@fda.hhs.gov></jennifer.jones@fda.hhs.gov></leeanne.palmer@fda.hhs.gov></siobhan.delancey@fda.hhs.gov>
Yes, excellent work! One question though B5 B5
Thanks in advance!
Martine
From: DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov > Date: May 17, 2018 at 2:27:35 PM EDT To: Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov >, Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >, Rotstein, David < David.Rotstein@fda.hhs.gov > Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren.Carey@fda.hhs.gov >, Norris, Anne < Anne.Norris@fda.hhs.gov >, Lovell, Randall A < Randall.Lovell@fda.hhs.gov >, Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >, Nemser, Sarah < Sarah.Nemser@fda.hhs.gov > Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
B5

From: Palmer, Lee Anne < <u>Lee Anne Palmer@fda.hhs.gov</u>>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >, Hartogensis, Martine

< <u>Martine.Hartogensis@fda.hhs.gov</u>>, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>, Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William Carey, Lauren < Lauren.Carey@fda.hhs.gov"> Norris, Anne < Anne.Norris@fda.hhs.gov"> Lovell, Randall A < Randall.Lovell@fda.hhs.gov"> Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov"> Ceric, Olgica < Olgica.Ceric@fda.hhs.gov"> Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne < <u>Lee Anne. Palmer@fda.hhs.gov</u>>; Hartogensis, Martine

< Martine. Hartogensis@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Norris, Anne < Anne.Norris@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Reimschuessel, Renate < Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to **B6** talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

 $\textbf{To:} \ Hartogensis, Martine < \underline{Martine.Hartogensis@fda.hhs.gov} >, Jones, Jennifer L < \underline{Jennifer.Jones@fda.hhs.gov} >,$

Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>

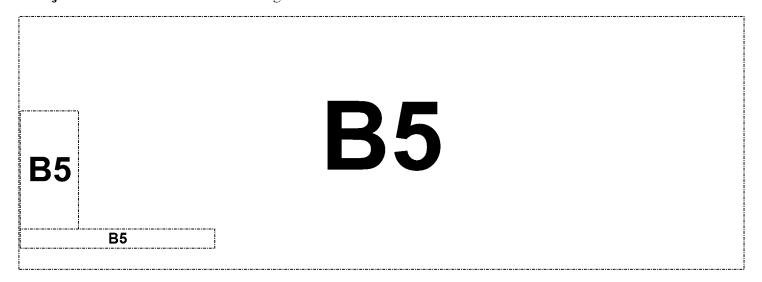
Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>,

 $Norris, Anne < \underline{Anne.Norris@fda.hhs.gov} >, DeLancey, Siobhan < \underline{Siobhan.Delancey@fda.hhs.gov} >, Lovell,$

Randall A < Randall.Lovell@fda.hhs.gov >, Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >,

Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >, Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >

Subject: RE: 800,267-DCM and meetign with Cardiac Care for Pets





B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Palmer,

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Reimschuessel@fda.hhs.gov</u>>;

Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

Just a few questions.	B5	
В5		
	B5	

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>;

Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

Cc: Burkholder, William "

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Monday, May 14, 2018 10:22 AM

To: Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>

Cc: Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5 Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine Martine.Hartogensis@fda.hhs.gov

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne < <u>Lee Anne Palmer@fda.hhs.gov</u>>, Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>, Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>

 $\textbf{Cc:} \ Burkholder, William < \underline{William.Burkholder@fda.hhs.gov} >, \ Carey, \ Lauren < \underline{Lauren.Carey@fda.hhs.gov} >, \ Norris, \ Anne < \underline{Anne.Norris@fda.hhs.gov} >, \ DeLancey, \ Siobhan < \underline{Siobhan.Delancey@fda.hhs.gov} >, \ Lovell, \$

Randall A < Randall.Lovell@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting. B5 ...Dave, do you have any idea

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>;

Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

 $Norris, Anne < \underline{Anne.Norris@fda.hhs.gov}>; DeLancey, Siobhan < \underline{Siobhan.Delancey@fda.hhs.gov}>; Lovell, Anne < \underline{Anne.Norris@fda.hhs.gov}>; DeLancey, Siobhan < \underline{Siobhan.Delancey@fda.hhs.gov}>; Lovell, Anne < \underline{Anne.Norris@fda.hhs.gov}>;

Randall A < Randall.Lovell@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>; Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic.	B5
I think B5	
В	5

From: Palmer, Lee Anne < <u>Lee Anne Palmer@fda.hhs.gov</u>>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>, Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>,

Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>,

Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >, Lovell,

 $Randall\ A < \underline{Randall\ Lovell@fda.hhs.gov} >$

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5



I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine < <u>Martine Hartogensis@fda.hhs.gov</u>>, Rotstein, David < <u>David Rotstein@fda.hhs.gov</u>>,

Jones, Jennifer L < Jennifer. Jones @fda.hhs.gov>

Cc: Burkholder, William < <u>William Burkholder@fda.hhs.gov</u>>, Carey, Lauren < <u>Lauren Carey@fda.hhs.gov</u>>,

Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi – the deeper I dig through this data, the more interesting it is become	ming. B5
B6	
B5	

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 PM

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Palmer,

Lee Anne < Lee Anne. Palmer @fda.hhs.gov >

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>;

Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with B6 Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:



As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6 (BB)











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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Palmer,

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine....

B5

I'm happy to share more info as needed. Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

B5



Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6 (BB)





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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM



Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

Subject: Re: DCM

Martine

В5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From:	Jones, Jennifer L
To:	'Andrea Fascetti'
Sent:	8/17/2018 2:48:55 PM
Subject:	B5
he B5 hope you and Fhanks again a Jen	
Jennifer L. A. Jo	·
eterinary Medical Of	
J.S. Food & Drug Adı Center for Veterinary	
Office of Research	PAINTE
	nvestigation and Response Network (Vet-LIRN)

Laurel, Maryland 20708 new tel: 240-402-5421 fax: 301-210-4685

From:	Jones, Jennifer L
T	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To:	'Andrea Fascetti'
Sent:	8/20/2018 10:47:59 AM RE: B5
Subject: Excellent, thank you, A	Andrea. Please give my thanks to B6 as well. We can make the B5 solution from the
B5	- Lancaca
Jennifer Jones, DVM Veterinary Medical Office Tel: 240-402-5421	er Ser
TOA U.S. FOOD & DRUG	
Sent: Saturday, Augus	<pre><jennifer.jones@fda.hhs.gov></jennifer.jones@fda.hhs.gov></pre>
Subject: Re:	В5
Hello Jen -	
I posed this question to	B5 and here is his reply:
	B5
•	hy he prefers using the chemical form - it may be as simple as cost. I sent an email but I have been on clinics all week and he has been pulling long hours.
•	down on Monday. We got in over 100 samples last week alone. Happy to catch up with y help with regard to the taurine matter.
	B5
Kind regards and I hop	be you are getting some time to enjoy the summer.
Andrea	
On Aug 17, 2018, at 7	:48 AM, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> > wrote:
Hi Andrea,	,
the B5 paper	. I'm trying to order the B6 , but does it matter B5 ? I referenced you sent but couldn't find any specifics of the chemical formula.

I hope you and your family are doing well, including your dog after the quarantine period J Thanks again and take care, Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704 Laurel, Maryland 20708 new tel: 240-402-5421 fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

<image001.png> <image004.png>

Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-

JENNIFER.JO>

To:

B6

Sent:

7/5/2019 4:34:49 PM

Subject:

FDA-CVCA Study for Dilated Cardiomyopathy

Importance: High

Attachments:

03-Vet-LIRN-Network ProceduresOwners-12.22.2015.pdf

Good afternoon

B6 I am sorry that you lost B6 Please accept my condolences. We have been working with CVCA to better understand Dilated Cardiomyopathy in dogs that ate pet foods labelled "grain free" and contain higher amounts of leaumes and/or potato products. As part of that investigation, we would like to ask you some questions about

B6 past diet and environmental exposures.

The phone interview lasts approximately 30 minutes. Please send me 3 times when you would be available to speak between 6:30 am and 3 pm the following days:

- 7/11
- 7/12
- 7/15
- 7/16
- 7/17
- 7/18

I attached a copy of our network procedures. They describe how owners help with our case investigations. Thank you kindly,

Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer U.S. Food & Drug Administration

Center for Veterinary Medicine Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704 Laurel, Maryland 20708 new tel: 240-402-5421 fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm





Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-

JENNIFER.JO>

To:

From:

B6

Sent:

7/5/2019 4:51:54 PM

Subject:

FDA-CVCA Study for Dilated Cardiomyopathy

High Importance:

Attachments: 03-Vet-LIRN-Network ProceduresOwners-12.22.2015.pdf

Good afternoon Mr. **B6**

We have been working with CVCA to better understand Dilated Cardiomyopathy in dogs that ate pet foods labelled "grain free" and contain higher amounts of legumes and/or potato products. As part of that investigation, we would like to ask you some questions about **B6** s past and current diet and environmental exposures.

The phone interview lasts approximately 30 minutes. Please send me 3 times when you would be available to speak between 6:30 am and 3 pm eastern time the following days:

- 7/11
- 7/12
- 7/15
- 7/16
- 7/17
- 7/18

I attached a copy of our network procedures. They describe how owners help with our case investigations. Thank you kindly,

Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer U.S. Food & Drug Administration Center for Veterinary Medicine Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704 Laurel, Maryland 20708 new tel: 240-402-5421 fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm





Network Procedures for Owners

The purpose of this Network Procedure is to help you, the owner, understand how the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) Program Office conducts case investigations (follow up to consumer complaints).

The following items are explained below:

- General Introduction
- Billing
- Step by Step Process
- Types of Services and Tests

1. General Introduction:

1.1. What is the goal of the case investigation?

The goal of the case investigation is to determine if the product is causing your pet's illness. Our case investigation MAY NOT provide a definitive diagnosis for your pet's illness, although we may rule out several other potential reasons for your pet's illness.

1.2. What is the focus of a case investigation?

Most case investigations focus on diagnostic samples (such as blood, urine or tissue from the pet), although we occasionally request and test pet food samples.

1.3. What is my veterinarian's role during the case investigation?

Your veterinarian helps our investigation into FDA- regulated products by providing information about your pet's medical history and by obtaining any diagnostic samples like blood, urine or tissue.

1.4. What will Vet-LIRN ask of me during a case investigation?

We may ask that your veterinarian perform certain tests or services or provide diagnostic samples to FDA or a Vet-LIRN cooperating laboratory.



1.5. Will Vet-LIRN pay for tests or services requested?

Yes, we will pay veterinarians or laboratories *for tests or services requested by Vet-LIRN* and approved through our government purchasing system. We cannot, however, reimburse owners for tests already performed or not specifically requested by Vet-LIRN. We recommend that you discuss with your veterinarian which tests and services will be billed to you and which will be covered by Vet-LIRN. For instance, Vet-LIRN may request that your veterinarian perform a urinalysis on your pet while he or she is hospitalized. Vet-LIRN will pay for the collection and testing of the sample, but would not cover the cost of your pet's stay in the hospital.

1.6. Is the information received in the consumer complaint confidential?

Generally, the information received in the consumer complaint is not kept confidential. In most cases, only protected personal information (such as names and addresses) is withheld in an effort to prevent the complaint from being traced back to the individual who submitted it.

2. Billing:

2.1. Will Vet-LIRN pay for bills related to the case investigation?

Vet-LIRN will cover the cost of services and testing that we specifically request. You should understand that Vet-LIRN *CANNOT* reimburse owners for any veterinary bills. Services *MUST* be pre-authorized and paid directly to the veterinarian.

2.2. Will Vet-LIRN pay for testing that was not requested by Vet-LIRN?

No, we will only pay for testing that we request and authorize.

2.3. Will Vet-LIRN pay for treatments or private cremation?

No, we cannot pay for treatment or cremation.



2.4. If I allow my veterinarian to submit my pet's body for testing, will I be able to have back his or her remains?

Each Vet-LIRN member laboratory has its own procedures for handling remains. Some Vet-LIRN member laboratories offer private cremation services for a fee payable directly to the laboratory. We advise you to discuss directly with the member laboratory the possibilities and costs for obtaining your pet's remains after examination are complete.

3. Step by Step Process:

Vet-LIRN will do the following during a case investigation:

- 3.1. Assign a case number which MUST be included in all correspondences
- 3.2. Discuss the case with you and your veterinarian
- 3.3. Request medical records from your veterinarian
- 3.4. Coordinate with your veterinarian and you to obtain and submit samples for testing
- 3.5. Provide results to your veterinarian who will discuss the results with you.

Vet-LIRN requests that:

- 3.6. Any follow-up veterinary visits related to the investigation are reported to Vet-LIRN
- 3.7. Additional laboratory reports are reported to Vet-LIRN by your veterinarian.

4. Types of Services and Tests:

4.1. What may a veterinary examination include once the case investigation is started?

A veterinary examination may include:

- an office visit and physical examination to assess your animals current health
- collection of clinical samples from your animal (blood, urine, feces).

4.2. Will your animal be tested more than once?



It is possible that Vet-LIRN may request additional tests or examinations depending on results from initial testing.

4.3. Will Vet-LIRN need to conduct a necropsy in the event of an animal death?

Yes, if you are willing, we may request that your veterinarian or another Vet-LIRN cooperating laboratory to conduct a necropsy to collect samples for testing. The samples collected may be tested right away or may be held for future testing or archiving. If the veterinarian completes the necropsy then the remains will be handled according the veterinarians normal procedures. If a Vet-LIRN cooperative laboratory completes the necropsy the remains are usually disposed of by that laboratory. Vet-LIRN cannot pay for private cremation. You are welcome to discuss normal procedures with the laboratory.

4.4. Will Vet-LIRN ask for a food sample?

Our main focus is on testing diagnostic tissue or fluid samples from the animal, but we may need to test the food. Please hold all food samples once the consumer complaint is submitted. If needed, we will make arrangements to collect the food.

4.5. What are some general tests that Vet-LIRN may request?

General tests that we may request include, but are not limited to:

- Hematology
- Microbial cultures
- Urinalysis
- Fecal examination
- Necropsy/Histology/Toxicology

4.6. Will I get results from Vet-LIRN requested tests?

Results of testing on your animal's diagnostic tissue or fluid samples will be forwarded to your veterinarian who will be asked to share the results with you.

From:

Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244
JENNIFER.JO>

To:

B6

Sent:

7/18/2019 11:11:54 AM

Subject:

RE:
B6
FDA-CVCA Study for Dilated Cardiomyopathy

Good morning Mr. **B6**

Are you interested in speaking with me about **B6** case? Please see my previous email below.

If so, please send me your availability for a 30-minute phone call on the following days:

- Tuesday July 23: 10 am to 12 noon eastern, or 1 to 3 pm
- Wednesday July 24: 6:30 am to 11 am eastern
- Thursday July 25: 6:30 am to 3 pm eastern

High

• Friday July 26: 6:30 am to 11:30 am eastern.

If you are unwilling to perform the interview, please let me know. I can then remove you from the interview list. Thank you,

Dr. Jones

Importance:

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Jones, Jennifer L

Sent: Friday, July 05, 2019 12:52 PM

To: B6

Subject: B6 FDA-CVCA Study for Dilated Cardiomyopathy

Importance: High

Good afternoon **B6**

We have been working with CVCA to better understand Dilated Cardiomyopathy in dogs that ate pet foods labelled "grain free" and contain higher amounts of legumes and/or potato products. As part of that investigation, we would like to ask you some questions about **B6** s past and current diet and environmental exposures.

The phone interview lasts approximately 30 minutes. Please send me 3 times when you would be available to speak between 6:30 am and 3 pm eastern time the following days:

- 7/11
- 7/12
- 7/15
- 7/16
- 7/17
- 7/18

I attached a copy of our network procedures. They describe how owners help with our case investigations. Thank you kindly,

Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708

new tel: 240-402-5421 fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm
U.S. FOOD & DRUG

ADMINISTRATION





From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To: 'Andrea Fascetti' **Sent:** 3/25/2019 6:57:47 PM

Subject: reference ranges for plasma amino acids

Hi Andrea,

Do you have specific reference B5

B5

Thank you in advance,

Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421

fax: 301-210-4685 e-mail: <u>jennifer.jones@fda.hhs.gov</u>

Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm



From: To:	Jones, Jennifer L; Andrea Fascetti
CC:	Guag, Jake
Sent: Subject:	4/1/2019 11:34:02 PM Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples
Subject.	Re. Fleads up. Vet-LIKN (FDA) shipped 600.207 samples
Hi Dr. Jones,	
I will correct the misla	abels and get back to you tomorrow.
Thanks, B6	
From: Jones, Jennifer Sent: Monday, April 1, To: Andrea Fascetti;	
Cc: Guag, Jake	o: Vet-LIRN (FDA) shipped 800.267 samples
acid values for cv-09 but inventory sheet). Can you	ts and needed some clarification of the results for 2 cases. The results you sent show plasma amino not cv-14. However, I did not send any plasma for cv-09. I did send plasma for cv-14 (attached a please clarify which set of plasma values belong to cv-14? d have a wonderful week,
Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 DA U.S. FOOD & DRUG ADMINISTRATION	
From: Andrea Fascetti < Sent: Saturday, March 23 To: B6	3, 2019 1:30 PM
<u> </u>	nag@fda.hhs.gov>; Jones, Jennifer L <jennifer.jones@fda.hhs.gov> Vet-LIRN (FDA) shipped 800.267 samples</jennifer.jones@fda.hhs.gov>
case someone in the lab of	se see attached file with your results. Thanks for the heads-up on the species. We have to know in somes in contact with the blood (especially through a cut). Our occupational health and safety eport and follow up on those cases to ensure vaccination status etc.
We will bill according to	your comments below.
Have a nice weekend.	
Andrea	
On Mar 21, 2019, at 10:5	1 AM. B6 wrote:
Hi Jake,	

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks

	٠,
D.C	:
Bb	!
	•

From: Guag, Jake < <u>Jake.Guag@fda.hhs.gov</u>> Sent: Tuesday, March 12, 2019 8:53 AM

To: B6
Cc: Jones, Jennifer L

Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi Joshua,

Hope you are well. We shipped 800.267 samples on dry ice to you.

Box#1 has urine samples its tracking number is 1ZA4420T0194520315 with UPS.

Box#2 has whole blood and serum samples and its tracking number is 1ZA4420T0192121929 with UPS. Both boxes are expected to arrive your location tomorrow (Mar. 13th, 2019)

Please charge the urine sample analysis under AA contract.

Please provide invoice for the blood and serum analysis.

Thank you Jake

Jake Guag, MPH, CPH Biologist (FDA/CVM/OR/Vet-LIRN) 8401 Muirkirk Road Laurel, Maryland 20708 Email: jake.guag@fda.hhs.gov

Tel: 240-402-0917

From: To:	Jones, Jennifer L B6 Andrea Fascetti
CC: Sent: Subject:	Guag, Jake 4/2/2019 11:19:19 AM RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples
Received. Thank you,	B6
Jennifer Jones, DVM Veterinary Medical Office Tel: 240-402-5421	r
DA U.S. FOOD & DRUG	
Cc: Guag, Jake <jake Subject: Re: Heads up</jake 	, 2019 8:06 PM Jennifer.Jones@fda.hhs.gov>; Andrea Fascetti <ajfascetti@ucdavis.edu></ajfascetti@ucdavis.edu>
Hi Dr. Jones,	
Attached please find	the corrected data file.
Kind Regards, B6	
Sent: Monday, April 1, To: Andrea Fascetti; Cc: Guag, Jake	
plasma amino acid valu plasma for cv-14 (attac	and B6 sults and needed some clarification of the results for 2 cases. The results you sent show ues for cv-09 but not cv-14. However, I did not send any plasma for cv-09. I did send ched inventory sheet). Can you please clarify which set of plasma values belong to cv-14? and have a wonderful week,
Jennifer Jones, DVM Veterinary Medical Office Tel: 240-402-5421 TDA U.S. FOOD & DRUG	Г
uuluukkusut	
Sent: Saturday, March To: B6 Cc: Guag, Jake < Jake	
-	

Hello Jen and Jake- Please see attached file with your results. Thanks for the heads-up on the species. We have to know in case someone in the lab comes in contact with the blood (especially through a cut). Our occupational health and safety folks then have us file a report and follow up on those cases to ensure vaccination status etc.

We will bill according to your comments below.

Have a nice weekend.

Andrea

В6

On Mar 21, 2019, at 10:51 AM, B6 @ucdavis.edu> wrote:

Hi Jake,

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks

From: Guag, Jake < <u>Jake.Guag@fda.hhs.gov</u>> Sent: Tuesday, March 12, 2019 8:53 AM

To: B6
Cc: Jones, Jennifer L

Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi B6

Hope you are well. We shipped 800.267 samples on dry ice to you.

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Please charge the urine sample analysis under AA contract. Please provide invoice for the blood and serum analysis.

Thank you Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Empil: jake guag@fda.hbs.gov

Email: jake.guag@fda.hhs.gov

Tel: 240-402-0917

From:	Jones, Jennifer L
To:	B6
CC:	'Guag, Jake * (Jake.Guag@fda.hhs.gov)'
Sent:	3/22/2019 10:35:43 AM
Subject:	RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples
Hi B6 They are all dogs. Thank you, Jen	
Jennifer Jones, DVM Veterinary Medical Office Tel: 240-402-5421 DA U.S. FOOD & DRUG ADMINISTRATION	
	a 21, 2019 2:09 PM :Jennifer.Jones@fda.hhs.gov> o: Vet-LIRN (FDA) shipped 800.267 samples
Jen, could you please	provide me info or where I can find the info?
Thanks Jake	
Cc: Guag, Jake < Jake.	<u>jfascetti@ucdavis.edu</u> >
Hi Jake,	
May you help to confirm	n the samples are for dogs or cats? I could not find the information
Thanks, B6	
Sent: Tuesday, March To: B6 Cc: Jones, Jennifer L	ke.Guag@fda.hhs.gov> 12, 2019 8:53 AM et-LIRN (FDA) shipped 800.267 samples
Box#1 has urine sampl Box#2 has whole blood	shipped 800.267 samples on dry ice to you. les its tracking number is 1ZA4420T0194520315 with UPS. If and serum samples and its tracking number is 1ZA4420T0192121929 with UPS. Both arrive your location tomorrow (Mar. 13 th , 2019)
Please charge the uring	e sample analysis under AA contract.

Please provide invoice for the blood and serum analysis.

Thank you Jake

Jake Guag, MPH, CPH Biologist (FDA/CVM/OR/Vet-LIRN) 8401 Muirkirk Road Laurel, Maryland 20708 Email: jake.guag@fda.hhs.gov Tel: 240-402-0917

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-

JENNIFER.JO>

To:

B6

CC:

Andrea Fascetti

Sent:

8/20/2019 11:44:03 AM

Subject:

Question about results

Good morning B6 and Andrea,

I had two quick general questions about the plasma and urine amino acid results.

B5

Thank you in advance,

Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer U.S. Food & Drug Administration Center for Veterinary Medicine Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704 Laurel, Maryland 20708 new tel: 240-402-5421

fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm



From:	Guag, Jake
To:	B6
Sent:	6/27/2019 4:48:27 PM
Subject:	RE: Fw: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples
<mark>ве</mark> Ј Could you please prov	ct. I forgot to update the CV-10 samples. ide me when we can expect to get results?
Thanks	
From England Lune 1	B6 ucdavis-edu>
Sent: Thursday, June 2	27, 2019 12:41 PM B 6
· · · i	ds up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples
Hello Jake-	
Attached please find the otherwise everything was a second control of the control	ne completed inventory form. The only thing of note is there were 2 vials of cv-10 plasma, vas in order
outerwise every aming w	
Kind regards-	
B	6
On Thu, Jun 27, 2019 Hi B6	at 9:26 AM B6 ucdavis.edu> wrote:
Could you fill their sa	imple inventory forms and email a PDF to Jake?
Thanks,	
From: Guag, Jake < Ja Sent: Thursday, June 2 To: B6	<u>ske.Guag@fda.hhs.gov</u> > 27, 2019 9:21 AM
	p: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples
Hi B6 Could you please prov	ide me filled out sample inventory forms?

Thanks
Jake

From: B6 __ucdavis.edu>
Sent: Tuesday, June 25, 2019 1:16 PM
To: Guag, Jake < Jake.Guag@fda.hhs.gov>
Cc: Andrea Fascetti < aifascetti@ucdavis.edu>; B6
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi Jake,

Thanks for the notice. I will Let Dr. Fasccetti know your plan. I am not in charge of the billing issues.

Kind Regards,

B6

From: Guag, Jake < <u>Jake.Guag@fda.hhs.gov</u>> Sent: Tuesday, June 25, 2019 9:17 AM

(Box#1) and **B6** (Box#2) with UPS.

To: B6 Cc: Jones, Jennifer L

Subject: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi B6

I shipped 800.267 R3 samples on dry ice to your place this morning. R3 Urine samples are in Box#1, and R3 whole blood and plasma samples are in Box #2.

Both boxes will be arrive tomorrow (Jun 26, 2019), and their tracking numbers are

Inside you will find sample an inventory sheet in each box. Please fill out and provide to me (Scan or Fax).

B5

Thanks Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov

Tel: 240-402-0917

ucdavis.edu>

From: To:	Andrea Fascetti <ajfascetti@ucdavis.edu> Jones, Jennifer L</ajfascetti@ucdavis.edu>	
Sent:	9/18/2018 12:16:47 PM	
Subject:	Re: control dog Taurine-urine	
TT: T TT : .!		
Hi Jen - Here is Be	jemaii address:	
В6		
And Josh:		
jstern@ucdavis.edu		
I hope this helps.		
•		
Andrea		
On Sep 18, 2018, at 1	:23 PM, Jones, Jennifer L < <u>Jennifer.Jones</u>	<u>@fda.hhs.gov</u> > wrote:
Cood manian Amalan	_	
Good morning Andre	a, hout the collaboration with Joshua Stern :	and B6 We will need to get some
documentation first. b	out otherwise we'd be happy to share the	control urine taurine data. I'm checking to see
what agreements we	need. Can you please provide B6 e	control urine taurine data. I'm checking to see mail? After I get the documents, I can send them
	iture, and then we can share the data.	•
Thank you for the col	laborative opportunity!	
	B6	
Take care,		
Jen		
Jennifer L. A. Jones, I	o∨M	
Veterinary Medical Officer U.S. Food & Drug Administra	tion	
Center for Veterinary Medicin		
Office of Research		
Veterinary Laboratory Investiges 8401 Muirkirk Road, G704	gation and Response Network (Vet-LIRN)	
Laurel, Maryland 20708		
new tel: 240-402-5421		
fax: 301-210-4685 e-mail: jennifer.jones@fda.hh	us aov	
	nalVeterinary/ScienceResearch/ucm247334.htm	
<image001.png> <in< th=""><th>nage002.png></th><th></th></in<></image001.png>	nage002.png>	

From:	Jones, Jennifer L
To:	Peloquin, Sarah
Sent:	9/18/2018 1:54:55 PM
Subject:	FW: control dog Taurine-urine
FYI	
Jennifer Jones, DVM Veterinary Medical Office Tel: 240-402-5421	er
U.S. FOOD & DRUG	
Sent: Tuesday, Septe	ti <ajfascetti@ucdavis.edu> mber 18, 2018 8:17 AM <jennifer.jones@fda.hhs.gov> log Taurine-urine</jennifer.jones@fda.hhs.gov></ajfascetti@ucdavis.edu>
Hi Jen - Here is B6	email address:
В6	
And Josh:	
jstern@ucdavis.edu	
I hope this helps.	
Andrea	
On Sep 18, 2018, at 1	:23 PM, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> > wrote:
documentation first, bu what agreements we r	out the collaboration with Joshua Stern and B6 We will need to get some ut otherwise, we'd be happy to share the control urine taurine data. I'm checking to see need. Can you please provide B6 email? After I get the documents, I can send them ure, and then we can share the data.
	B6
Take care,	

Jennifer L. A. Jones, DVM

Veterinary Medical Officer U.S. Food & Drug Administration Center for Veterinary Medicine Office of Research Veterinary Laboratory Investigation and Response Network (Vet-LIRN) 8401 Muirkirk Road, G704 Laurel, Maryland 20708 new tel: 240-402-5421

fax: 301-210-4685

Jen

e-mail: jennifer.jones@fda.hhs.gov
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm
jennifer.jones@fda.hhs.gov
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm
jennifer.jones@fda.hhs.gov
<a href="mailto:jennifer.jones.jo



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To: Peloquin, Sarah

Sent: 9/18/2018 2:12:18 PM

Subject: RE: control dog Taurine-urine

No-this is different. We can chat tomorrow.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Peloquin, Sarah

Sent: Tuesday, September 18, 2018 10:08 AM **To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: control dog Taurine-urine

Is that the urine that CVCA will be collecting?

How many dogs are in the study so far, with the original requirements?

From: Jones, Jennifer L

Sent: Tuesday, September 18, 2018 9:55 AM

To: Peloquin, Sarah < <u>Sarah.Peloquin@fda.hhs.gov</u>>

Subject: FW: control dog Taurine-urine

FYI

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Andrea Fascetti <a i row | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti | Andrea Fascetti

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>

Subject: Re: control dog Taurine-urine

Hi Jen - Here is **B6** email address:

B6 @ucdavis.edu

And Josh:

jstern@ucdavis.edu

I hope this helps.

Andrea

On Sep 18, 2018, at 1:23 PM, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>> wrote:

Good morning Andrea,
I got your message about the collaboration with Joshua Stern and B6 We will need to get some
documentation first, but otherwise, we'd be happy to share the control urine taurine data. I'm checking to see
what agreements we need. Can you please provide B6 email? After I get the documents, I can send them
to the group for signature, and then we can share the data.
Thank you for the collaborative opportunity!
B6
Take care,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421

e-mail: jennifer.jones@fda.hhs.gov

fax: 301-210-4685

 $Web: \underline{http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm}\\$

<image001.png> <image002.png>

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee

Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David

Sent: 10/9/2018 1:48:13 PM

Subject: house mate of EON-366516 (attached) FW: Taste of the Wild (various flavors) since Nov 2013:

Lisa Freeman - EON-367899

Attachments: 2055822-report.pdf; Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were

Southwest Canyon flavor-Before that: Lisa Freeman - EON-366516; 2055822-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

(BB)





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From: PFR Event cpfreventcreation@fda.hhs.gov>

Sent: Tuesday, October 09, 2018 9:45 AM

To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification

<HQPetFoodReportNotification@fda.hhs.gov>;
B6

Subject: Taste of the Wild (various flavors) since Nov 2013: Lisa Freeman - EON-367899

A PFR Report has been received and PFR Event [EON-367899] has been created in the EON System.

A "PDF" report by name "2055822-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055822-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367899

ICSR #: 2055822

EON Title: PFR Event created for Taste of the Wild (various flavors) since Nov 2013; 2055822

AE Date	10/02/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2

Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 /ears		
District Involved	PFR-New England DO		

_		_		_	_			
D١	·^	d	c+	ir	ıf∩	rm	ati	on

Individual Case Safety Report Number: 2055822

Product Group: Pet Food

Product Name: Taste of the Wild (various flavors) since Nov 2013

Description: Asymptomatic but is housemate of **B6** who was diagnosed with DCM recently (FDA ICSR ID 2055229). Eating same diet until mid-September when switched to Pro Plan Weight Management dry. Note **B6** does not have clear DCM but has reduced contractility. Will recheck in 6 months. Taurine pending -

will submit when available. **Submission Type:** Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 2 Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Taste of the Wild (various flavors) since Nov 2013		

Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner information

B6

To view this Pf	R Event, please click th B6	ne link below:	
To view the PF	R Event Report, please	click the link below:	
B6			
========			

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Report Details - EON-	5				
ICSR:	2055822				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)		
Reporting Type:	Voluntary				
Report Submission Date:			7-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1		
Reported Problem:	Problem Description:	switched to Pro Plan	ID 2055229). Eating same diet until mid-September when Weight Management dry. Note B6 does not have clear contractility. Will recheck in 6 months. Taurine pending -		
	Date Problem Started:	10/02/2018			
	Concurrent Medical Problem:				
	Outcome to Date:	Stable			
Product Information:	Product Name:	Taste of the Wild (va	rious flavors) since Nov 2013		
	Product Type:	7			
	Lot Number:				
	Package Type:	BAG			
	Product Use Information:				
	Manufacturer /Distributor Information: Purchase Location Information:				
Animal Information:	Name: Type Of Species:	B6 Dog			
		Doberman Pinscher			
	Gender:	Female			
	Reproductive Status:	Neutered			
	Weight:	33.4 Kilogram			
	Age:	B6 Years			
	Assessment of Prior Health:	Excellent			
	Number of Animals Given the Product:				
	Number of Animals Reacted:	7			
	Owner Information:	Owner Information provided:	Yes		
		provided.			
		7	Name:		
		Contact:	Name: B6		
		7			
		7	Phone: B6		
		Contact:	Phone: B6 B6		
		Contact:	Phone: B6		

				Email: lisa.freeman@tufts.edu
		Add	dress:	200 Westboro Rd North Grafton Massachusetts 01536 United States
ender Information:	Name:	Lisa Freeman		
		200 Westbord North Grafton Massachusett 01536 United States	n ts	
	Contact:	Phone:		5088874523
		Е	Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Additional Documents:				
	Attachment:			records combined.pdf
	Description:	i		records
	Туре:	Medical Recor	rds	

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 9/22/2018 10:40:31 PM

Subject: Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were Southwest

Canyon flavor-Before that: Lisa Freeman - EON-366516

Attachments: 2055229-report.pdf; 2055229-attachments.zip

A PFR Report has been received and PFR Event [EON-366516] has been created in the EON System.

A "PDF" report by name "2055229-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055229-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-366516

ICSR #: 2055229

EON Title: PFR Event created for Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that fed 3-4 bags of Pine Forest Before that had been feeding Pacific Stream for several years; 2055229

AE Date	09/08/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055229

Product Group: Pet Food

Product Name: Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor

Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years **Description:** DCM and CHF Probably primary DCM in predisposed breed but given diet history, some

possibility of diet-associated DCM Taurine WNL

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 2 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years		

Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner information

B6

USA

	, vic vv	tills	1110	DVCIIt,	prease	CITCIC		111111		011
T_{c}	view	this	PFR	Event,	nlease	click	the	link	held	OW/

To view the PFR Event Report, please click the link below:

B6

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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ICSR:					
OOIX.	2055229				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)		
Reporting Type:	Voluntary				
Report Submission Date:	2018-09-22 18:33:37 EDT				
Reported Problem:	Problem Description:	ion: DCM and CHF Probably primary DCM in predisposed breed by some possibility of diet-associated DCM Taurine WNL			
	Date Problem Started:	09/08/2018			
	Concurrent Medical Problem:	No			
	Outcome to Date:	Stable			
Product Information:	Product Name:		st 1-2 bags (for 2 dogs) before diagnosis were Southwest e that, fed 3-4 bags of Pine Forest Before that, had been im for several years		
	Product Type:	;			
	Lot Number:				
	Package Type:	BAG			
	Product Use Information:	Description:	Owner has given consent to have FDA contact her for any additional questions		
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:	В6			
	Type Of Species:	Dog			
		Doberman Pinscher			
	Gender:	4			
	Reproductive Status:	1			
		34.2 Kilogram			
	I	B6 Years			
	Assessment of Prior Health:	7			
	Number of Animals Given the Product:	2			
	Number of Animals Reacted:	1			
	Owner Information:	Owner Information provided:	Yes		
		Contact:	Name:		
			Phone: B6		
		Address:	\(\tag{\tag{\tag{\tag{\tag{\tag{\tag{		
		Addicas.	B6		
			United States		
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine		
	Information:	Contact:	<u> </u>		

			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	discharge 9-20-18.p	df
		Discharge 9-20-18	
	Type:	Medical Records	
	Attachment:	bnp.pdf	
	Description:		
	Type:	Laboratory Report	
	Attachment:	cardio appointment	
		Cardio appt 9-20-18	
		Echocardiogram	
	Attachment:	cardio consult 9-8-18	
		cardio consult 9-8-18	8
		Echocardiogram	
	Attachment:	discharge 9-9-18.pd	f
		Discharge 9-9-18	
	Type:	Medical Records	

Client B6 Patient B6 Species CANIN Breed: DOBERI Gender: MALE Age: 8Y	.i IE MAN_PINSCH	Date: 09/10/2018 Requisition#: 42 Accession# Ordered by	6657	200 WES	A F. W.
CARDIOPET T est	proBNP - CANINE Result	Reference Range	Low	Normal F	ligh
CARDIOPET p	roBNP B6	0 - 900 pmol/L	HIGH		<u> </u>
Comments:					
		B			
Please no	te: Complete inte	rpretive comments for	all concentration	ons of Cardio	pet

Page 1 of 1

Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

B6

Batient ID: \$200408

Canine
Canine
Cars Old Male (Neutered) Doberman
Pinscher
Black/Tan

Cardiology Appointment Report

Date: 9/20/2018		
Attending Cardiologi	st: DVM, MS, DACVIM (Cardiology), DACVEC	œ
	B6	
Cardiology Resident:		
	B6	
Cardiology Technicia B6	cvt, vts (Cardiology)	
Student B6	V19	

Presenting Complaint:

Recheck of DCM with active CHF

General Medical History:

Has been his normal self, went on one 20 min walk since he was last here and had no trouble at all. PU/PD (due to lasix)

Diet and Supplements:

Fromm Mature: 4 cups a day

Cardiovascular History:

Prior CHF diagnosis? Yes

Prior heart murmur? Yes, grade III/VI

Prior ATE?, N

Prior arrhythmia? Y, VPCs

Monitoring respiratory rate and effort at home? N, but havent noticed any labored breathing

Cough? N

Shortness of breath or difficulty breathing? N

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? N

Current Medications Pertinent to CV System:

Medication: B6	· :
B6	
Medication: B6	
B6	
Medication: B6	
B6	
Medication: B6	
Can we call their pharmacy with a script fo	r this?
Cardiac Physical Examination:	
General PE:	Heart rate:
MM Color and CRT:	Respiratory rate:
BCS (1-9):	Temp (if possible):
BW (kg): 34.2 Kg	
Muscle condition:	
Normal	■ Moderate cachexia
Mild muscle loss	Marked cacheda
Cardiovascular Physical Exam:	
Murmur Grade:	
None	<u>₩</u> IV/VI
□ I/NI □ uba	■ V/M
∭ II/VI ∭ III/VI	■ vi/vi
= y =.	
Murmur location/description:	
Jugular vein:	
Bottom 1/3 of the neck	1/2 way up the neck
Middle 1/3 of the neck	Top 2/3 of the neck
Arterial pulses:	☐ Bounding
Fair	Pulse deficits
Good	Pulsus paradoxus
Strong	Other:
Arrhythmia:	
None None	Bradycardia
Sinus arrhythmia	Tachycardia
Premature beats	

Gallop:	_
Yes Yes	■ Pronounced
☑ No	Other:
Intermittent	
Pulmonary assessments:	
Eupneic	Pulmonary crackles
Mild dyspnea	■ Wheezes
Marked dyspnea	Upper ainway stridor
Normal BV sounds	- Oppo an may sunton
III IACH IIICE DA ZONING	
Abdominal exam:	
Addomna exam:	Mild ascites
Hepatomegaly	Marked ascites
Abdominal distension	
<u>Problems:</u>	
Differential Diagnoses:	
on a crass oraginate.	
Diagnostic plan:	
Echecardiegram	🖳 Dialysis profile
Chemistry profile	Thoracic radiographs
ECG ECG	III NT-proBNP
Renal profile	Trepenin I
Blood pressure	Other tests:
Assessment and recommendations:	
Final Diagnosis:	
Heart Failure Classification Score:	
ISACHC Classification:	
■ la	🔲 Illa
□lb	□ IIIb
	III 0
■II	
ACVIM Classification:	
■ A	□ c
■ B1	■ D
□ B2	= 5



B6

Patient ID: \$200408 B6 Canine ears Old Male (Neutered) Doberman Pinscher Black/Tan BW: Weight (kg) 32.00

Cardiology Consultation

Date: 9/8/2018 Weight: Weight (kg) 32.00	
,	M (Resident - Emergency & Critical Care)
Attending Cardiologist John E. Rush DVM, MS, DAC	/IM (Cardiology), DACVECC
	B6
Cardiology Resident:	
	B6
Thoracic radiographs available for r Yes - in SS Yes - in PACS No	eview?
Patient location: ER	
soft cough after exercise and at rest, getting more frequent over the past	it concurrent diseases: 8 y.o doberman presenting for acute onset , worse at night. Owners report coughing episodes have been 3 days. Grade IV/VI right sided systolic murmur ausculted on exam een with cardiology 9/20/18 based on arrhythmia heard at rDVM.
STOP - remai	nder of form to be filled out by Cardiology
Physical Examination	
Heart rate: 120	Respiratory rate: 28
MM Color and CRT: pk, <2	BCS (1-9): 4
Muscle condition:	
Mild muscle loss	 ■ Moderate cachexia ■ Marked cachexia
■ Mild muscle loss Cardiovascular Physical Exam	
Mild muscle loss Cardiovascular Physical Exam Murmur Grade:	Marked cachexia
■ Mild muscle loss Cardiovascular Physical Exam	

on exam. rDVML

□ II/VI ☑ III/VI	
Murmur location/description: systo	lic right apical
Jugular vein: Bottom 1/3 of the neck Middle 1/3 of the neck	☐ Top 2/3 of the neck ☐ 1/2 way up the neck
Arterial pulses: Weak Good Strong	 Bounding Pulse deficits Pulsus paradoxus Other (describe):
Arrhythmia: None Sinus arrhythmia Premature beats	■ Bradycardia ■ Tachycardia
Gallop: ☐ Yes ☑ No ☐ Intermittent	Pronounced Other:
Pulmonary assessments: Eupneic Mild dyspnea Marked dyspnea Normal BV sounds	 Pulmonary Crackles Wheezes Upper airway stridor Other auscultatory findings:
Abdominal exam: Normal Hepatomegaly	Abdominal distension Mild ascites
	B6
Mitual inflow: Summated Normal Delayed relocation	Pseudonormal Restrictive

	B6
	ngs consistent with DCM and active congestive heart failure.
Simpson and sphericity index revealed adv advanced DCM.	vanced LV dilation and enlarged LA are consistent with B6
	B6
Treatment plan:	
В	6
<u>Final Diagnosis</u> : L-CHF secondary to DCM	
Addendum:	
9/9/18 - Patient did well overnight, rare e	pisodes of cough and respiratory rate stayed stable B6
Heart Failure Classification Score: ISACHC Classification: la lb ll	■ IIIa ■ IIIb
ACVIM CHF Classification: A B1 B2	☑ c □ D

Cummings Veterinary Medical Center

Emergency & Critical Care Liaison: (508) 887-4745

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://webmed.tufts.edu/

<u>Patient</u> Name: Signalment:	B6 Years Old Black/Tan Male (Neutered) Doberman Pinscher	Owner Name: Address:	B6	
Patient ID: Emergency Clinician: Consulting Clinician:	S200403 B6 DVM (Intern)	.	······································	
ESO Si mercurrilaren	В	6		

Discharge Instructions

Admit Date: 9/8/2018 10:52:58 AM Check Out Date: 9/8/2018

Case Summary Diagnosis:

1. Dilated cardiomyopathy with active congestive heart failure.

Case Summary:

Thank you for bringing B6 to Tufts ER for evaluation of his persistent cough. You reported that he suddenly developed a cough three days ago and that it is worse after exercise or when he is resting at night. On presentation he was bright and alert. His vital signs (heart rate, respiratory rate, and temperature) were all within normal limits. He had an audible bilateral heart murmur. He coughed when his trachea was palpated lightly.

Based on his breed and clinical presentation, we opted to do radiographs and have an emergency consult with the cardiology department because of concerns of dilated cardiomyopathy (DCM). This is a common condition for this breed. Also, grain-free diets may predispose animals to developing dilated cardiomyopathy or make a pre-existing disease to get worse.

On his cardiology consult, ultrasound showed significantly decreased contraction of the heart, confirming dilated cardiomyopathy. EKG showed occasional abnormal heartbeats originating from the ventricle. Based on the results of his radiographs and cardiology consult, $\begin{array}{c} 86 \\ \hline \end{array}$ was started on diuretics to relieve some of the fluid building up in his lungs. He was also started on pimobendan, which increases the strength of heart contractions. As grain free diet can affect absorption of some nutrients, Taurine supplementation was started. He was placed on an EKG overnight to determine if any arrhythmias are present.

Patient Care Instructions: 1. Exercise restrictions: Do not allow B6 to overevert himself. He may still go for short walks and play with his sister but avoid strenuous activity like hiking or chasing squirrels which may overevert his heart. 2. Diet: We recommend to discontinue the gran free diet - a sheet that has suggestions for diet and low sodium treats can be found on the HeartSmart web site (http://vet.tults.edu/heartsmart/diet/). We recommend as dry options: - Royal Canin Early Cardiac; - Royal Canin Boxer; - Purina ProPlan Adult Weight Management. Medications: Recommended Medications:
B6
Recheck Visits: Please come in for your scheduled cardiology appointment on September 20th at 1PM as a re-check appointment.
Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@turks.edu for scheduling and non-emergent questions or concerns.
Please visit our HeartSmart website for more information http://vet.tults.edu/heartsmart/

Prescription Refill Discloimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarions within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us,
please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered
from online retailers with a prescription/veterinary approval.

tudies in which our vete est or treatment. Please	-		your pet to investigate a specific disease process or mc/clinical-studies
Case B6	Owner:	В6	Discharge Instructions

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fat (508) 839-7951 http://wetmed.turks.edu/

Discharge Instructions

<u>Patient</u>	Owner		
Name B6	Names	B6	Patient ID: S200403
Species: Canine	Address:	B6	
Black/Tan Male (Neutered) Do	bernan	DU	
Pinscher		L	. .
Birthdate: B6			
Attending Cardiologist:			
John E. Rush DVM, M	S, DACVIM (Cardiology), I	DACVECC	
	B6		
	DU		
Cardiology Resident:	B6	//2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/1	
Cardiology Technician:			
	TS (Cardiology)		
B6	13 (caraoresy)		
	J		
Student: B6 V19			
,			
Admit Date: B6 1:05:3	1 PM		
Discharge Date B6			
Diagnoses:			
1. Dilated cardiomyopathy (DC	JM)—stable		
2. Congestive heart failure— r	esolved		
_			
Case summary:		mont with a steady to the	is such a great had Wassa sa base eta base
			e is such a sweet boy! We are so happy to hear lifficulty breathing, or exercise intolerance.
We are so glad B6 is respon			
we are so Barri Be is restru	wal Sur Men in the titerin	auur aru e iezaig su	cumuratie
Today was reaformed a rectued	k anick ultraan ord of hic	hoort on ECG to rocko	ck his ventricular arrythmias, and took some
blood to enchark his kirkun un	k quak una asum morres kanc cinco hoine en the	Be Sectored	His heart seems to be contracting a little
	_	-	trium was smaller today since his last visit,
			arrythmias when we performed his ECG
			n his current medication doses (see list
below), and also continue ese			
mary was unvestment the		-) -H-1444A	
Monitoring at home:			
	monitor 86 breathir	e rate and effort at ho	me, ideally during sleep or at a time of rest.
	il be adjusted based on ti		

O In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is

fairly minimal if heart failure is controlled.

- O An increase in breathing rate or effort will usually mean that you should give an extra close of B6 it difficulty breathing is not improved by within 60-90 minutes after giving extra furosemide then we recommend that a recheck example scheduled and/or that your dog be evaluated by an emergency clinic.
- O There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24hours/day.

Recommended Medications:



Diet suggestions:

We suggest 186 to be in one of the diets we recommended (see list). Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (http://vet.tufls.edu/heartsmart/diet/)

Exercise Recommendations:

Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that $\begin{bmatrix} B6 \end{bmatrix}$ is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck echocardiogram for B6 is recommended in 3-4 months. B6 as an appointment with us on October 2nd at 4 pm.)

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tuits.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information http://vet.tulits.edu/heartsmart/

Prescription Refill Discloimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: <u>vet.tufts.edu/crmc/dinical-studies</u>

Case B6 Discharge Instructions

Cummings Veterinary Medical Center

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

All Medical Records

Patient: **B6**

Breed: Doberman Pinscher

DOB: **B6**

Species: Canine Sex: Female

(Spayed)

Client: Address: **B6**

Home Phone: Work Phone: Cell Phone: (

B6

Refe	rring	Info	rmation

B6

B6

Client: Patient: **B6**

Initial Complaint:

intestinal foreign material, vomiting

SOAP Text Mar 8 2015 7:14AM 3/8/2015 7:33:38 AM NEW VISIT (ER)

Doctor: B6

Presenting complaint: vomit x 10 this AM

B6

Objective (O)

B6

Client: B6
B6
Diagnostics Completed: AXR (2 view): foreign material (midabdomen on lateral, overlapping L3 on VD), no obstructive pattern, stomach is not distended NOVA: PCV/TS:
Assessment (A) A1: GI foreign object - r/o unobstructive v obstructive A2: B6
Plan (P) P1 P2 P3 P4 P5 P6
Communication Summary: Discussed presence of foreign object in intestines. Hopefully this can move along with hydration. B6
B6
Additional requests submitted: none
Estimate given: \$ B6
3/8/2015 8:52:32 AM Prescribed Instructions B6
3/8/2015 8:52:50 AM Prescribed - B6 Instructions TS (FHSA): 6.8
PCV **: 54
SOAP Text Mar 8 2015 10:01AM B6 3/8/2015 B6 DVM Presenting complaint: vomit x 10 this AM
D C

Client: B6 Patient:	
Visit is a referral: No	
	co
B6	
Diagnostics Completed:	
B6	
Assessment (A)	
Al: R6	
AZ.i.	
Plan (P) P1	
P2 P3	
P3 P4 P5 B6	
P6. P7.	
r/ _{ii}	
B6	
<u></u>	
Prescribed - Instructions B6	
B6	
Prescribed - B6	
BW 31 kg, AR5 - Expires: 3/8/2016 6 Refills	
SOAP Text Mar 9 2015 1:13PM - B6 2 vs SE Debberroen Director was presented early vactorday marring Synday 02/08/2015 for severy court varniting	
2 yo SF Dobberman Pinscher was presented early yesterday morning Sunday 03/08/2015 for severe acute vomiting.	
Vomitted once overnight and given B6 , no vomiting since. Urinating well; no defecation yet. Still NPO.	
B6	

Client: Patient:

B6

B6

B6

SOAP Text Mar 10 2015 1:55PM

B6

2 yo SF Dobberman Pinscher was presented Sunday 03/08/2015 for severe acute vomiting. Vomited once since admit. Started refeeding last night and has been eating ravenously.

S/O: overall unchanged with no significant findnes

B6

B6

Initial Complaint:

Emergency

Client: B6 Patient: B6
SOAP Text Sep 21 2015 5:20PM - B6
9/21/2015 5:20:18 PM NEW VISIT (ER) Doctor: B6
Presenting complaint: Left carpal pad laceration
B6
Objective (O)
B6

Page 5/22

Client: B6 Patient:				
Assessment (A) A1: Carpal pad lacerations A2: Hx of HBC A3: Hx of fever of unknown ori A4: Hx of intestinal FB	gin			
Plan (P) 1. 2. 3. 4.		36		
Communication Summary:		B6	 	
		DO	 	
Estimate given: \$	Deposit collected: \$			
9/21/2015 7:06:22 PM Prescribed - Instructions		B6	 	
Initial Complaint: New B6 - DCM protocol			I	

Disposition/Recommendations

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Client:	B6	
Veterinarian	:	
Patient ID:	314074	
Visit ID:		

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Patient:	_B6
Species:	Canine
Breed:	Doberman Pinscher
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU	3/8/2015 8:55:00 AM	Accession ID: B6	
Test	Results	Reference Range	Units
nCA		0 - 0	mmol/L
FiO2		O - O	%
BEb		0 - 0	mmol/L
TCO2 (POC)		0 - 0	mmol/L
GAP		0 - 0	mmol/L
BEecf		0 - 0	mmol/L
CREAT (POC)		0.2 - 2.1	mg/dL
NOVA SAMPLE		0 - 0	
MG (POC)		0.1 - 0.4	mmol/L
CA/MG		0 - 0	mol/mol
HCT (POC)	B6	38 - 48	%
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dI.
SO2%		94 - 100	%
nMG		0 - 0	mmol/L
CL(POC)		109 - 120	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
K (POC)		3.6 - 4.8	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
HB (POC)		12.6 - 16	g/dL
A		0 - 0	mmIIg

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8/22 **B6**

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		B6	
CHLORIDE		106 - 116	mEq/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
ALT		14 - 86	U/L
I BILIRUBIN		0 - 0.2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
Γ. PROTEIN		5.5 - 7.8	g/dL
GLOBULINS	B6	2.3 - 4.2	g/dL
ALK PHOS	DC	12 - 127	U/L
CREATININE		0.6 - 2	mg/dL
SODIUM		140 - 150	mEq/L
NA/K		29 - 40	mg di
F BILIRUBIN		0.1 - 0.3	mg/dL mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL mg/dL
CALCIUM2	Results	9.4 - 11.3	mg/dL
Nova Full Panel-ICU Test	3/9/2015 9:50:00 AM Results	Reference Range	Units
HGB(ADVIA)	2/0/2015 0.50.00 AM	Accession ID: B6	g/dL
RBC(ADVIA)		3.8 - 8.5 13.3 - 20.5	
PLT(ADVIA)		173 - 486 5.8 - 8.5	K/uL M/uL
HCT(ADVIA)		39 - 55	% V (vI
RDW (ADVIA)		11.9 - 15.2	0/
MPV (ADVIA)	B6	8.29 - 13.2	fl
MCV(ADVIA)		64.5 - 77.5	fL
WBC (ADVIA)		4.4 - 15.1	K/uL
MCHC(ADVIA)		31.9 - 34.3	g/dL
MCH(ADVIA)		21.3 - 25.9	pg
[est	Results	Reference Range	Units
Nova Full Panel-ICU	3/9/2015 9:50:00 AM	Accession ID: B6	
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
TS (FHSA)	D.0	0 - 0	g/dl
[est	Results	Reference Range	Units
Nova Full Panel-ICU	3/8/2015 9:01:30 AM	Accession ID: B6	
HCO3		18 - 24	mmol/L
PO2		80 - 100	mmHg
PCO2		36 - 44	mmHg
PH	B6	7.337 - 7.467	
PCO2	DC	36 - 44	mmHg
PO2		80 - 100	mmHg
`		140 - 154	mmol/L
NA (POC)		140 - 134	IIIIIOI/L

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	10/22	B6	
ΓS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
ΓS (FHSA)		0 - 0	g/dl
Test	Results	Reference Range	Units
Nova Full Panel-ICU	3/9/2015 10:22:42 AM	Accession ID: B6	
VWF:AG	B6	0 - 0	%
Test	Results	Reference Range	Units
Nova Full Panel-ICU	3/9/2015 9:50:00 AM	Accession ID: B6	
No Morphologic Abnormalities	L!		
WBC MORPHOLOGY		0 - 0	
MONOS%		1 - 15	%
LYMPHS%		7 - 47	%
EOS (ABS)ADVIA		0 - 1.4	K/uL
SEGS (AB)ADVIA		2.8 - 11.5	K/ul
MONOS (ABS)ADVIA	B6	0.1 - 1.5	K/uL
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
SEGS%		43 - 86	%
No morphologic abnormalities			
RBC MORPHOLOGY		0 - 0	
EOS%		0 - 16	%
Test	Results	Reference Range	Units
Nova Full Panel-ICU	3/9/2015 9:50:00 AM	Accession ID: B6	
A/G RATIO	u	0.7 - 1.6	
ALBUMIN	1	2.8 - 4	g/dL
GLUCOSE		67 - 135	mg/dL
CHOLESTEROL	B6	82 - 355	mg/dL
POTASSIUM		3.7 - 5.4	mEq/L
UREA		8 - 30	mg/dL
AST		9 - 54	U/L

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Emergency Form: PACS



TUFTS UNIVERSITY
Foster Hospital for Small Animals
Hospital for Large Animals
200 Westboro Road,
N. Grafton, MA 01536

EMERGENCY SERVICES

This form must be submitted to accounting within 24 hours of entry on bill. Einergency less within a state of the state of	overtime incurred for treatment of emergency cases to ensure timely \$4.0Thin form must be completed in full or it will not be accepted.
Doctor or Technician name: B6	, DVM
Client name: B6	Animal name: B6
Date of services 8 Mar 2015 Case # 306	Animal name: B6
TECHNICIAN	CLINICIAN Equine Farm Small
S1X2 Surgery A1X2 Anesthesia	SAH
M8X2 Ophthalmology M1D9 Intensive Care	Surgery Anesthesia
R1X2 Radiology	S1X3 Surgeon A1X3 Anesthesiologist
RIAZ <u>nadiology</u>	S1X3 Resident A1X3 Resident
Procedure:	- LAH
O at the compact	Surgery Anesthesia
Overtime hours incurred:	S1X5 Surgeon A1X6 Anesthesiologist<4hrs
Time paged/called:	S1XA Surgeon w/sx<4hrs A1X7 Anesthesiologist>4hrs
estive property and the second	S1XB Surgeon w/sx>4hrs A1X3 Resident
Arrived:	- S1X3 Resident
Start surgery/procedure:	LAH & SAH
Start surgery/procedure.	Medicine Pathology
End surgery/procedure:	M1X1 Resident P1X1 Pathologist
	M1X4 Clinician < 4 hrs P1X1 Resident
Left building:	M1X5 Clinician > 4 hrs G1X1 Ambulatory
RADIOLOGY Equine Farm Sma	all Ophthalmology Equine Farm Small
R1X5 ER Radiologist:	M8X4 Ophthalmologist 1 hr:
R1X1 ER Resident:	
R1X3 Celiogram:	MONTH OLD I I CARLON
R1X4 Cysto/Urethogram:	M8X7 Ophthalmologist 4 hrs:
R1X6 Myelogram:	- 100 100 100 100 1
R1X7 Ultrasound:	(RIXH Radiologist (PACS)
R1X8 Intrav/Urogram (IVU):	
DAVA. III. Castos HICI).	- DC
	Bh
Kh	Supervisor Signature
	The state of the s
	Print Name
- T. P. C.	
Form: #255 C.C. Nov. 12 H 12 WHITE-Accounting YELL	OW-Payroll PINK-Employee

Diet history 10-2-18

	GARDIO_08	DIET HISTOR'	FORL		
e:	ts name B6 Owners name	В6			10/02/18
	How would you assess your patra appoints upon the	marine and an arrival			
	How would you assess your pet's appetite? (man: the Example Poor	noth on the the be			's appetite
	- A Man Man Man Man Man Man Man Man Man Man		=xc	elien:	
	Poor		l Exc	elien:	
	Have you noticed a change in your pet's appetite over Eats about the same amount as usua	ess than usus	? (cneck all that a D≘ats more than	apply n usua	
	Over the last few weeks, has your pet (check one) □Lost weight: □Gained weight: ☑Stayed about to	ne same weigh; 🛚	Don't know		
	Prease list pelow \underline{AU} pet foods, people food, treats, sourcentry eats. Prease include the brand, specific productions are the presented by the present of the present	snack, dental chews luct, and flavor so w	. rawhides, and a /e know exactly w	any otner food ite /nat you bet is ea	em that your det
	Food (include specific product and flavor) Examples are snown in the table – please provide end	Form 6 mm	milima 11		
			oodio go do nie s	tore and buy the	exact same foot.
	Food (include specific product and flavor) Nutro Grain Free Chickeri, Lentil, & Sweet Potato Adi	Form	Amount	How often?	Fed since
+	85% lean nampurger		1. ½ CUE	2x/ga	Jan 2018
1	Supperoni original peef fiavo:	microwavec	3 oz	1x/wee	Jan 2015
-	Rawhige	treat	另	1x/da:	Αυσ 2015
1	Toste of the Wild	trea:	6 inon twis:	1x/wee/	Dec 2015
-	Purina Pro Weight manage	ary	Lcup	3xda	NOV 2018
	various regains (fresh)		Louip	-3xdd	1 Sen 2018
Ì	K9 Granola Factory	treat	-	- aanv	2 NOV DOL
T	Raw marrow Bones	treat	5-10	daily	NOV 2013
1 22	The state of the s	treat		1x weel	C_ 2015_
-	*Any additional diet information can be listed on the b	аск of trus snee:			
	Do you give any dietary supplements to your pet (for supplements)? ☐Yes ☐Yes ☐Yes ☐ If yes, please list to Bran	examble: vitamins, i which ones and give nd/Concentration	alucosamine fatt orangs and amo	DUNTS	
	Taurine Tyes Tilvo			Amo	unt per day
	Carnitine Tyes TANG				
	Antioxidants DYes Mac		20.00	200	
	Multivitamir Tyes Thic				
	Fish of Pyes Phys				
	Coenzyme Q10				
		Nature's Bount		500 mg tabie	IS — 1 Der dəy
				4 5 7	
	how do you administer pills to your pet?				
	□ I do not give any medications				
	D out them directly in my pet's mouth without food				
	put them in my pet's god/cat food				
	1 put them in a Pill Pocket or similar product				
	□ put them in foods (list toods)				

Client:
Patient

B6

Vitals Results

3/8/2015 7:00:15 AM Nursing note 3/8/2015 8:04:09 AM Temperature (F) 3/8/2015 8:04:09 AM Heart Rate (/min) 3/8/2015 8:04:49 AM Heart Rate (/min) 3/8/2015 8:05:10 AM Weight (kg) 3/8/2015 9:01:51 AM Notes 3/8/2015 9:01:51 AM Notes 3/8/2015 9:05:22 AM Quantify IV fluids (mls) 3/8/2015 9:05:22 AM Perint Rate (/min) 3/8/2015 9:05:24 AM Respiratory Rate 3/8/2015 1:14:46 PM Respiratory Rate 3/8/2015 1:15:08 PM Eliminations 3/8/2015 5:10:50 PM Quantify IV fluids (mls) 3/8/2015 5:10:50 PM Respiratory Rate 3/8/2015 5:10:50 PM Respiratory Rate 3/8/2015 9:14:21 PM Quantify IV fluids (mls) 3/8/2015 9:14:21 PM Quantify IV fluids (mls) 3/8/2015 9:14:21 PM Quantify IV fluids (mls) 3/8/2015 9:14:21 PM Quantify IV fluids (mls) 3/8/2015 9:28:24 PM Nursing note 3/8/2015 9:34:23 PM Respiratory Rate 3/8/2015 9:34:23 PM Respiratory Rate 3/8/2015 1:25:05 PM Quantify IV fluids (mls) 3/8/2015 1:25:05 PM Cage or Walk notes 3/9/2015 1:21:29 AM Quantify IV fluids (mls) 3/9/2015 1:21:29 AM Quantify IV fluids (mls) 3/9/2015 1:24:43 AM Respiratory Rate 3/9/2015 1:24:43 AM Respiratory Rate 3/9/2015 1:24:43 AM Respiratory Rate 3/9/2015 5:1:30 AM Quantify IV fluids (mls) 3/9/2015 1:24:18 AM Respiratory Rate 3/9/2015 1:24:18 AM Respiratory Rate 3/9/2015 1:25:34 AM Respiratory Rate 3/9/2015 1:25:34 AM Respiratory Rate 3/9/2015 1:25:34 AM Respiratory Rate 3/9/2015 1:25:34 AM Eliminations 3/9/2015 1:25:34 AM Eliminations 3/9/2015 1:25:34 AM Respiratory Rate 3/9/2015 1:25:34 AM Eliminations 3/9/2015 1:25:34 AM Respiratory Rate 3/9/2015 1:25:34 AM Respiratory Rate 4/9/2015 1:25:34 AM Respiratory Rate 3/9/2015 1:25:34 AM Respiratory Rate	Vitais Results		
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3/9/2015 11:56:50 AM Quantify IV fluids (mls)	3/9/2015 11:56:11 AM	Temperature (F)	
	3/9/2015 11:56:23 AM		
3/9/2015 11:57:02 AM Respiratory Rate	3/9/2015 11:56:50 AM	Quantify IV fluids (mls)	
	3/9/2015 11:57:02 AM	Respiratory Rate	

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Vitals Results		
3/9/2015 1:27:57 PM	Eliminations	
3/9/2015 3:32:11 PM	Quantify IV fluids (mls)	
3/9/2015 3:35:18 PM	Respiratory Rate	
3/9/2015 3:35:30 PM	Heart Rate (/min)	
3/9/2015 3:37:40 PM	Temperature (F)	
3/9/2015 5:27:01 PM	Eliminations	
3/9/2015 7:04:35 PM	Eliminations	
3/9/2015 7:07:59 PM	Weight (kg)	
3/9/2015 7:08:08 PM	Temperature (F)	
3/9/2015 7:08:44 PM	Quantify IV fluids (mls)	
3/9/2015 7:14:28 PM	Heart Rate (/min)	
3/9/2015 7:14:36 PM	Respiratory Rate	
3/9/2015 9:09:44 PM	Amount eaten	
3/9/2015 11:42:29 PM	Heart Rate (/min)	
3/9/2015 11:42:36 PM	Respiratory Rate	
3/9/2015 11:42:45 PM	Eliminations	
3/9/2015 11:43:13 PM	Quantify IV fluids (mls)	
3/10/2015 3:38:41 AM	Quantify IV fluids (mls)	
3/10/2015 3:43:03 AM	Heart Rate (/min)	B6
3/10/2015 3:43:09 AM	Respiratory Rate	
3/10/2015 3:43:19 AM	Eliminations	
3/10/2015 5:09:16 AM	Amount eaten	
3/10/2015 7:01:03 AM	Heart Rate (/min)	
3/10/2015 7:01:09 AM	Weight (kg)	
3/10/2015 7:01:19 AM	Respiratory Rate	
3/10/2015 7:01:25 AM	Temperature (F)	
3/10/2015 7:01:36 AM	Eliminations	
3/10/2015 7:02:01 AM	Quantify IV fluids (mls)	
3/10/2015 11:38:03 AM	Heart Rate (/min)	
3/10/2015 11:39:59 AM	Respiratory Rate	
3/10/2015 11:40:05 AM	Quantify IV fluids (mls)	
3/10/2015 11:40:13 AM	Eliminations	
3/10/2015 1:43:47 PM	Amount eaten	
9/21/2015 5:20:19 PM	Heart Rate (/min)	
9/21/2015 5:20:20 PM	Temperature (F)	
9/21/2015 5:20:21 PM	Respiratory Rate	
9/21/2015 5:20:22 PM	Weight (kg)	
10/2/2018 3:58:13 PM	Weight (kg)	

Patient History

1 attent History		
03/08/2015 06:47 AM	Purchase	
03/08/2015 07:00 AM	Vitals	
03/08/2015 07:51 AM	UserForm	
03/08/2015 07:54 AM	Treatment	
03/08/2015 07:54 AM	Purchase	
03/08/2015 08:03 AM	UserForm	
03/08/2015 08:04 AM	Treatment	
03/08/2015 08:04 AM	Vitals	
03/08/2015 08:04 AM	Vitals	
03/08/2015 08:04 AM	Vitals	
03/08/2015 08:05 AM	Vitals	
03/08/2015 08:08 AM	UserForm	
03/08/2015 08:10 AM	Purchase	
03/08/2015 08:55 AM	Purchase	
03/08/2015 08:59 AM	Purchase	
03/08/2015 08:59 AM	Purchase	
03/08/2015 09:01 AM	Labwork	
03/08/2015 09:01 AM	Vitals	
03/08/2015 09:02 AM	Treatment	
03/08/2015 09:02 AM	Treatment	B6
03/08/2015 09:02 AM	Vitals	Kh
03/08/2015 09:05 AM	Purchase	
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03/08/2015 09:05 AM	Treatment	
03/08/2015 09:05 AM	Vitals	
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03/08/2015 09:08 AM	Treatment	
03/08/2015 09:08 AM	Treatment	
03/08/2015 09:08 AM	Vitals	
03/08/2015 09:08 AM	Purchase	
03/08/2015 09:08 AM	Treatment	
03/08/2015 09:08 AM	Vitals	
03/08/2015 09:09 AM	Prescription	
03/08/2015 09:18 AM	Treatment	
03/08/2015 09:50 AM	Purchase	
03/08/2015 09:51 AM	Purchase	
03/08/2015 01:07 PM	Treatment	
03/08/2015 01:07 PM	Treatment	
03/08/2015 01:14 PM	Treatment	
03/08/2015 01:14 PM	Vitals	
03/08/2015 01:14 PM	Treatment	
03/08/2015 01:14 PM	Vitals	
03/08/2015 01:15 PM	Treatment	
03/08/2015 01:15 PM	Vitals	

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Client:	R6
Patient:	D 0

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Patient History		
03/08/2015 03:03 PM	Treatment	
03/08/2015 03:03 PM	Vitals	
03/08/2015 05:10 PM	Treatment	
03/08/2015 05:10 PM	Vitals	
03/08/2015 05:10 PM	Treatment	
03/08/2015 05:10 PM	Vitals	
03/08/2015 05:11 PM	Treatment	
03/08/2015 05:16 PM	Treatment	
03/08/2015 05:16 PM	Treatment	
03/08/2015 05:16 PM	Vitals	
03/08/2015 07:53 PM	Treatment	
03/08/2015 07:53 PM	Vitals	
03/08/2015 09:13 PM	Purchase	
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03/08/2015 09:14 PM	Treatment	
03/08/2015 09:14 PM	Vitals	
03/08/2015 09:26 PM	Treatment	
03/08/2015 09:26 PM	Treatment	
03/08/2015 09:26 PM	Treatment	
03/08/2015 09:26 PM	Vitals	
03/08/2015 09:28 PM	Vitals	
03/08/2015 09:34 PM	Treatment	
03/08/2015 09:34 PM	Vitals	Bh
03/08/2015 09:34 PM	Treatment	B6
03/08/2015 09:34 PM	Vitals	
03/08/2015 11:25 PM	Vitals	
03/09/2015 12:41 AM	Vitals	
03/09/2015 01:21 AM	Treatment	
03/09/2015 01:21 AM	Vitals	
03/09/2015 01:21 AM	Treatment	
03/09/2015 01:21 AM	Vitals	
03/09/2015 01:22 AM	Treatment	
03/09/2015 01:22 AM	Treatment	
03/09/2015 01:22 AM	Vitals	
03/09/2015 01:24 AM	Treatment	
03/09/2015 01:24 AM	Vitals	
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03/09/2015 01:35 AM	Treatment Treatment	
03/09/2015 01:36 AM	Treatment	
03/03/2013 01.39 AIVI	rreaument	
03/09/2015 04:31 AM	Treatment	
03/09/2015 04:31 AM	Vitals	
03/09/2015 05:39 AM	Treatment	
03/09/2015 05:39 AM	Treatment	
03/09/2015 05:42 AM	Treatment	
03/09/2015 05:42 AM	Vitals	
03/09/2015 05:51 AM	Treatment	
55,05,2015 05.51 / MVI	11 outiliont	<u> </u>

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Client: B	6

Patient History		
03/09/2015 05:51 AM	Vitals	
03/09/2015 05:51 AM	Treatment	
03/09/2015 05:51 AM	Vitals	
03/09/2015 08:26 AM	Vitals	
03/09/2015 09:10 AM	UserForm	
03/09/2015 09:11 AM	Purchase	
03/09/2015 09:11 AM	Purchase	
03/09/2015 09:42 AM	Purchase	
03/09/2015 09:44 AM	Treatment	
03/09/2015 09:49 AM	Purchase	
03/09/2015 09:49 AM	Purchase	
03/09/2015 09:49 AM	Purchase	
03/09/2015 10:22 AM	Labwork	
03/09/2015 10:22 AM	Treatment	
03/09/2015 10:39 AM	Prescription	
03/09/2015 10:39 AM	Prescription	
03/09/2015 10:40 AM	Purchase	
03/09/2015 10:49 AM	Purchase	
03/09/2015 11:40 AM	Treatment	
03/09/2015 11:55 AM	Treatment	Kh
03/09/2015 11:56 AM	Treatment	B6
03/09/2015 11:56 AM	Treatment	
03/09/2015 11:56 AM	Treatment	
03/09/2015 11:56 AM	Vitals	
03/09/2015 11:56 AM	Treatment	
03/09/2015 11:56 AM	Treatment	
03/09/2015 11:56 AM	Vitals	
03/09/2015 11:56 AM	Treatment	
03/09/2015 11:56 AM	Vitals	
03/09/2015 11:57 AM	Treatment	
03/09/2015 11:57 AM	Vitals	
03/09/2015 01:27 PM	Treatment	
03/09/2015 01:27 PM	Vitals	
03/09/2015 02:06 PM	Purchase	
03/09/2015 03:32 PM	Treatment	
03/09/2015 03:32 PM	Vitals	
03/09/2015 03:34 PM	Treatment	
03/09/2015 03:35 PM	Treatment	
03/09/2015 03:35 PM	Vitals	
03/09/2015 03:35 PM	Treatment	
03/09/2015 03:35 PM	Vitals	
03/09/2015 03:37 PM	Vitals	

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Patient History		
03/09/2015 04:47 PM	UserForm	
03/09/2015 05:27 PM	Treatment	
03/09/2015 05:27 PM	Vitals	
03/09/2015 06:52 PM	Prescription	
03/09/2015 06:53 PM	Prescription	
03/09/2015 07:04 PM	Treatment	
03/09/2015 07:04 PM	Vitals	
03/09/2015 07:04 PM	Treatment	
03/09/2015 07:07 PM	Treatment	
03/09/2015 07:07 PM	Vitals	
03/09/2015 07:08 PM	Treatment	
03/09/2015 07:08 PM	Vitals	
03/09/2015 07:08 PM	Treatment	
03/09/2015 07:08 PM	Vitals	
03/09/2015 07:14 PM	Treatment	
03/09/2015 07:14 PM	Vitals	
03/09/2015 07:14 PM	Treatment	
03/09/2015 07:14 PM	Vitals	
03/09/2015 09:09 PM	Treatment	
03/09/2015 09:09 PM	Vitals	Kh
03/09/2015 09:13 PM	Purchase	B6
03/09/2015 11:42 PM	Treatment	
03/09/2015 11:42 PM	Vitals	
03/09/2015 11:42 PM	Treatment	
03/09/2015 11:42 PM	Vitals	
03/09/2015 11:42 PM	Treatment	
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03/09/2015 11:43 PM	Treatment	
03/09/2015 11:43 PM	Vitals	
03/09/2015 11:44 PM	Treatment	
03/10/2015 03:38 AM	Treatment	
03/10/2015 03:38 AM	Vitals	
03/10/2015 03:43 AM	Treatment	
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03/10/2015 03:43 AM	Treatment	
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03/10/2015 05:49 AM	Treatment	
00,10,2010 00,00 11111	Traditiont	
03/10/2015 05:09 AM	Vitals	
03/10/2015 07:01 AM	Treatment	
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Patient History		
03/10/2015 07:01 AM	Vitals	
03/10/2015 07:01 AM	Treatment	
03/10/2015 07:01 AM	Vitals	
03/10/2015 07:01 AM	Treatment	
03/10/2015 07:01 AM	Vitals	
03/10/2015 07:01 AM	Treatment	
03/10/2015 07:01 AM	Vitals	
03/10/2015 07:01 AM	Treatment	
03/10/2015 07:01 AM	Vitals	
03/10/2015 07:02 AM	Treatment	
03/10/2015 07:02 AM	Vitals	
03/10/2015 09:11 AM	Purchase	
03/10/2015 09:11 AM	Purchase	
03/10/2015 11:38 AM	Treatment	
03/10/2015 11:38 AM	Vitals	
03/10/2015 11:39 AM	Treatment	
03/10/2015 11:39 AM	Vitals	
03/10/2015 11:40 AM	Treatment	
03/10/2015 11:40 AM	Vitals	
03/10/2015 11:40 AM	Treatment	
03/10/2015 11:40 AM	Vitals	
03/10/2015 12:12 PM	Purchase	
03/10/2015 12:12 PM	Treatment	
03/10/2015 01:33 PM	UserForm	B6
03/10/2015 01:43 PM	Treatment	
03/10/2015 01:43 PM	Vitals	
09/21/2015 05:17 PM	UserForm	
09/21/2015 05:20 PM	Vitals	
09/21/2015 05:24 PM	Prescription	
09/21/2015 05:24 PM	Prescription	
09/21/2015 05:49 PM	Prescription	
09/21/2015 07:16 PM	Purchase	
09/21/2015 07:16 PM	Purchase	
09/21/2015 07:18 PM	Purchase	
09/21/2015 07:28 PM	Prescription	
09/05/2018 08:11 AM	Appointment	
09/20/2018 01:47 PM	Appointment	
10/02/2018 03:53 PM	UserForm	
10/02/2018 03:54 PM	UserForm	
10/02/2018 03:55 PM	UserForm	
10/02/2018 03:55 PM	Treatment	

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Client:	B6
Patient:	D 0

Patient History

 10/02/2018 03:58 PM
 Vitals

 10/02/2018 04:25 PM
 Purchase

 10/02/2018 04:25 PM
 Purchase

 10/02/2018 04:59 PM
 UserForm

10/02/2018 05:25 PM Purchase

В6





To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification;

В6

Sent: 6/11/2019 6:36:57 PM

Subject: Pure Balance Salmon and Pea dry: Lisa Freeman - EON-390200

Attachments: 2068093-report.pdf; 2068093-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390200] has been created in the EON System.

A "PDF" report by name "2068093-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068093-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390200

ICSR #: 2068093

EON Title: Related PFR Event created for Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry;

2068093

AE Date	10/31/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	B6 (ears		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068093

Product Group: Pet Food

Product Name: Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry **Description:** DCM and CHF diagnosed 10/31/18. On BEG diet. Normal taurine levels

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie dry		
Pure Balance Salmon and Pea dry		

This report is linked to:

Initial EON Event Key: EON-370760

Initial ICSR: 2058697

Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner	inform	ation
OWNER	11111 (71 11)	IALIUII

B6 USA

To view this Related PFR Event,	please click the link below
D6	į

To view the Related PFR Event Report, please click the link below:

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.



Report Details - EON-	7	
ICSR:	2068093	
Type Of Submission:	Followup	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	7	, reaction or disease associated with the product)
Reporting Type:	Voluntary	
Report Submission Date:		
Initial Report Date:	11/10/2018	
Parent ICSR:	2058697	
Follow-up Report to FDA Request:	Yes	
Reported Problem:	Problem Description:	DCM and CHF diagnosed 10/31/18. On BEG diet. Normal taurine levels
	Date Problem Started:	
	Concurrent Medical Problem:	
	Pre Existing Conditions:	3
	Outcome to Date:	Stable
Product Information:	Product Name: Product Type: Lot Number:	M
	Package Type:	BAG
	Product Use Information:	Description: Fed for last 3 months until 2 weeks ago when changed to
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Pure Balance Salmon and Pea dry
	Product Type:	Pet Food
	Lot Number: Package Type:	
	Product Use Information:	Description: Fed for past 6 years until about 3 months ago
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed: Gender:	Retriever - Golden Female
	Reproductive Status:	
	2)	25.5 Kilogram
	·5 [B6 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	
	Number of Animals Reacted:	

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UCDavis Taurine Panel

PL: 24421 WB: 24422

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616

Telephone: 530-752-5058, Fax: 530-752-4698

Email: ucd.aminoacid.lab@ucdavis.edu

www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Conta	ct: _ B6]			
Clinic/Company Na	me: Tufts Cumming	s School of Vet. Med	d Clinical Pathology	Laboratory	
Address: 200 West	ooro Road, North Gra	fton MA 015369			
Email:Clinpath@	tufts.edu (ard	LIQUET @ +	4945, edy		
Telephone	В6	Fax:	B6	<u></u>	
Billing Contact:	В6	Email	В6	<u> </u>	
Billing Contact Pho	ne: B6	Tax IC):		
Patient Name:	B6	Speci	es: <u>Jol</u>	den	
Breed: Gold	leh	Owne	er's Name: _	36	
Current Diet :	Seneral-	wason	grainifree	taste shu	ld and
Sample type:	Plasma Whole I	Blood Urine	Food Other _		Belance
Test: Taurine	Complete Amino	Acids Other:			
Taurine Resul	ts (lab use only)	 			
Plasma: B6	_ Whole Blood:	B6 Urin	e: F	ood:	-
	Plasma (r	nMol/ml)	Whole Bloc	od (nMol/ml)	
	Normal Range	No known risk	Normal Range	No known risk	_

for deficiency

>40

>40

300-600

200-350

80-120

60-120

Cat

Dog

for deficiency

>200

>150

^{*} Please note with the recent increase in the number of dogs screened for taurine deficiency, we are seeing dogs with values within the reference ranges (or above the "no known risk for deficiency range") yet are still exhibiting signs of cardiac disease. Veterinarians are welcome to contact our laboratory for assistance in evaluating your patient's results.

Client:	B6
Patient:	DU

Prescription: Pimobendan 15mg 12/14/18

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NTION ATTEI ions, please c	[RIAN: Your patient h	as requested a prescription.	. Please complete and fa	x back. If you have any
ions, piedae o		SECTION A: PET O	WNER – please print infor	mation below	
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ING	B6			SHIPPING _	
RESS	B6	B6	В6	ADDRESS (if different)	
	City	State	Zip	PREFERRED SHIPP	_
NE į	B6	EMAIL		Ground S	Second Day Air Overnigh
SECTI	ON B: VETERINAR	RIAN - please print	prescription info (or attac	h RX below) and fax to	B6
		***** Thic	Area for Prescriber U	so Only *****	
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RESCRIBER				11	DEA # (for controls)
	Et al Name				
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LINIC HONE ET'S NAME	FOSTER A! Office Name Address City 508-839-539	95 FAX	State Zip 508-839-7951	Bill to Offic	Ship to e
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BNP



Page 1 of 1

Texas A and M Troponin



Gastrointestinal Laboratory

Dr. J.M. Steiner

Department of Small Animal Clinical Sciences

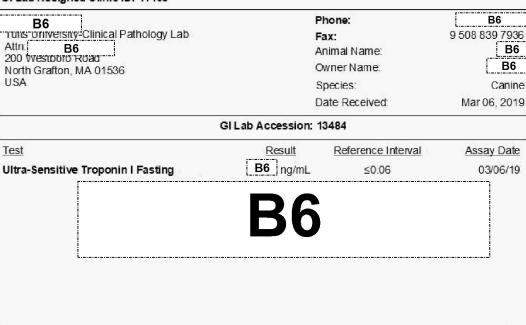
Texas A&MUniversity

4474 TAMU

College Station, TX 77843-4474

Website User ID: Cardiovet@tufts.edu OR clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405



GI Lab Contact Information

Phone: **B6** Fax: (979) 862-2864

Comments:

Email: gilab@cvm.tamu.edu vetmed.tamu.edu/gilab

Diet Hx 5/16/2019

) 6	Please	answer the follo		ns about yo	ur pet	
	36	2	_ Owner's name :	B6		Today's	L
How would you Example:	assess yo Poor	ur pet's a	opetite? (mark the po	oint on the line	below that bes	t represents you Excellent	ur pet's appetite)
	Poor	<u> </u>			+	Excellent	
Eats about the	ne same am	nount as u	pet's appetite over the sual □Eats less an usual □Other_	than usual	ks? (check all t □Eats more		_
Over the last few weeks, has your pet (check one) Lost weight Gained weight Stayed about the same weight Don't know							
Please list belo	w <u>ALL</u> pet f and that you	foods, ped a have fed	ople food, treats, sna in the last 2 years.	ick, dental chev	vs, rawhides, a	and any other fo	od item that your pet
Please provide	enough de	tail that w	e could go to the sto	re and buy the	exact same fo	od - examples a	are shown in the table
			ict and flavor)	Form	Amount	How often?	Dates fed
		Lentil, &	Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2016-present
85% lean hami	ourger			microwaved	3 oz	1x/week	June -Aug 2016
Pupperoni orig	inal beef fla	vor		treat	1/2	1x/day	Sept 2016-present
Rawhide				treat	6 inch twist	1x/week	Dec 2018-present
Galturi	1a Ore	truel	Lend tuncey	dru	iaip	2x/day	Dec ROR
		1 50 4074 34- 01.004	+ venisor	3	1)	
Alpo tre	ets			treat	5/day-	→	Dec 2018
*Anv additiona	diet inform	ation can	be listed on the back	k of this sheet			
			s to your pet (for exa		alucosamine	fatty acids or s	any other
supplements)?	□Yes	□No I	f yes, please list whi	ch ones and give	ve brands and	amounts:	
Taurine	MVoc	□No N		Concentration		(2)50	Amount per day
		□No	4010			- (D) 300	Drag turice/d
Carnitine	□Yes					-	
Carnitine Antioxidants						·	
Antioxidants	DYes	DNo			7.7	-	
Antioxidants Multivitamin		DNo				-	
Antioxidants Multivitamin Fish oil)					-	
Antioxidants Multivitamin) □Yes						tablets – 1 per day
Antioxidants Multivitamin Fish oil Coenzyme Q10	st):		Nat	ure's Bounty		500 mg	. por day
Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please li	st):	_	Nat	ure's Bounty		500 mg	, por day
Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please li	st):	<u> </u>	Nat	ure's Bounty		500 mg	
Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please li	st):		Nat	ure's Bounty		500 mg	
Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please li Example: Vitan	of the state of th			ure's Bounty		500 mg	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please li Example: Vitan	ist): nin C minister pills	s to your p		ure's Bounty		500 mg	
Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please li Example: Vitan	ist): inin C minister pills any medica rectly in my	s to your pations	pet?	ure's Bounty		500 mg	
Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please li Example: Vitan	ist): inin C minister pills any medica rectly in my my pet's do	s to your pations	pet? uth without food	ure's Bounty		500 mg	

Chem 21 5/16/19



Tufts Cummings School Of Veterinary Medicine

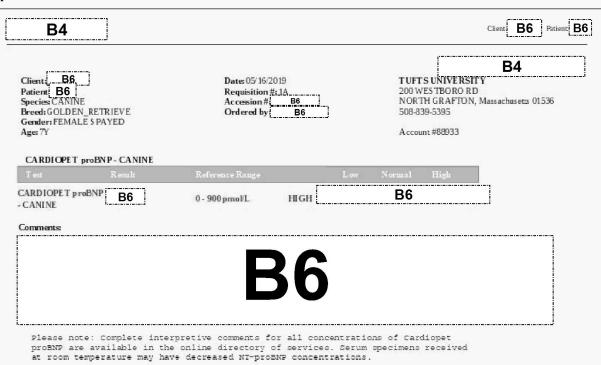
200 Westboro Road North Grafton, MA 01536

-			pre-manus-ma
	Name/DOB: B6		Provider B6
	Patient ID: 4 B6	Sex: U	Order Location: V320559: Investigation into
	Phone number:	Age: 7	Sample ID: B6
	Collection Date: 5/16/2019 3:55 PM	Species: Canine	
	Approval date: 5/16/2019 6:36 PM	Breed: Golden Retreiver	

Research Chemistry Profile - Small Animal (Cobas) SMACHUNSKI Ref. Range/--67-135 mg/dL Glucose Urea 8-30 mg/dL 0.6-2.0 mg/dL Creatinine Phosphorus 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L Calcium 2 Magnesium 2+ Total Protein 5.5-7.8 g/dL Albumin 2.8-4.0 g/dL Globulins 2.3-4.2 g/dL L A/G Ratio Η 0.7-1.6 140-150 mEq/L Sodium Chloride 106-116 mEq/L **B6** Potassium 3.7-5.4 mEq/L tCO2(Bicarb) 14-28 mEq/L AGAP 8.0-19.0 NA/K 29-40 0.10-0.30 mg/dL Total Bilirubin Alkaline Phosphatase 12-127 U/L GGT 0-10 U/L ALT 14-86 U/L AST 9-54 U/L Creatine Kinase 22-422 U/L Cholesterol 82-355 mg/dL Triglycerides L 30-338 mg/dl 409-1250 U/L Amylase Osmolality (calculated) 291-315 mmol/L

Sample ID: B6	Reviewed by:
END OF REPORT (Final)	

B4 NT-proBNP 5/16/2019



Result is greater than 10000 pmol/L

	l
Client:	R6
Patient:	В

script submitted В6 **B6** 05/29/2019 11:07 Page: 1/1 Pharmacy Fax: **B6** Prescription Refill Request (This fax contains sensitive patient information. If you are not the intended party, please destroy this fax) Date printed / faxed 5/29/2019 mm TO: В6 55 WILLARD ST NORTH GRAFTON, MA 01536 Phone 508-839-5395 Fax 508-887-4275 FROM: **B6** Phone **B6** Fax Patient: Phone Birthdate Age 7 **B6 B6** Rx# Quantity 60... Current Drug FLEX DOSETAB 7.5MG TABLET **B6** Date written 12/14/2018 Last refill 5/28/2019 Prescription expiration date 12/14/2019 Directions GIVE 1 TABLET BY MOUTH EVERY 12 HOURS Suggested formula: If approved, please initial: DOSETAB TABLET 7.5MG #90 GIVE 1 TABLET BY MOUTH THREE TIMES DAILY OWNER STATES DOSE FREQUENCY HAS INCREASED TO TID Refill Response: Fax back to the pharmacy at **B6 B6** PRN, or ____ Time(s) as Consistent with State Law or Until Authorized by Date 5 10/19 Comments or Questions:

Troponin 5/31/2019



Gastrointestinal Laboratory

Dr. J.M. Steiner

Department of Small Animal Clinical Sciences

Texas A&MUniversity

4474 TAMU

Result

College Station, TX 77843-4474

Website User ID: lisa.freeman@tufts.edu OF B6 @tufts.edu

GI Lab Assigned Clinic ID: 23523

B6 Tuffs Cummings School of Vet Med - Cardiology/Nutrition 200 Westboro Road North Grafton, MA 01536 USA

Owner Name: Species: Date Received:

Animal Name:

Phone:

Fax:

B6 Canine

508 887 4696

May 30, 2019

Assay Date

05/31/19

Tufts Cummings School of Vet Med -Cardiology/Nutrition Tracking Number: 427078 GI Lab Accession:

Reference Interval

≤0.06

B6

Ultra-Sensitive Troponin I Fasting B6 ng/mL

Comments:

Test

GI Lab Contact Information

Phone **B6** Fax: (979) 862-2864 Email: gilab@cvm.tamu.edu vetmed.tamu.edu/gilab

B6

2/14/2019 4:16:11 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

В6

2/14/2019 4:16:11 PM

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Tufts University
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Cardiology

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Tufts University Tufts Cummings School of Vet Med Cardiology

B6

2/14/2019 4:16:25 PM

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Tufts University
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Cardiology

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Tufts University Tufts Cummings School of Vet Med Cardiology

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Tufts University Tufts Cummings School of Vet Med Cardiology

В6

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Tufts University Tufts Cummings School of Vet Med Cardiology

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Far (508) 839-7951 http://vetmed.turks.edu/

Discharge Instructions

<u>Patient</u>	Owner	,
Name: B6	Maure: B6	Patient ID: B6
Species: Canine	Address: B6	
Bionde Female (Spayed) Golden	В	
Retriever		
Birthdate: B6		
Attending Cardiologist:		
John E. Rush DVM, MS, DACVIM ((Cardiology), DACVECC	
DC		
Bo		
Cardiology Resident:		
В	36	
Çardioloav Technician:	₁	
DC		
Bo		
L		
Student: B6 V19		
<u> </u>		
Admit Date: B6		
Discharge Date: B6		
Diagnoses:		
Dilated cardiomyopathy (DOM);		
Intermittent ventricular arhytmia.		
Case summary:		
Thank you for bringing B6 to the Tufts C	ardiology Service for a recheck vis	it. On examination today B6 had mild
abdominal effort when breathing and had		
echocardiogram, her dilated cardiomyopa		
		cular bigeminy whereone part of her heart has
electrical activity that is abnormal. On the		
•		
While she was here today, we were worri	ed about how B6 was breathing	, so we gave her an extra injectable dose of
		r. This makes us believe that she needs some
adjustments in her medications, as descr		
,,,		

Monitoring at home:

- We would like you to monitor her breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- O in general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 36 breaths.

per minute. In addition, the breathing effort, note	d by the amount of belly wall motion used for each breath, is
fairly minimal if heart failure is controlled.	

- O An increase in breathing rate or effort will usually mean that you should give an extra close of B6 if difficulty breathing is not improved by within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- O There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- O We also want you to watch for wealness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24hours/day.

B6

5. Taurine supplementation: Give 1000mg (2 capsules) by mouth twice daily. (Brands we recommend include TwinLab, Swanson, NOW and GNC brands).

Taurine is an amino acid that is shown to be necessary for appropriate heart health. Supplemening Taurine, in some cases, has lead to reduction in heart enlargement and an increase in heart health in dogs with DCM. Even though Kiwi has normal taurine levels, this supplement could still help her heart contract better.

Diet suggestions:

Dogs with heart failure accumulatemore fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (http://web.tufls.edu/heartsmart/diet/)

Your dog's usual diet may also have more sodium than recommended - we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50.50, etc.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

O The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.

- Werecommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and childpeas.
- O The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/uom613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://wetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise	Recour	men	زاط	ons

B6 can continue to have controlled leash walks. However, if you find that she is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck visit is recommended at B6, when we will recheck her echocardiogram and perform some blood tests.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tuits.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information http://vet.tulits.edu/heartsmart/

Prescription Refill Discloimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: <u>vet.tufts.edu/cvmc/dinical-studies</u>

Cause: B6	Owner: B6	Discharge Instructions

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://vetmed.tufts.edu/

Radiology Request & Report

Patient	Owner	<u>,</u>
Name: B6	Name: B6	Patient ID: B6
Species: Canine Blanda Canala /Council Colden	Address: B6	Date of request: B6
Blunde Fernale (Spayed) Golden Retriever	iJ	
Birthdate: B6		
Attending Clinician B6	DVM (Resident - Cardiology)	Student: B6 V19
		_
Date of exam: 2/14/2019		
Patient Location: Ward/Cage:	cardio room	Weight (kg) 25.70
	Sedation	
Inpatient Inpatient	<u>■</u> BAG	
Outpatient Time:	OBAG	
Waiting	■ 1/2 dose 08	
Emergency		/Butorphanol to sedate/anesthetize
	M Anestnesia 1	to sedate/anestnetize
Examination Desired: Thoracio	rads RL + DV	
Presenting Complaint and Clin	-	
echo today.	iry of CUE ou October 2019' 2	hortness of breath today. Worse DCM on
ecilo today.		
Pertinent History:		
	B6	

Conclusions:

-Moderate to marked generalized cardiomegaly with moderate to marked left atrial enlargement are consistent with previous diagnosis of dilated cardiomyopathy. On this study, cardiogenic edema is thought less likely. Follow-up radiographs can be consider to monitor this possibility.

-Mild non-specific hepatomegaly.

Radiologi	sts	
Primary.	B6	,DVM
Reviewing	 - -	3
_		
Dates		
Reported	В6	
Finalized		

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY Cardiology Liaison: 508-887-4696

Diet and Supplements:

Patient ID: B6

B6 Canine
Years Old Female (Spayed) Golden Retriever
Blonde

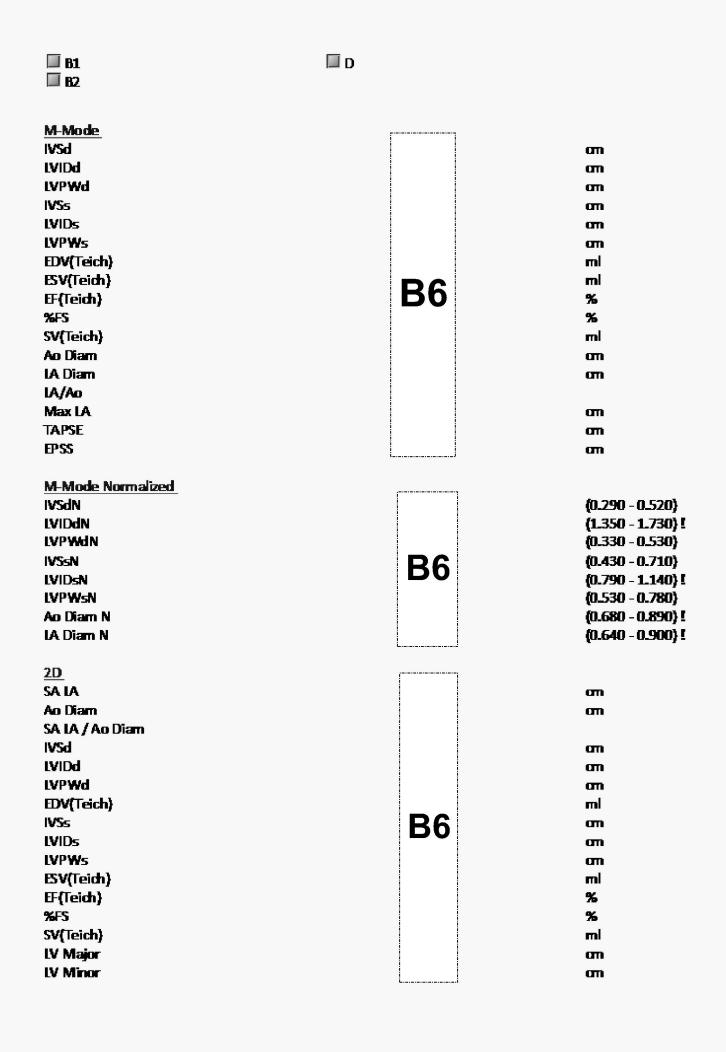
Cardiology Appointment Report ENROLLED IN DCM STUDY

Date: 2/14/2019
Attending Cardiologist: John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6
Cardiology Resident:
B6
B6
Student: B6 V19
Presenting Complaint: Recheck DCM with a history of CHF
Concurrent Diseases: None
General Medical History: Diagnosed with DCM and CHF on B6 , enrolled in DCM study.
In the past week or so she is not as energized, not as interactive with O which is abnormal for her, going to sleep a lot earlier, slowing down significantly on her daily walk. Coughing/gagging again, about twice a day which also started about a week ago. Breathing sounds like she is wheezing on occasion especially when sleeping, also started in the last week. O unsure of respiratory rate during these episodes, though she does seem to have abdominal effort. Great appetite still, drinks a lot but has been since starting meds. Only change in routine is that O has been home more frequently in the last week or so.
Around christmas she had an episode where she collapsed on a walk and was unconscious. She had spit out some B6 pills that day. Took some time to get back on track but had been normal up until this last week.

Cardiovascular History: Prior CHF diagnosis? yes Prior heart murmur? yes Prior ATE? no Prior arrhythmia? no Monitoring respiratory rate and eff they do check it is around 24 on aw Cough? Yes Shortness of breath or difficulty bre Syncope or collapse? Yes in decemb	eathing? Yes
	B6
Muscle condition: Normal Normal Mild muscle loss Cardiovascular Physical Exam: Murmur Grade: None I/VI	

□ III/VI	
Murmur location/description: left apical systolic	C
Jugular vein: Bottom 1/3 of the neck Middle 1/3 of the neck	■ 1/2 way up the neck ■ Top 2/3 of the neck
Arterial pulses:	■ Bounding
☑ Fair	Pulse deficits
☐ Good ☐ Strong	Pulsus paradoxus Other:
Arrhythmia:	■ Bradycardia
Sinus arrhythmia Premature beats	■ Tachycardia
Gallop:	Pronounced
☐ Yes ☐ No	Other:
Intermittent	
Pulmonary assessments:	Pulmonary craddes
i≡ coµnec ☑ Mild dyspnea	Wheees
■ Marked dyspnea ■ Normal BV sounds	Upper airway stridur
Abdominal exam:	Mild ascites
☐ Hepatomegaly	Marked ascites
M Abdominal distension-mild cranial distension, i	non-painful on palpation, no masses/organomegaly/fluid wave noted
<u>Problems</u> : DCM with a hx of CHF 10/31/18	
Diagnostic plan:	
☑ Echocardiogram ☐ Chemistry profile	☐ Dialysis profile ☐ Thoracic radiographs
ECC ECC	✓ NT-proBNP
Renal profile Blood pressure	✓ Troponin I Other tests:
	B6

	······································
B6	
Mitral inflow: Summated Normal Delayed relaxation	Restrictive
——————————————————————————————————————	B6 were LA enlargement. The pulmonary vessels appear to be at the interstital pattern in the caudal lung lobe consistent with mild
Assessment and recommendations: Findings consistent with poor but stable s	ystolic dyfunction and cardiac size. Thoracic radiographs
-	requent ventricular arrhythmias which were not present before.
Thus, medication adjustment is needed an	
recommended. B6	It is unclear at this point whether patient has
	athy. However, it has been only 4 months and current diet should
	ne 1000mg BID was started. Recommend recheck case patient develops clinical signs consistent with worsening
of the disease.	case patient develops clinical signs consistent with worsening
Final Diagnosis: - DCM with marked LA enlargement r/o pr - Suspected active CHF. Heart Failure Classification Score: ISACHC Classification:	☑ IIIa
□ lb	■ IIIb
□п	
ACVIM Classification:	
ACVIM Classification:	 c



		
Sphericity Index LVLd LAX LVAd LAX LVEDV A-L LAX LVEDV MOD LAX LVLs LAX LVAS LAX LVESV A-L LAX LVESV MOD LAX LVESV MOD LAX LVEF MOD LAX SV A-L LAX SV MOD LAX SV MOD LAX CO A-L LAX CO MOD LAX	B6	om om ml om om ml ml BPM % ml ml l/min l/min
Doppler MR Vmax MR maxPG MV E Vel MV DecT MV Dec Slope MV A Vel MV E/A Ratio E' E/E' A' S' AV Vmax AV maxPG PV Vmax PV maxPG	B 6	m/s mmHg m/s ms m/s m/s m/s m/s mmHg m/s

TR Vmax TR maxPG m/s

mmHg

Cummings Veterinary Medical Center

B6

B6 Fernale (Spayed)
Canine Golden Retriever Blonde
Patient ID: B6

Outside Prescription Log

B6

8. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

9. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

10. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Far (508) 839-7951 http://wetmed.turks.edu/

Discharge Instructions

Patient	Owner		
Name: B6	Maines	B6	Patient ID: B6
Species: Canine	Address:	B6	L
Blande Female (Spayed) Golden	Ĺ	DU	
Retriever			
Birthdate: B6			
Attending Cardiologist: John E. Rush DVM, MS, DACVIM (Cardiology), D	ACVECC	
B6			
Cardiology Resident:			·;
Be	<u> </u>		
Cardioloey Technician:			
B6			
Student:			
Admit Date: 5/16/2019			
Diagnoses: O Dilated cardiomyopathy (DOM)			
at home on her current medication regime rate) were within normal limits. On echoca	n. On examin rdiogram, he	ation today, B6 ; vi r dilated cardiomyop	We are happy the hear that B6 is doing well tal parameters (heart rate and respiratory athy (DOM) is similar to when we last saw hering her echocardiogram and weadministered
Today we drew blood to submit a serum d call you tomorrow with the results of these		redhedk NT-Pro-BNP	and also collected urine for a urinalysis. We will
dose of B6 (another diuretic that is	more potent ive her any de	tha B6 use. In case you notic	ncreased n rate and effort, you can give one This medication can be used as a "rescue", e that she is breathing with a respiratory rate f congestive heart failure.
When we call you tomorrow with bloodwo	rk results we	will discuss how her l	oreathing has been at home.
Monitoring at home:			

 We would like you to monitor her breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
O in general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 36 breaths
per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
O An increase in breathing rate or effort will usually mean that you should give an extra close of B6 If
difficulty breathing is not improved by within 30-60 minutes after giving extra furosemide then we recommend
that a recheck exam be scheduled and/or that your dog be evaluated by an emergency dinic.
O There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on
the Tufts HeartSmart web site (<u>http://vet.tufts.edu/heartsmart/at-home-monitoring/</u>). O Wealso want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the
bely as these findings indicate that we should do a recheck examination.
O if you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24
hours/day.
B6
Exercise Recommendations: Continue to exercise restrict B6 at home. Repetitive or strenuous high energy activities (repetitive ball chasing, running
fast off-leash, etc.) are generally not advised at this stage of heart failure
Parkark \\ \text{firster}

A recheck visit is recommended at Tuesday, August 19th at 1pm, when we will recheck her echocardiogram and perform some blood tests.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tults.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/

Prescription Refill Discloiner:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/dinical-studies

p.=.=q			
Case: B6	Owner: B6	Discharge Instructions	
	L	_	

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 4/1/2019 9:48:46 PM

Subject: ACANA - Heritage Red Meat Formula Dog Food (Grain-free): Kelsey Weeks -

EON-383914

Attachments: 2065085-report.pdf; 2065085-attachments.zip

A PFR Report has been received and PFR Event [EON-383914] has been created in the EON System.

A "PDF" report by name "2065085-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2065085-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383914

ICSR #: 2065085

EON Title: PFR Event created for ACANA - Heritage Red Meat Formula Dog Food (Grain-free); 2065085

AE Date	03/15/2019	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Shepherd Dog - German		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2065085

Product Group: Pet Food

Product Name: ACANA - Heritage Red Meat Formula Dog Food (Grain-free)

Description: 3/15/2019 - Acute onset of difficultly breathing on walk, increased resp rate, wheezing and short of

breath. Diagnosed with DCM and CHF

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 2 Number of Animals Reacted With Product: 1

B6

Product Name	Lot Number or ID	Best By Date
ACANA - Heritage Red Meat Formula Dog Food (Grain-free)		

Sender information
B6
USA
Owner information
B6 USA
To view this PFR Event, please click the link below: B6
To view the PFR Event Report, please click the link below:

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-	383914				
ICSR:	2065085				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)		
Reporting Type:	Voluntary				
Report Submission Date:	2019-04-01 17:42:39 EDT				
Reported Problem:	Problem Description:	3/15/2019 - Acute onset of difficultly breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF			
	Date Problem Started:	03/15/2019			
	Concurrent Medical Problem:	TOTAL STATE OF THE			
	Outcome to Date:	Stable			
Product Information:	Product Name:	ACANA - Heritage R	ed Meat Formula Dog Food (Grain-free)		
	Product Type:	<u> </u>	-3 (/ / / / / / / / / /		
	Lot Number:				
	Package Type:	BAG			
	Product Use Information:				
	Manufacturer /Distributor Information:	79 79 79 79 79 79 79 79 79 79 79 79 79 7			
	Purchase Location Information:				
Animal Information:	Name:				
	Type Of Species:	: Dog			
	7	: Shepherd Dog - German			
		Female			
	Reproductive Status:	Neutered			
	Weight:	25.9 Kilogram			
	Age:	B6 Years			
	Assessment of Prior Health:	Excellent			
	Number of Animals Given the Product:	2			
	Number of Animals Reacted:	1			
	Owner Information:	Owner Information provided:	Yes		
		Contact:	Name: B6		
		Address:	B6		
			United States		
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine		
	Information:	Contact:	5		
		Joniagi.	Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu		
		Address:	200 Westboro Road North Grafton		

			NA		
			Massachusetts 01536		
			United States		
		Type of Veterinarian:	Referred veterinarian		
		Permission to	Vec		
		Release Records to FDA:	163		
Sender Information:	Name:				
	Address:	B6			
	į	United States			
	Contact:	Phone:	D.O.		
		Email:	B6		
	Permission To Contact		i	!	
	Sender:	165			
	Preferred Method Of Contact:	Email			
	Reported to Other Parties:	None			
Additional Documents:					
		Medical record 4-1-2	2019.pdf		
		Medical records			
	Туре:	Medical Records			

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Client:	B6
Veterinarian	ı.
Patient ID:	B6
Visit ID:	

Lab Results Report

stringsoft

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Patient:	B6
Species:	Canine
Breed:	German Shepherd
Sex:	Female (Spayed)
Age:	В6

CBC (Research) (Advia)	3/22/2019 3:35:09 PM	Accession ID: B6		
Test	Results	Reference Range	Units	
WBC (ADVIA)		4.4 - 15.1	K/uL	
RBC(ADVIA)		5.8 - 8.5	M/uL	
HGB(ADVIA)		13.3 - 20.5	g/dL	
HCT(ADVIA)		39 - 55	%	
MCV(ADVIA)	B6	64.5 - 77.5	fL	
MCH(ADVIA)		21.3 - 25.9	pg	
MCHC(ADVIA)		31.9 - 34.3	g/dL	
CHCM		0 - 0	g/dl	
RDW (ADVIA)		11.9 - 15.2		
COMMENTS (HEMATOLOGY)	·	0 - 0		
Hemolysis present 0-1 platelets per High power field				

CBC (Research) (Advia)	3/22/2019 3:35:10 PM	Accession ID: B6	
Test	Results	Reference Range	Units
SEGS%		43 - 86	%
LYMPHS%		7 - 47	0/0
MONOS%		1 - 15	%
EOS%	D.C	0 - 16	%
NRBC	B6	0 - 1	/100 WBC
SEGS (AB)ADVIA		2.8 - 11.5	K/ul
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
	4/61	B6	

Printed Monday, April 1, 2019

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Client: B6 Patient:			
EOS (ABS)ADVIA		0 - 1.4	K/uL
WBC MORPHOLOGY	D6	0 - 0	
No Morphologic Abnormalities	B6		
POIKII OCYTOSIS		0 - 0	

CBC (Research) (Advia)	3/22/2019 3:35:26 PM	Accession ID: B6	
Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CIILORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)	B6	14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	

5/61 B6

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Printed Monday, April 1, 2019

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Medical records

		Color: black and red
Date Type	Staff	History
719/2019 CM	В6	EMAIL Recipients: TO: B6 (Other) Attachments: B6 2739-2 ph.pdf (Patient History) Subject: Patient History from B6 for Message: No message entered.
/19/2019 CM	В	EMAIL Reciplents: TO: ATTN Guardian (Other) Attachments: [B6]2739-2_ph.pdf (Patient History) Subject: Patient History from B6 for Message: No message entered.
/18/2019 D /18/2019 I	4	Dilated or Congested Cardiomyopathy Tentative B6 IT WILL CAUSE INCREASED THIRST AND DESIRE TO URINATE. BE SURE YOUR PET HAS FRESH, CLEAN DRINKING WATER AT ALL TIMES. ALLOW YOUR PET TO HAVE ACCESS OUTDOORS MORE OFTEN WHILE ON A DIURETIC MEDICATION.
/18/2019 P	:4/	B6
/18/2019 P	/ 4 /-	DU
18/2019 TC	4	B6
		Heart: Irregular rhythm, extra beats occasionally. ECG has VPC's, Radiograph reveal enlarged heart, tall, dorsal displacement of trachea, loss of caudal waist, congestion of veins
		B6

		Patient History Report
Client: Phone: Address:	B	Patient: B6
Date Type	Staff	History
3/18/2019 T 3/18/2019 P		not grain free. Call the food company and let them know. Image: Thorax B6
3/18/2019 C	В6	Technician Note Here for coughing on and off, Started 3 days ago. Its worse in the morning. No change in diet. No medications other then a joint supplement.
3/18/2019 T 3/18/2019 V	4	Image: Mar 18, 2019 04:24 PM Staff: 4 Weight : 67.20 pounds
1/23/2019 L	4:	Microbiology results from IDEXX Reference Laboratory Requisition ID: 117388426 Posted Final Test Result Reference Range OVA&PARA WHIPWORM HOOKWORM ROUNDWORM Ascn: B6
		B6
	M:Image cases	ck-in, CM/Communications, DrDiagnosis, DH:Declined to history, Elexamination, ES:Estimates, s, P:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PR.PVL Recommended, mediinate, V:Vital signs
B6	İ	Page 2 of 30 Date: 3/20/2019 11:15 AM

		Patient History Report
Cilent:		Patient: B6
Phone:	B6	Species: CANINE Breed: GERMAN SHEPHERD
Address:		Age: Bo Sex: Spayed Female
<u> </u>		Color: black and red
Date Type	Staff	History
1/22/2019 L	4 :	infectious agents using RealPCR (canine diarrhea panel: test code 2625; feline diarrhea panel: test code 2627). SNAP Assays results from IDEXX VetLab In-clinic
11/20/2013 C		Laboratory Requisition ID: 19361 Posted Final Test Result Reference Range HW = Lyme = AP_spp = EC-EE =
1/22/2019		
1/22/2019	B6	B6
1/22/2019		50
1/22/2019	4	
1/22/2019 V	B6	
		Weight : 69.20 pounds
1/22/2019 E	4	Adult Canine: 0 Abnormals
1/22/2019 C	B6	Tech History-Canine - Closed Jan 23/2019
		B6
		DU
	lt, M.Image cases	in, 'CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, cd note, V:Vital signs
В6		Page 3 of 30 Date: 3/20/2019 11:15 AM

Client: Patient: **B6**

Medical records

Patient History Report Patient: B6 Species: CANINE Cllent: Phone: Breed: GERMAN SHEPHERD Address: Age: B6 Sex: Spayed Female Color: black and red Date Type Staff History 10/16/2018 C 22 Exam/Medical Notes 10/16/2018 P 22 10/16/2018 P 22 10/16/2018 C Technician Note B6 **B6** 10/16/2018 V 22 Oct 16, 2018 03:27 PM Staff: 22 Weight : 69.00 pounds B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history. E.Examination, ES:Estimates, 1.Departing instr., Litab result, M.Image cases, P:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs. В6 Page 4 of 30 Date: 3/20/2019 11:15 AM

		Patient	History Repor	t	
Client: Phone: Address:	B	6	Patient: B6 Species: CANINE Age: 11 Yrs. 6 Color: B6	Breed:	GERMAN SHEPHERD Spayed Female
Date Type	Staff	History			
9/13/2018 D	4 [B6	Final		
9/13/2018 C	4	Exam/Medical Note		36	
9/13/2018 I	4		R	86	
9/13/2018 P	4				
9/13/2018 C	В6	Technician Note	E	36	
9/13/2018 V	4	Sep 13, 2018 0 	2:46 PM Staff: 4 : 69.40 poun	•	
6/20/2018 R	22	Rabies Certificate v	w/Dr Signature 2 GL	OSED_06/21/2018	
	В	6	B6	b	
	t, M:Image cases	ck-in, CM:Communications, D:C s, P:Prescription, PA.PVL Accep medIncte, V:Vital signs i			
B6		Pag	e 5 of 30	Date: 3/20/2019	11:15 AM

Client: Patient:

B6

Medical records

Patient History Report

Cllent: Phone:

Address:

Patlent: **B6**

Species: CANINE

Breed: GERMAN

SHEPHERD Sex: Spayed Female

GERMAN SHEPHERD

Spayed Female

black and red

В6

Age: B6 Color: black and red

Date Type Staff History

Rabies Certificate

Client ID:

Phone:

Client Name: Address:

Patient ID:

Patient Name:

CANINE

Species: Breed:

Sex:

Color:

Markings: Birthdate:

65.8

Weight: Microchip#:

B6

B6

Tag Number: Lot Number: Vaccination Date: **Expiration Date:**

Producer: K/MLV:

B6

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history. E.Examination, ES:Estimates, 1.Departing instr., Litab result, M.Image cases, P:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs.

B6

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Client: Phone: Address:	B	6	Patient: Species: CA Age: Color: blace	В6		GERMAN SHEPHERD Spayed Female
Date Type	Staff	History				
5/20/2018	22					
6/20/2018	22		_			
			F	3(3	
6/20/2018	22					
5/20/2018 E	22					
5/20/2018 C	В6	Technician Note):			
			B	6		
				U		
	DC			De		!
6/20/2018 V (B6 -	/ Jun 20, 2018 Weight	3 05:03 PM Staf : 65.80	· · · · · · · · · · · · · · · · · · ·	j	

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B6

		Patient History	Report		
Client: Phone: Address:	B	Patient Species Age Color	CANINE B6		GERMAN SHEPHERD Spayed Female
<u> </u>			~\J		j
Date Type	Staff	History			<u> </u>
5/24/2018 P	4	В	6		
1/41/2018 L	22	Microbiology results f Laboratory Requisition Test Result OVASPARA WHIPWORM HOOKWORM ROUNDWORM Ascn: B6 OVA & PARASITES	ID: 10861017	0 Po	sted Final Range
1/10/2018 L	22	SNAP Assays results fr Laboratory Requisition Test Result HW = Lyme = AP_spp = EC-EE =	ID: 17113	do In-clin Posted Reference	l Final
1/10/2018 1	22	Your pet was vaccinated with on the left side of the chest wi			
	M:Image cas	eck-in, CM:Communications, D:Diagnosis, DH:D es, P:Prescription, PA.PVL Accepted, PB:problen medinate, V:Vital signs			
В6		Page 8 of 30	Date	3/20/2019	11:15 AM

Patient History Report Patient: В6 Cllent: Phone: Species: CANINE Breed: GERMAN SHEPHERD Address: Age: В6 Sex: Spayed Female Color: black and red Date Type Staff History 5,2018 Have you checked out your Petly page? This free service allows you to access pet 1/10/2018 F 22 information including bloodwork and vaccine reminders, order prescription refills, request appointments, and more! Please be sure to provide us with your email address so you can take advantage of this opportunity. 1/10/2018 P 22 1/10/2018 E 22 1/10/2018 C Tech History-Canine - Closed Jan 11/2018 **B6** 1/10/2018 V Jan 10, 2018 02:57 PM Staff: B6 B6 : 60.20 pounds Weight **B6** 7/11/2017 C Tech History-Canine - Closed Jul 12/2017 B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history. E.Examination, ES:Estimates, 1.Departing instr., Litab result, M.Image cases, P:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs.

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B6

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Patient History Report

Cllent: Phone:

Address:

Patient: B6 Species: CANINE

Age: B6 Color: black and red Breed: GERMAN

SHEPHERD Sex: Spayed Female

Date Type Staff History

B6

7/11/2017 E 2 Small Animal: 0 Abnormals 7/11/2017 2 7/11/2017 L 2 7/11/2017 L **B6 B6** 7/11/2017 P

B.Billing, C.Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E.Examination, ES:Estimates, t.Departing instr. Litab result, M.Image cases, P.:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs

B6

Page 10 of 30

Phone: Address:	Patient: B6 Species: CANINE Breed: GERMAN SHEPHERD Age: B6 Sex: Spayed Female Color: black and red
Date Type Stat	f History
7/11/2017 P 7/11/2017 V	Jul 11, 2017 12:05 PM Staff B6 Weight : 59.40 pounds
2/4/2017 L 2	UA/Microscopy results from IDEXX Reference Laboratory Requisition ID: 103441206 Posted Final Test Result Reference Range BACTERIA BILIRUBIN BLOOD CASTS CLARITY COLOR CRYSTALS EPI CELL GLUCOSE KE TONES MUCUS OTHER PH PROTE IN RBC SP GRAVITY UROB WBC Ascn: B6 UCUP RE: 900 COLLECTION METHOD FREE-CATCH
1/20/2017 L 2	Microbiology results from IDEXX Reference Laboratory Requisition ID: 103265539 Posted Final Test Result Reference Range OVASPARA WHIPWORM B6
	c.Check-in, OM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, attive medinate, V:Vitalisigns

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B6

Medical records

Patient History Report Patlent: Cllent: Phone: Species: CANINE Breed: GERMAN SHEPHERD Address: Age: B6 Sex: Spayed Female Color: black and red Date Type Staff History **B6** Hematology results from IDEXX Reference 1/20/2017 L 2 103265148 Posted Laboratory Requisition ID: Final Result Reference Range Test 38.3 - 56.5 13.4 - 20.7 32.6 - 39.2 HCT HGB MCHC 4.9 - 17.6WBC LYMPHS MONOS EOS BASO RBC **B6** 5.39 - 8.7059 - 76 21.9 - 26.1 MCV MCH NEUT SEG PLATELETS RETIC CNT 143 - 448

B.Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, 1:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA.PVL Accepted, PB:problems, PP.PVL Performed, PR:PVL Recommended, R:Comespondence, T:Images, TC:Tentative medinate, V:Vital signs.

ABS BASO ABS EOS ABS LYMPHS ABS MONOS ABS NEUTS

В6

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Date: 3/20/2019 11:15 AM

0 - 100 70 - 1490 1060 - 4950 130 - 1150 2940 - 12670

Patient History Report Patient: B6 Client: Phone: Species: CANINE Breed: GERMAN SHEPHERD Address Age: **B6** Sex: Spayed Female Color: black and red Date Type Staff History ABS RET В6 10 - 110 B6 Ascn: B6 RE: 3034 REMARKS REMARKS Chemistry results from IDEXX Reference Laboratory Requisition ID: 103265148 Posted Final Reference Range 1/20/2017 L 2 Reference Range Result 2.7 - 3.9 5 - 160 ALB ALKP 18 - 121 337 - 1469 16 - 55 9 - 31 ALT AMYL AST BUN/UREA 8.4 - 11.8 108 - 119 131 - 345 Ca Chloride CHOL 10 - 200 0.5 - 1.5 0.0 - 0.1 CK CREA DBIL 0 - 13 GGT 63 - 114 138 - 755 2.5 - 6.1 GLU LIPA PHOS 4.0 - 5.4 142 - 152 0.0 - 0.3 Potassium Sodium TRIL 5.5 - 7.5TP 2.4 - 4.0GLOB 11 - 26 13 - 27 0.0 - 0.2 0.7 - 1.5 ANION GAP BICARB IBIL A/G Ratio B/C Ratio 28 - 37 0 - 14 Na/K Ratio SDMA В6 Ascn: RE: 281 HEMOLYSIS INDEX N Index of N, 1+, 2+ exhibits no significant effect on chemistry values. RE: 282 LIPEMIA INDEX N Index of N, 1+, 2+ exhibits no significant effect on chemistry values. B. Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimales, I:Departing instr., L:Lab result, M:Image cases, P:Prescription, PA.P.VL. Accepted, PB:problems, PP.P.VL. Performed, PB:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs Page 13 of 30

B6

Patient History Report В6 Client: Patlent: Phone: Species: CANINE Breed: GERMAN SHEPHERD Address В6 Sex: Spayed Female Age: Color: black and red Date Type Staff History Endocrinology results from IDEXX Reference Laboratory Requisition ID: 103265148 1/20/2017 L 2 Posted Final Reference Range Test Result T4 **B6** 1.0 - 4.0В6 Interpretive ranges: <1.0 Low 1.0-4.0 Normal >4.0 High 2.1-5.4 Therapeutic Dogs with no clinical signs of hypothyroidism and results within the normal reference range are likely euthyroid. Dogs with low concentrations may be hypothyroid or euthyroid sick . Occasionally, hypothyroid dogs can have T4 concentrations that are low normal. Dogs with clinical signs of hypothyroidism and low or low normal **T4** concentrations may be evaluated further by submission of free T4 and canine TSH. A high T4 concentration in a clinically normal dog is likely variation of normal; however elevations may occur secondary to thyroid autoantibodies or rarely thyroid neoplasia. For dogs thyroid supplement, acceptable 4-6 hour post pill total T4 concentrations generally fall within the higher end or slightly above the reference range. 1/20/2017 L 2 Miscellaneous results from IDEXX Reference B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr. L:Lab result, M:Image cases, P:Prescription, PA.PVL Accepted, PB:problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vita/signs

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B6

Client: Phone: Address:	B	Patient History Report Patient: B6 Species: CANINE Breed: GERMAN SHEPHERD Age: B6 Sex: Spayed Female Color: black and red
Date Type	Staff	History
		Laboratory Reculsition ID: 103265148 Posted Final Ascn: B6 RE: 950 UPC IF INDICATED UPC IF INDICATED
719/2017 E		SNAP Assays results from IDEXX VetLab In-clinic Laboratory Requisition ID: 15201 Posted Final Test Result Reference Range HW = Lyme = AP_spp = EC-EE =
/19/2017 I	2	
/19/2017 E	2	
/19/2017 I	2	B6
/19/2017 P	2	
/19/2017 E	2	
/19/2017 C	B6	Tech History-Canine - Closed Jan 20/2017 B6

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В6

Client: Phone: B6 Address: B6 Address: B6 Address: B6 Species: CANNE Age: B6 Color: black and red B6 Spayed Female Date Type Staff History B6 Jan 19, 2017 02:01 PM staff: B6 Weight: 64:00 pounds 5/25/2016 C 4 Exam/Medical Notes B6 S25/2016 D 4 Sprain Final B6 S25/2016 C B8 Technician Notes B6 S25/2016 C B8 Technician Notes B6 S25/2016 C B8 Technician Notes B6 S25/2016 C B8 Technician Notes B6 S25/2016 C B8 Technician Notes B6			Patient History Report	
B6 1/19/2017 V B6 Jan 19, 2017 02:01 PM Staff: B6 Weight : 64,00 pounds 5/25/2016 C 4 Exam/Medical Notes B6 5/25/2016 D 4 Sprain Final 5/25/2016 C B6 Technician Note B6 B66 Significant Little wall It Along cross P. Peacipion, PAPVL Accepted, PR problems S. PPVL Performed PR PVL Recommended Excesspondance, Timages, To Tendative rectinate, Vivintages	Phone:	B	Patlent: B6 Species: CANINE Age: B6	SHEPHERD
1/19/2017 V B6 Jan 19, 2017 02:01 PM Staff: B6 Weight : 64.00 pounds 5/25/2016 C 4 Exam/Medical Notes B6 5/25/2016 D 4 Sprain Final 5/25/2016 I 4 B6 5/25/2016 C B6 Technician Note. B6 B6 B6 B6 B6 B6 B6 B6 B6 B	Date Type	Staff	History	
Weight: : 64,00 pounds 5/25/2016 C 4 Exam/Medical Notes B6 5/25/2016 D 4 Sprain Final 5/25/2016 I 4 B6 5/25/2016 C B6 Technician Note B6 Spling CMed rote, CB Cell back, CK-Checkin, CM-Communications, DN-Declined to history, Elexaminator, ES-Estimates, Departing instr. LLab result, M Image cases, P. Prescription, PA PVL Accepted, PB problems, PP-PVL Performed, PR-PVL Recommended, 15Correspondence, Timages, TC-Terinative medinale, Vivial signs			B (6
5/25/2016 D 4 Sprain Final 5/25/2016 I 4 B6 5/25/2016 C B6 Technician Note B6 Splilling, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined b history, E:Examination, ES:Estimates, Departing instr. Lizb result, M.Image cases, P. Prescription, PAPVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, RCorrespondence, T:Images, TC:Tentative medi note, V:Vial signs.	1/19/2017 V	B6	The state of the s	
5/25/2016 C B6 Technician Note. B6 S/25/2016 C B6 Technician Note. B6 Selling, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, Departing instr. Litab result, M. Image clases, P:Prescription, PA.PVL Accepted, PB:problems, PP.PVL Performed, PR:PVL Recommended, PC:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs	5/25/2016 C	4		
Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, Departing instr. LLab result, Milnage doses, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, CConsespondence, T:Images, TC:Tentative medinate, V:Vital signs		4		
Departing instr. L.Lab result, M.Image cases, P:Prescription, PA.P.VL Accepted, PB:problems, PP.P.VL Performed, PR:P.VL Recommended, t.Correspondence, T:Images, TC:Tentative medi note, V:Vital signs			B6	
	Departing instr. L:Lab result	. Milmage cases	s, P. Prescription, PA.PVL Accepted, PB:problems, PP.PVL Performed, medinate, V:Vital signs	

Client: Phone: Address:	B	Patient History Rep Patlent: Species: CAN Age: Color: black	B6 Breed: GERMAN SHEPHERD B6 Sex: Spayed Female
Date Type	Staff	History	
5/25/2016 V	B6	May 25, 2016 03:47 PM Staff Weight : 65.20 p Temperature : 101.5	de carde resear separe.
11/23/2015 L	2	SNAP Assays results from ID Laboratory Requisition ID: Test Result HW = Lyme = AP_spp = EC-EE =	
11/23/2015	2		
11/23/2015	2	-	36
11/23/2015	2	•	
11/23/2015(2	information including bloodwork and request appointments, and more! Pla	al? This free service allows you to access pet vaccine reminders, order prescription refills, ease be sure to provide us with your email
11/23/2015 I	2	address so you can take advantage	of this opportunity.
			36
11/23/2015 P	2		
11/23/2015 P	2		
	. Milmage cases	t. ck-in, CM:Communications, D:Diagnosis, DH:Declined to s, P:Prescription, PA:PVL Accepted, PB:problems, PP:PV medingle, V:Vital skins	
B6		Page 17 of 30	Date: 3/20/2019 11:15 AM

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B6

		Patie	nt History Rep			
Client Phone Address	B	3	Patient: Species: CAN Age: Color: black	B6		GERMAN SHEPHERD Spayed Female
Date Type	Staff	History				
11/23/2015 V	3 <u>4</u> :	Nov 23, 201 Weight	5 11:34 AM : 60.00 p	B6		
11/23/2015 P	2		B6			
11/23/2015 P 11/23/2015 E	2		D)		
	L		E	36		
11/23/2015 L	2		results from 1 Requisition ID: Result B6 FS CAN	100159968 Ref	nce Pc erence	sted Final Range
	. M:Image case	s, P. Prescription, PA PVL A	. D:Diagnosis, DH:Declined to accepted, PB:problems, PP:P\			
В6		P	age 18 of 30	Date: 3	/20/2019	11:15 AM

Patient History Report Patient: Client: Phone: Species: CANINE Breed: GERMAN SHEPHERD Address: Age: B6 Sex: Spayed Female Color: black and red Date Type Staff History 5/7/2015 C 4 Exam/Medical Notes RV right hip SQ. 5/7/2015 R Rabies Certificate w/Dr Signature 2 - CLOSED 05/08/2015 **B6** В6 **Rabies Certificate** Client ID: Patient ID: Client Name: Patient Name: Address: Species: CANINE Breed: GERMAN SHEPHERD Spayed Female Sex: Color: black and red Phone: Markings: **B6** B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E.Examination, ES:Estimates, t.Departing instr. L:Lab result, M:Image cases, P:Prescription, PA.PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medit note, V:Vital signs

B6

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Date: 3/20/2019 11:15 AM

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Client: Patient:

B6

Medical records

			ent History Patlent:			
Client: Phone:			Species:	'	Breed:	GERMAN
Address:	B6		Age:	В6	Cavi	SHEPHERD Spayed Female
Audiess.				black and red	⇒e∧.	phaten i emaie
L		!				
Date Type	Staff	History				
				Birthdate:	B6	
				Weight:	59.8	
				Microchip#.	39.0	B6
				wicrosiip#.	L,	<u> </u>
	į					
		J	В	6		
Producer K≢MLV:			В	6		
			В	6		
	4	Rabies accord vaccination by first vaccinatio	y Connecticut st ing to State stati 6 months of age n. Booster vacci	ate law that all do ites. Currently, do a. Revaccination is	gs and cats required w be done wif	als be vaccinated must receive a ra ithin 12 months of ihin 36 months of on its rabies

B.Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr. L:Lab result, M:Image cases, P:Prescription, PA.PVL Accepted, PB:problems, PP.PVL Performed, PR:PVL Recommended, R:Conespondence, T:Images, TC:Tentative medinate, V:Vital signs

B6

5/7/2015 V

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7, 2015 10:44 AM Staff: 4

· · · · · · · · · · · · · · · · · · ·		Patient History Report	
Client: Phone: Address:	B	Patient: B6 Species: CANINE Age: B6 Color: black and red	Breed: GERMAN SHEPHERD Sex: Spayed Female
Date Type	Staff	History	
2/14/2015 V	В6	<pre>weight : 59.80 pounds Feb 14, 2015 12:46 PM Staff(B6) Weight : 59.40 pounds</pre>	
2/6/2015 I 2/6/2015 V	2 B6	B6	
		Weight : 59.60 pounds	
9/9/2014 C	2.	Exam/Medical Notes B6	
9/9/2014 P	4	B6	
9/9/2014 C	:4:	Exam/Medical Notes B6	
9/9/2014 C _a :	В6	Technician Note B6	
9/9/2014 V	: 2	Sep 9, 2014 11:32 AM Staff: 2 Weight : 66.60 pounds	
	t, Milmage cases	ck-in. CM:Communications, D:Diagnosis, DH:Declined to history, E:Examinations, P:Prescription, PA.P.VL Accepted, PB:problems, PP.P.VL Performed, PR:P.V. medinate, V:Vitalisigns	
B6	1	Page 21 of 30 Date: 3	/20/2019 11:15 AM

		Patient History Report	
Client: Phone:	$D_{\mathcal{L}}$	Patient: B6 Species: CANINE E	reed: GERMAN
Address:	B6	Age: B6	SHEPHERD Sex: Spayed Female
		Color: black and red	and the second section of the section of the second section of the section of the second section of the section of th
Date Type	Staff	History	
	,		
8/5/2014 C	B6	Phone Call Notes LMOM re: fecal negative	
8/4/2014 L	2		-clinic Posted Final Pence Range
8/4/2014 P	.2		
8/4/2014	.2		
8/4/2014	, 2)	B6	
8/4/2014	:2 <u>;</u>		
8/4/2014 E 8/4/2014 P	2 2		
8/4/2014 V	В6	Aug 4, 2014 03:27 PM Staff B6	
		Weight : 69.20 pounds Temperature : 102.1	
8/4/2014 C	В6	Tech History-Canine - Closed Aug 05/2014	
	ill, M:Image cases	k-in, OM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, B. P:Prescription, PA.PVL Accepted, PB:problems, PP.PVL Performed, PR:PVL Brited index, V:Vitalisigns	
B6		Page 22 of 30 Date: 3/20)/2019 11:15 AM

Patient History Report Patlent: Cllent: В6 Phone: Species: CANINE Breed: GERMAN SHEPHERD Address Age: Sex: Spayed Female B6 Color: black and red Date Type Staff History Microbiology results from IDEXX Reference Laboratory Requisition ID: 2739-2 P 8/4/2014 L Final Reference Range Test Result OVASPARA_ SEE NOTES В6 Ascn: FS CAN INE 3/6/2014 | Simply snap the two disks together to puncture the safety seal. Part fur at the base of the tail and begin applying in a continuous motion up to the shoulder blades. Allow drying before intreracting with your pet. http://www.vectrapet.com/how-to-apply/ ALL FLEA PRODUCTS ARE INSECTICIDES. PLEASE FOLLOW THE 3/6/2014 [DIRECTIONS ON THE LABEL. USING TOO MUCH CAN HARM YOUR PET. IF B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history. E.Examination, ES:Estimates, 1.Departing instr., Litab result, M.Image cases, P:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs. В6 Date: 3/20/2019 11:15 AM Page 23 of 30

Cllent:			nt History Patlent:	B6		
Phone:	B 6		Species:		Breed:	GERMAN SHEPHERD
Address:		J		B6 black and red	Sex:	Spayed Female
L						
Date Type	Staff	History				
3/6/2014 P		to hatch from th	e environment tall pets in the on does not rec	ormonths after household, as w ur. Please call	the adult pop elf as the env is if you are f	TAL. Fleas continue ulation is eradicated. rironment, to be sure naving trouble
3/6/2014						
overder a	В6			D		
3/6/2014	В			B		
erenal e						
3/6/2014 P						
		L				
2/24/2013 C	2	Exam/Medical N	lotes	D 6	·	
				B 6		
2/24/2013 P	2		B6			
12/24/2013 V	2	Dec 24, 2013	11:39 AM S	taff: 2	<u>j</u>	
	- 40	Weight	: 71.	40 pounds		
9/9/2013 PB 9/9/2013 PB	4 4	В	6			
		t				
	it. Milmage cases	ck-in, CM:Communications, s, P. Prescription, PA PVL Av medinate, V:Vital signs				
B6			age 24 of 30	Da	te: 3/20/2019	TITE AM

Cllent: Phone: Address:	B	Age: L	B6 NINE Breed:	GERMAN SHEPHERD Spayed Female
Date Type	Staff	History		
9/9/2013 C	4	Exam/Medical Notes	B6	
9/9/2013 P	∘4 ⁸	В6		
9/9/2013 C	B6	Technician Note	B6	
9/9/2013 V	B6	Temperature : Pulse :	B6 pounds B6	
		SNAP Assays results from Laboratory Requisition ID Test Result HW = Lyme = AP_spp = EC-EE = B6	: 9501 Posted Reference	Final Range
Departing instr. L'Lab resu L'Correspondence, T:Image	es, TC:Tenfative	s, P: Prescription, PA.P.V.L. Accepted, PB.problems, PP medinate, V: Vital signs Page 25 of 30	Date: 3/20/2019	

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		Patient History	Report		
Client: Phone: Address:	B	Species: Age:	B6 CANINE B6 black and red		GERMAN SHEPHERD Spayed Female
Date Type	Staff	History			•
8/7/2013	2	Your pet was vaccinated with the on the left side of the chest with	n a Serial # 522112	2A with exp	
8/7/2013 P	2	July 12.2014.	_		
8/7/2013 E	2	B	b		
8/7/2013 C	В6	Tech History-Canine - Closed A	Aug 08/2013		
			B6		
8/7/2013 V	B6	Aug 7, 2013 03:41 PM St Weight : 65. Body Score (1-9) : Temperature : Respiration : Alert/Attitude : Pain Scale : Mucous Membranes : Capillary Refill : Dental Score : Appetite : Urine Output : Fecal Output :	B6 40 pounds	3	
	t. Milmage cases	ck-in, CM:Communications, D:Diagnosis, DH:Dec P:Prescription, PAPVL Accepted, PB:problems medinate, V:Vital signs Page 26 of 30	s, PP:PVL Performed, PR:1		ded,
DO	j	Page 20 UI 3U	Date.	DIZ0/2019	1145 WM

Cllent: Phone: Address:	B6	Patient History Report Patient: B6 Species: CANINE Age: B6 Color: black and red		GERMAN SHEPHERD Spayed Female
Date Type	Staff	History		
4/19/2013 C	B6	Client Communication - Closed Apr 20/2013		
4/18/2013	4			
4/18/2013 I	ď.	B6		
4/18/2013 P	:4:			
4/18/2013 C	,4°	Exam/Medical Notes B6		
4/18/2013 C	В6	Technician Note B6		
4/18/2013 V	4_	Apr 18, 2013 03:47 PM Staff: 4 Weight : 62.40 pounds		
4/18/2013 E	4	OVASPARA SEE NOTES Ascn: B6	Post: eference	Range
	. M:Image cases	k-in, OM:Communications, D:Diaghosis, DH:Declined to history, E:Examina , P:Prescription, PA.P.V. Accepted, PB:problems, PP:P.V. Performed, PR:F read note, V:Vitalisigns		

		Patient History Report	
Client: Phone:	B6	Patient: B6	
Address:		Age: B6 Sex: Spayed Female Color: black and red	
Date Type	Staff	History	
Date Type	Stail	nistory	
	r.	B6 FS CANINE	
		B6	
	į		
	į,		
2/25/2013 V	<u>B6</u>	Feb 25, 2013 04:37 PM Staff: B6	
		Weight : 59.20 pounds	
2/25/2013 C	В6	Phone Call Notes	
2/25/2015 (2	БО	Phone Call Notes B6	
		DO	
2/25/2013 P	4	1.00 BOX B6 (2670)	
E/20/2010 1	h		
9/28/2012 P	D		
9/28/2012	B6		
		B 6	
B:Billing, C:Med note, CB:Ca	all back, CK;Check	k-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates,	
1:Departing instr. L:Lab resul R:Correspondence, T:Image	t, M:Image cases;	P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended,	

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В6

Patient History Report Patient: B6 Cllent: Phone: Species: CANINE Breed: GERMAN SHEPHERD Age: B6 Address: Sex: Spayed Female Color: black and red Date Type Staff History recommended by the American Healtworm Society (AHS) and the Companion Animal Parasite Council (CAPC) that these agents are used year-around in all areas of the U.S. SNAP Assays results from IDEXX VetLab In-clinic 8/23/2012 L 2 Laboratory Requisition ID: 7599 Posted Final Test Result Reference Range HW = Lyme = E. canis = A. ph. = 8/23/2012 E 8/23/2012 | 2 8/23/2012 I 2 8/23/2012 1 2 8/23/2012 C B6 8/21/2012 C RT Records received by Fax - CLOSED 08/23/2012 - Records received by Fax B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history. E.Examination, ES:Estimates, 1.Departing instr., Litab result, M.Image cases, P:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs. Date: 3/20/2019 11:15 AM **B6** Page 29 of 30

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Client: **B6**

Medical records

Patient History Report

Client:
Phone:
Address:
B6

Patient: B6 Species: CANINE Age: B6

Color: black and red

Breed: GERMAN SHEPHERD Sex: Spayed Female

Date Type Staff History

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history. E.Examination, ES:Estimates, 1.Departing instr., Litab result, M.Image cases, P:Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PB.PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vital signs.

B6

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Diet Hx 3/22/19

CARDIOLOG	Y DIET HISTOR	Y FORM	net	
Pet's name: B6 Owner's name :	B6		Today's date	3/22/19
 How would you assess your pet's appetite? (mark the remarks) 	point on the line be	alow that hast ro	n	
Example: Poor		Exit	presents your pe cellent	t's appetite)
Poor		Exc	cellent	
Have you noticed a change in your pet's appetite over t Eats about the same amount as usual □Eats les □Seems to prefer different foods than usual □Other_	e than usual	? (check all that □Eats more tha	apply) in usual	
Over the last few weeks, has your pet (check one) Lost weight	e same weight	Don't know		
 Please list below <u>ALL</u> pet foods, people food, treats, snown currently eats. Please include the brand, specific productions are shown in the table – please provide enough. 	ct, and flavor so w	e know exactly v	what you pet is ea	ating.
Food (include specific product and flavor)				OXUGE SUITE IC
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	Form dry	Amount	How often?	Fed since
85% lean hamburger	microwaved	1 ½ cup 3 oz	2x/day	Jan 2018
Pupperoni original beef flavor	treat	The second secon	1x/week	Jan 2015
Rawhide	treat	½ 6 inch twist	1x/day	Aug 2015
	irout	O IIIGII IWISI	1x/week	Dec 2015
ACAMA TREIMING (MSTY RED MAAT FORMULA & FREE PLAN POMERTY FORMULA)	DRY	144 (ur	2x Dry	2015
HOMEMADE LIVER TREATS MOTOR OF 116.	TRUNT		Da V	
CITICAN LINERS, 1-12 CUIS FORN FOND	11411		Dnuy	
3 LOUS + GARLIC POWDER)				
Roter MARRON RONKS				
*Any additional diet information can be listed on the back	k of this sheet			ŕ
Do you give any dietary supplements to your pet (for exa supplements)?	Concentration	lucosamine, fatty brands and amo	ounts:	ner unt per day
Taurine DYes DNo			Alloc	ant per day
Carriune Lives Lino			16. The	
Multivitamin UYes UNo Fish oil UYes UNo	191 5		-	
Coenzyme Q10				
Other (please list):			\(\frac{1}{2}\)	
Example: Vitamin C Nat	ure's Bounty	500 mg tablet	s – 1 per day	
			2 TABS/	DAY
How do you administer pills to your pet?				
☐ I do not give any medications ☐ I put them directly in my pet's mouth without food				
■ I put them in my pet's dog/cat food ■ I put them in a Pill Pocket or similar product				
☐ I put them in foods (list foods):				

B6

CBC/Chem 3/22/19



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

DUPLICATE

Name/DOB: B6	Sex: SF	Provider. B6 Order Location: V320559: Investigation into
Phone number:	Age. B6	Sample ID: 1903220112
Collection Date: 3/22/2019 3:35 PM	Species: Canine	
Approval date: 3/22/2019 5:02 PM	Breed: German Shepherd	

CBC (Research) (Advia) DNOYES Ref. Range/Females WBC (ADVIA) 4.40-15.10 K/uL RBC (Advia) 5.80-8.50 M/uL Hemoglobin (ADVIA) 13.3-20.5 g/dL 39-55% Hematocrit (Advia) **B6** MCV (ADVIA) 64.5-77.5 fL MCH (ADVIA) 21.3-25.9 pg MCHC (ADVIA) Η 31.9-34.3 g/dL CHCM RDW (ADVIA) 11.9-15.2 Comments (Hematology) Hemolysis present 0-1 platelets per High power field Microscopic Exam of Blood Smear (Advia) **DNOYES** Ref. Range/Females Seg Neuts (%) 43-86% Lymphocytes (%) L 7-47% B6 Monocytes (%) 1-15% Eosinophils (%) 0-16% Nucleated RBC 0-1 /100 WBC 03/22/19 4:07 PM White blood cell count has been corrected for the presence of nucleated red blood cells Seg Neutrophils (Abs) 2.800-11.500 K/ul Advia Lymphs (Abs) Advia L 1.00-4.80 K/uL Mono (Abs) Advia 0.10-1.50 K/uL Eosinophils (Abs) Advia 0.00-1.40 K/uL WBC Morphology Poikilocytosis Research Chemistry Profile - Small Animal (Cobas) CSTCYR Ref. Range/Females Glucose 67-135 mg/dL Urea 8-30 mg/dL $0.6\text{-}2.0\,\text{mg/dL}$ Creatinine Phosphorus 2.6-7.2 mg/dL Calcium 2 9.4-11.3 mg/dL **B6** Magnesium 2+ 1.8-3.0 mEq/L Total Protein 5.5-7.8 g/dL Albumin 2.8-4.0 g/dL Globulins 2.3-4.2 g/dL A/G Ratio 0.7 - 1.6Sodium 140-150 mEq/L Chloride 106-116 mEq/L Sample ID: 1903220112/1 Reviewed by: _

Page 37/61

This report continues... (Final)

CBC/Chem 3/22/19



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

DUPLICATE

Name/DOB: B6	Sex: SF	Provider. B6 Order Location: V320559: Investigation into
Phone number:	Age: B6	Sample ID: 1903220112
Collection Date: 3/22/2019 3:35 PM	Species: Canine	50 000100 - 000000 00000 000000000000000
Approval date: 3/22/2019 5:02 PM	Breed: German Shepherd	

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

CSTCYR	Ref. Range/Female:
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40
Total Bilirubin	0.10-0.30 mg/dL
Alkaline Phosphatase	12-127 U/L
GGT DC	0-10 U/L
GGT ALT AST	14-86 U/L
AST LJ U	9-54 U/L
Creatine Kinase	22-422 U/L
Cholesterol	82-355 mg/dL
Triglycerides	30-338 mg/di
Amylase	409-1250 U/L
Osmolality (calculated)	291-315 mmol/L
Comments (Chemistry)	

Sample ID: 1903220112/2 REPRINT: Orig. printing on 3/22/2019 (Final) Reviewed by: _____ Page 2 Client: **B6**

NT-proBNP 3/22/19

Client B6 Patient: EM I IDEXX Reference Laboratories IDEXX VetConnect 1-888-433-9967 Client: Date: 03/22/2019 TUFTS UNIVERSITY **B6** 200 WESTBORO RD NORTH GRAFTON, Massachusetts 01536 Patient: Requisition #: 1A Accession #:2303942774 Species CANINE Breed: GERMAN_S HEPHERD Gender: FEMALE S PAYED Age(_B6) Ordered by: RUSH 508-839-5395 Account #88933 CARDIOPET proBNP - CANINE CARDIOPET proBNP **B6** HIGH 0 - 900 pmol/L **B6** - CANINE Comments: 1. Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Patient's at-home monitoring sheet 3/26/19

В6	Tufts Pa German Birthdat	atient I Sheph e: B	D: [<u>в6</u> nerd 6]]		HE	ART FA	AILURE	MONI	TORING	3 W	юк	SH	EE.	т
	Respira	ation									Excellent		etite		
Date	Rate/Minute	Time									Ě	Good	Fair	Poor	Comments
03/23/19	30	22:00	D	C	D	6	D	6	D	C	V				No coughing, rested comfortably during day, slightly restless at night-moved from one spot to another for about an hour before falling asleep.
03/24/19	34	23:10	D	6	D	O	D	O	D	O	~				Spent some time lying outside, seemed pretty comfortable throughout the day. Stool softer than normal.
03/25/19	34	07:00					5				v				Food: 1/2 cup Acana & 3/4 cup Royal Canin Early Cardiac 2x day. Emi pooped once today at 7pm stool was normal, formed.
	28	22:56					5								
03/26/19	30	10:45		,							V				Food: 1/2 cup Acana & 3/4 cup Royal Canin Early Cardiac 2x day. Emi had accident last night, urinated in dog bed.
	13														
2	8														
			<u>(</u>											i	
	8 3		8 9										E		

Respiration Rate: Count the number of breaths for 30 seconds and multiply times 2 to get the respiratory rate per minute. In dogs, obtain the respiratory rate when they are at rest and not panting. In cats get the respiratory rate at rest when they are not purning. In animals with well controlled heart failure the breathing rate is often less than 35-40 breaths per minute. When the breathing rate is climbing, or when there is more effort to the chest wall or belly muscles during breathing, then fluid is likely accumulating in the lungs and more furosemide may be indicated. Please bring this sheet with you to your next veterinary exam.

Client:	B6
Patient:	DV

Vitals Results

3/22/2019 1:43:08 PM

Weight (kg)

25.9000

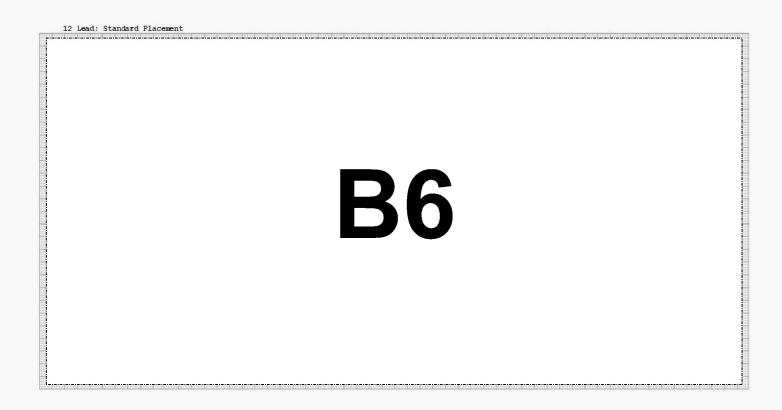
ECG from Cardio

B6

3/22/2019 2:18:38 PM

Page 1 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology



ECG from Cardio

В6

3/22/2019 2:18:38 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology



Patient History

Patient Account History	Description	Qty	price	Extended Disc	Pmt
		<u> </u>			
03/27/2019 12:41 PM	Appointment				
03/23/2019 09:47 AM	Email				
03/22/2019 04:18 PM	Purchase				
03/22/2019 04:00 PM	Prescription				
03/22/2019 03:57 PM	Prescription				
03/22/2019 02:43 PM	UserForm				
03/22/2019 01:56 PM	Treatment				
03/22/2019 01:43 PM	Purchase	į		36	
03/22/2019 01:43 PM	Vitals	į			
03/22/2019 01:13 PM	UserForm	į			
03/22/2019 01:11 PM	UserForm				
03/20/2019 01:33 PM	Appointment				
03/20/2019 11:52 AM	Appointment				

Client: **B6**

Patient Account History Description	Qty	price	Extende	d Disc	Pmt	
Friday, 22 March 2019 Appointment: Cardiology Study 13:43	y 1.000	0.000	0.0000	0.0000	0.0000	

Client: **B6**

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Friday, 22 March 2019 [B6	60.000	0.390	28.4000 0.0000	0.0000

Client: **B6**Patient:

Patient Account History	Description	Qty	price	Extende	d Disc	Pmt
Friday, 22 March 2019 16:00	B6	30.000	0.110	8.3000	0.0000	0.0000

Client: **B6**

Patient Account History Description	Qty	price	Extende	d Disc	Pmt
Friday, 22 March 2019 Pharmacy Finished	1.000	0.000	0.0000	0.0000	0.0000

Cummings Veterinary Medical Center



STANDARD CONSENT FORM

Lam the owner, or agent for the owner, of the above described animal and have the authority to execute consent. It hereby authorize the Cummings School of Veterinary Medicine at Tults University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly adknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

Lunderstand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 1.6% applied to the average daily balance outstanding, with a minimum fee of \$.50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above agreed upon time of payment or payments, the entire balanceshall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name	В6] [Date: 3/22/2019	
Owner's address:		В6		
Owner's Name Sę	36 grature			3 22 (9 Date

If the individual admitting the arimal is someone other than the legal owner, please complete the portion below:

		anted me authority to obtain medical treatment and to bind th at Cummings School pursuant to the terms and conditions descr	
Authorized Agent - Please Pr	int	Agent's Signature	
Street Address			
Town/City State	e Zip		

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Far (508) 839-7951 http://wetmed.turks.edu/

Discharge Instructions

ame.	В6	Name:	B6	Patient ID: B6
	: Canine	Address	D6]
	ed Fernale (Spayed) German	į	B6	j
epher	r			
irthdal	EE B6			
ttendi	ng Cardiologist:			
2	John E. Rush DVM, MS, DACVIM	(Cardiology), D	ACVEO Ç	
	DG			
	DU			
	ogy Resident:		j	
de Calle		B6		······································
ardiok	nev Technicians			<u>.</u>
	B6			
_	,	.=.=,		
tudent	B6			
ا النساء	Date: 3/22/2019 1:09:07 PM			
	ge Date: 3/22/2019			
r-r-r-i	5c 100 00 34 224 2013			
iagnos	es: Dilated cardiomyopathy (DO	A) with conges	tive heart failure, ve	ntricular premature depolarizations
•	, · , ·	, ,	•	•
	stic test results and findings:			
0	Echocardioeram findines:		D	R6.
			B6	
0	EOG findings:		B6	
			B6	
۰	Labwork findings:		B6	
_ :	B6			
·			i	

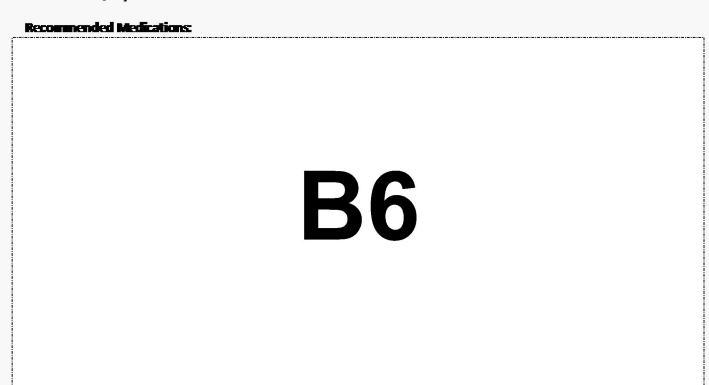
Case summary:

Dations

B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DOM). This disease is more common in large and giant breed dogs and is characterized by thirning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DOM will also have significant anhythmias which can be life-threatening and also require medical management. The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs (pulmonary edema). Unfortunately this is a progressive disease and we cannot reverse the changes to the heart muscle, however we can use cardiac medications and some changes to the diet to make your dog comfortable and have her breathing easier.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest.
 The doses of drugs will be adjusted based on the breathing rate and effort.
- O In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- O An increase in breathing rate or effort will usually mean that you should give an extra close of furosemide (Lasix). If difficulty breathing is not improved by within 30-60 minutes after giving extra furosemide then we recommend giving 1 more close and if that cloes not help then a recheck exam be scheduled and/or that your clog be evaluated by an emergency clinic.
- O There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheckeramination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24hours/day.



We might add in a medication for arrhythmia in the future, especially it B6 has a collapse or if the ECG shows worsening arrhythmia - a drug like B6 would likely be added.

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (http://wei.turits.edu/heartsmart/diet/)

Your dog's usual diet may also have more sodium than recommended – we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50.50, etc.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and
 does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo,
 tapioca, barley, and chickpeas.
- O The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/uom613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufls.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)

Royal Canin Boxer

Purina Pro Plan Adult Weight Management

Purina Pro Plan Bright Mind Adult Small Breed Formula

Canned Food Options:

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew

Royal Canin Mature 8+

Exercise Recommendations:

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find tha $\begin{bmatrix} B_0 \end{bmatrix}$ is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or stremuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck visit is recommended in 1-2 weeks after any medication adjustments are made. At this visit we will check your dog's breathing effort and heart function, do a blood test to recheck kidney values, and recheck an ECG. A recheck cardiac exam for the study and an echocardiogram is recommended in 3 months.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tuits.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

http://vet.tufts.edu/heartsmart/

Prescription Refil Discloimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: yet.tufts.edu/cvmc/clinical-studies

Case B6	Owner: B6	Discharge Instructions	



Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://wetmed.tults.edu/

Alivecor/Kardia Handout

If you have an iPhone or Android, you may want to explore the option of purchasing an AliveCor/Kardia. ECG monitor which will allow you to record and email your pet's heart rate and rhythm at home.

The device (Kardia) can be purchased at <u>www.alivecor.com</u> or <u>www.amazon.com</u>. The app for your phone is free.

If you have an iPhone:

- Search for 'Veterinary AliveECG' app in the Apple Store
- O You will need to sign-up for an account
- O Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker portal, say 'OK/allow'

If you have an Android:

- Search for 'Kardia' app in the Google Playstore
- You will need to sign-up for an account.
- O Make sure to have your pet's name in the information so we know whom it is from
- O If the app asks for permission to access headphone port/speaker portal, say 'OK/allow'
- Once downloaded, it will require you to send a "test ECG" for activation of the app. Just place your fingers on the sliver sensors and let it record
- O If the test ECG is unable to record, try again, with less movement. If it still fails, then your phone is not compatible with the device

Recording an BCG:

- Apply rubbing alcohol (soaked cotton ball will work) to the chest region behind your pet's elbow (where you can feel the heartbeat)
- Enough to wet the regions where both silver boxes will touch the animal
- O If your pet is fluffy, you may have to clip a small patch of fur to allow for better contact
- O Hold the device against your pet's chest with the silver areas being up and down (vertical) in contact with the animal
- With the app open, hold your phone near (within a few inches) the device.
- O There is a signal bar in the upper left corner of the app to show whether it detects the device.
 If there are no bars then move your phone around/get closer to the device until they appear.
- Once you see a recording, hold everything in place for at least 30 seconds if possible.
- O The human Kardia app will attempt to interpret the ECG; just ignore this as it is not always accurate.
- O The heart rate that the apps report is also not always accurate.

Saving an ECG:

- The app will automatically save the ECG as long as the recording is long enough (>20seconds).
- You can click on the ID (box with pencil icon) in the Veterinary AliveECG app to add your pet's name

Emailing an ECG:

- O If you are in the recording screen on the Veterinary AliveECG app, click on 'ECGs' to see the list of saved ECGs
- O If you are in the home screen on the Kardia app, click **'History'**.
- O Select the ECG you wish to send. Go to "Share". Select "Email PDF". SKIP the Password protect feature and select the email app you wish to send it by (Gmail, outlook, yahoo, etc). You must have a working email on your phone for this to work.
- O Select an ECG that you wish to send
- O Click the mail icon (either a box with arrow or a letter symbol), and select "Email"
- Email to: <u>cardiovet@tufts.edu</u> (only monitored Monday-Friday 9AM-5PM)

Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

E	36
Patient B6	D: B6 anine B6 Female (Spayed) Germa
Shepha	अर्च
Black/F	ted

Cardiology Appointment Report ENROLLED IN DCM DIET STUDY

Date: 3/22/2019	
Attending Cardiologist. John E. Rush DVM, MS, DACVIM (Cardiolog	gy), DACVECC (primary)
B6	
Cardiology Resident:	
B6	
B6	
Student: B6 Presenting Complaint: referred for evaluation of	DCM and for grain-free diet study
Concurrent Diseases: none reported	
be okay. Next morning, the same thing happened. with DCM. Usually a "lowkey dog". Owner noted i	described as wheezing (very brief) and then seemed to . Took in to rDVM on Monday where she was diagnosed increased breathing effort during rest (quidk, short). infected anal gland, resolved with antibiotics by rDVM.
No "wheezing" spells since starting the E	36 but still tachypneic.

Diet and Supplements:

Eating and drinking are normal.

Acana heritage red meat formula (grain-free) has been on for a few years (occasionally a different). Eats homemade liver treats in treat balls (chicken mixed with comflour, eggs, garlic). Occasional raw marrow bone

Cardiovascular History:

Prior ATE? N	
<u> </u>	me? Y, has had increased effort during rest (not counting)
Cough? Y	
Shortness of breath or difficulty breathing?	f
Syncope or collapse? N	
Sudden onset lameness? N	
	ally low energy - has been sometimes avoiding going upstair:
when she usually would	
Current Medications Pertinent to CV System	m:
Medication: B6	 -
Formulation/Tab Size: B6 Administration Frequency: B6	
Need refills?	
Medication: B6	
Formulation/Tab Size: B6 Administration Frequency:	
Administration Frequency:	B6
Need refills?	
Cardiac Physical Examination:	
B6	
na I be I I I I I I	1 •
Muscle condition: muscle loss mostly in the p	peivic area Moderate cachexia
Mild muscle loss	Marked cacheda
I FING TREASE, 1033	
Cardiovascular Physical Exam:	
Murmur Grade:	
Mone to	□ I V/V I
<u>₩</u> I/VI	<u> </u>
	□ vi/vi
■ III /V I	
86	
Murmur location/description: left apical	
h	
Jugular vein: ☑ Bottom 1/3 of the neck	1/2 way up the neck
Middle 1/3 of the neck	Top 2/3 of the neck
	= 10p 45 to the first
Arterial pulses:	
Weak	Bounding
Fair	Pulse deficits
Good	Pulsus paradoxus
Strong	Other:

Arrhythmia: None Sinus arrhythmia Premature beats	■ Bradycardia ■ Tachycardia						
Gallop: S3 ☑ Yes ☑ No ☑ Intermittent	Pronounced Other: Impressive gallop						
Pulmonary assessments: Eupneic Mild dyspnea Marked dyspnea Normal BY sounds	Pulmonary crackles Wheezes Upper ainway stridor						
Abdominal exam: Normal - minimal exam Hepatomegaly Abdominal distension	■ Mild ascites ■ Marked ascites						
Problems: DCM with CHF Mildly increased effort of breathing (likely second pulmonary hypertension)	DCM with CHF Mildly increased effort of breathing (likely secondary to CHF vs less likely pulmonary disease vs PTE vs						
Diagnostic plan: ☐ Echocardiogram ☐ Chemistry profile ☐ ECG ☐ Renal profile ☐ Blood pressure	☐ Dialysis profile ☑ Theracic radiographs +/- ☑ NT-proBNP ☑ Troponin I ☐ Other tests:						
B6							

Radiographic findings: None available at time of exam

ASSESSMENT BIRD LESSIMMENTSBOO	<u> </u>		,
Dilated cardiomyopathy with mild	l pulmonary edema toda	y and some ventricular	rann hythmia. B6
	В6		
prescribed), enter into DCM diet s	tudy, start taurine pendi	ng taurine levels, and	we talked for some time
about the pros and cons of startin	g an antiarrhythmic. The	dog did not have colla	apse and sustained
arrhythmia was npt documented.			B6
B6	Get long lead II EC	G and recheck renal v	alues and electrolytes in
about 10 days and then consider i	ncreasing t B6	0 mg AM and 5 mg PN	VI), B6 pased
on current bloods (liver enzymes)	and recheck ECG. Discus	sed diet change.	Li
Heart Failure Classification Score	•		
ISACHC Classification:	_		
<u>□</u> la	<u></u> Illa		
<u> </u>	Піів		
🗷 II to			
action of the company			
ACVIM Classification:	Πo		
A	☑ C □ D		
■ B1	■ D		
■ B2			
<u>M-Mode</u>		ı ₁	
IVSd			cm
LVIDd			cm
LVPWd			om
IVSs			om
LVIDs			om
LVPWs			om
EDV(Teich)			ml
ESV(Teich)			ml
EF(Teich)			%
%FS			%
SV(Teich)		DC	ml
Ao Diam		B6	om
LA Diam			om
LA/Ao			
Max LA			om
TAPSE			cm
EPSS			cm
M-Mode Normalized			
IVSdN			(0.290 - 0.520)
LVIDdN			(1.350 - 1.730) !
LVPWdN			(0.330 - 0.530)
IVSeN			(0.550 0.550) (0.430 _ 0.710)

LVIDsN $\{0.790 - 1.140\}$! **LVPWsN** $\{0.530 - 0.780\}$! Ao Diam N $\{0.680 - 0.890\}$! LA Diam N $\{0.640 - 0.900\}$! 2D SALA an Ao Diam an SALA / Ao Diam **IVSd** an LVIDd an LVPWd an EDV(Teich) ml **IVSs** an **LVIDs** an **LVPWs** an ESV(Teich) ml % EF(Teich) %FS % SV(Teich) ml LV Major an LV Minor an Sphericity Index **LVLd LAX** an **LVAJ LAX** am **LVEDV A-L LAX** ml LVEDV MOD LAX ml LVLSLAX an LVAs LAX cm. **LVESV A-L LAX** ml **LVESV MOD LAX** ml HR **BPM** EF A-L IAX % **LVEF MOD LAX** % SV A-L LAX ml SV MOD LAX ml **∤min** CO A-L IAX **Vmin** CO MOD LAX LA Area an R-Rms HR **BPM** CO A-L IAX **//min** CO MOD LAX **Vmin** Doppler **MR Vmax** m/s MR maxPG mmHg MV E Vel m/s **MV** DecT ms MV Dec Slope m/s

MV A Vel m/s MV E/A Ratio m/s E/E' A' m/s **B6** S' m/s m/s **AV Vmax** AV maxPG mmHg PV Vmax m/s mmHg PV maxPG

Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To:

Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee

Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David

4/11/2019 9:16:05 PM Sent:

Tuft's cases-FW: ACANA - Heritage Red Meat Formula Dog Food (Grain-free) Subject:

B6

EON-384833

Attachments:

2065712-report.pdf; 2065712-attachments.zip

Echo is likely, but the dog collapsed and died **B6** Not sure if necropsy done.

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

B6













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Sent: Thursday, April 11, 2019 4:53 PM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet

Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; usha.gulati@doveltech.com Subject: ACANA - Heritage Red Meat Formula Dog Food (Grain-free): **B6** EON-384833

A PFR Report has been received and Related PFR Event [EON-384833] has been created in the EON System.

A "PDF" report by name "2065712-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2065712-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-384833

ICSR #: 2065712

EON Title: Related PFR Event created for ACANA - Heritage Red Meat Formula Dog Food (Grain-free);

2065712

AE Date	03/15/2019	Number Fed/Exposed	2
Best By Date		Number Reacted	1

Animal Species	Dog	Outcome to Date	Died Other
Breed	Shepherd Dog - German		
Age	B6 Years		
District Involved	PFR-New England DO		

D	r۸	d١	ict	info	rm	atio	n

Individual Case Safety Report Number: 2065712

Product Group: Pet Food

Product Name: ACANA - Heritage Red Meat Formula Dog Food (Grain-free)

Description: 3/15/2019 - Acute onset of difficultly breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF B6 Patient suddenly collapsed, within seconds of collapse

patient died.

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Died Other

Number of Animals Treated With Product: 2 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
ACANA - Heritage Red Meat Formula Dog Food (Grain-free)		

This report is linked to:

Initial EON Event Key: EON-383914

Initial ICSR: 2065085

Sender information

B6

USA

Owner information

B6 USA

To view this Related F	PFR Event, please c	lick the link below:
E	36	

To view the Related PFR Event Report,	please click the link below:	
	B6	
В6		

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Report Details - EON-										
ICSR:	2065712									
Type Of Submission:	Followup			ntaannitaannaan totaan taan taan ta	TARIO DE LA RETRIA DE LA ADRIGA A DEL CARRETTO DE LA COMPANSIONA DE LA COMPANSIONA DE LA COMPANSIONA DE LA COM					
Report Version:	FPSR.FDA.PETF.V.V1									
Type Of Report:	Adverse Event (a symptom,	reaction or disease	associated with th	ie product)	***************************************					
Reporting Type:	Voluntary									
Report Submission Date:	2019-04-11 16:39:13 EDT									
Initial Report Date:	04/01/2019									
Parent ICSR:	2065085									
Follow-up Report to FDA Request:	Yes									
Reported Problem:	Problem Description:	3/15/2019 - Acute or wheezing and short Patient suddenly col	of breath. Diagno	sed with DCM						
	Date Problem Started:	03/15/2019								
	Concurrent Medical Problem:	No								
	Outcome to Date:	Died Other								
	Date of Death	В6								
Product Information:	Product Name:	ACANA - Heritage F	ted Meat Formula	Dog Food (G	rain-free)					
	Product Type:	Pet Food								
	Lot Number:									
	Package Type:	BAG								
	Product Use									
	Information:									
	Manufacturer /Distributor Information:									
	Purchase Location Information:									
Animal Information:	Name:									
	Type Of Species:	Dog								
	5 <u></u>	Shepherd Dog - Ger	man							
	Gender:	{								
	Reproductive Status:	į								
	5.2	25.9 Kilogram			n niidaa nota nian taan taan taan taa notaa notaa notaa notaa notaa niidaa notaa nii taan notaa notaa notaa no					
	3 }	B6 Years			***************************************					
	Assessment of Prior Health:	r Excellent								
	Number of Animals Given the Product:	2								
	Number of Animals Reacted:	1								
	Owner Information:	Owner Information	Yes							
		provided: Contact:		B6						
			Phone							
		Address:	B6							
			United States							

	Healthcare Professional	Practice Name:	Tufts Cumming	s School of Veterinary Medicine				
	Information:	Contact:	Name:	Lisa Freeman				
			Phone:	(508) 887-4523				
				lisa.freeman@tufts.edu				
		Address:	200 Westboro North Grafton Massachusetts 01536 United States	Road				
		Type of Veterinarian:	Referred veteri	narian				
		Permission to Release Records to FDA:	Yes					
Sender Information:	Name:]					
	Address:	DO						
		United States						
	Contact:	Phone: Email:	В6					
	Permission To Contact Sender:	Yes						
	Preferred Method Of Contact:							
	Reported to Other Parties:	None						
Additional Documents:								
	Attachment:	Troponin 4-4-19.pdf						
	Description:	Lab results						
	Type:	Laboratory Report						
	Attachment:	Diet hx 4-4-19 and o	wners patient lo	g.pdf				
		Patient notes						
		Medical Records						
	Attachment:							
		Chem 4-4-19.pdf						
	Description:	Laboratory Report						

B6 Tufts Patient ID: 441842 German Shepherd Birthdate **B6**

HEART FAILURE MONITORING WOKSHEET

						E	26					Арр	etite	9	
	Respira	ation	! ! ! !				,0				Fxcellent	þ		L	
Date	Rate/Minute	Time	AM	PM	AM	PM	AM	PM	AM	PM	Ä	Good	Fair	Poor	Comments
03/23/19	30	22:00	50mg	50mg	10mg	=	7.5mg	7.5mg	500mg	500mg	1				No coughing, rested comfortably during day, slightly restless at night-moved from one spot to another for about an hour before falling asleep.
03/24/19	34	23:10	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg	1				Spent some time lying outside, seemed pretty comfortable throughout the day. Stool softer than normal.
03/25/19	34	07:00	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg	1				Food: 3/4 cup Acana & 1/2 cup Royal Canin Early Cardiac 2x day. Emi pooped once today at 7pm stool was normal, formed. Squints a bit when outside.
"	28	22:56													·
03/26/19	30	10:45	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg	1				Food: 3/4 cup Acana & 1/2 cup Royal Canin Early Cardiac 2x day. Emi had accident last night, urinated in dog bed.
03/27/19	32	08:26	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg	1				Food: 1/2 cup Acana & 3/4 cup Royal Canin Early Cardiac 2x day. A little more active and engaging.
03/28/19	34	23:15	50mg	50mg	10mg	139	7.5mg	7.5mg	500mg	500mg	1				Food: 1/2 cup Acana & 3/4 cup Royal Canin Early Cardiac 2x day. Slept through night, about 6 hours, no accidents.
03/29/19	30	22:55	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg	1				Food: 1/4 cup Acana & 1 cup Royal Canin Early Cardiac 2x day. Urinated while asleep last night. Acting a little more like herself, follows Pandora outside.
03/30/19	30	23:16	50mg	50mg	10mg		7.5mg	7.5mg	500mg	500mg		1	ş - 1		Food: 1/4 cup Acana & 1 cup Royal Canin Early Cardiac 2x day. Ate most of her food this evening.
03/31/19	28	19:32	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg		1			Food: 1/4 cup Acana & 1 cup Royal Canin Early Cardiac 2x day. Left a little food in her bowl in the morning and evening. Followed Pandora around yard.
04/01/19	24	23:02	50mg	50mg	10mg	13	7.5mg	7.5mg	500mg	500mg	1		(a-3)		Food: 1-1/4 cup Royal Canin Early Cardiac 2x day.
04/02/19	16	22:53	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg		1			Food: 1-1/4 cup Royal Canin Early Cardiac 2x day. Loose stool around 7pm. Didn't eat all her food am or pm.
я	16	22:56													
04/03/19	20	15:04	50mg	50mg	10mg	-	7.5mg	7.5mg	500mg	500mg		1			Food: 1-1/4 cup Royal Canin Early Cardiac 2x day. Loose stool 12:30pm. Alert, more active when outside. Didn't eat all her food am or pm.
u	32	21:41													and the state of t
4/04/19			50mg		10mg		7.5mg		500mg		1				Food: 1-1/4 cup Royal Canin Early Cardiac 2x day.
										Spirit on					

Respiration Rate: Count the number of breaths for 30 seconds and multiply times 2 to get the respiratory rate per minute. In dogs, obtain the respiratory rate when they are at rest and not panting. In cats get the respiratory rate at rest when they are not purring. In animals with well controlled heart failure the breathing rate is often less than 35–40 breaths per minute. When the breathing rate is climbing, or when there is more effort to the chest wall or belly muscles during breathing, then fluid is likely accumulating in the lungs and more furosemide may be indicated. Please bring this sheet with you to your next veterinary exam.

CARDIOLOGY DIET HISTORY FORM ease answer the following questions about your pet **B6 B6** Pet's name Owner's name Today's date: 1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite) Example: Excellent Poor_ Excellent 2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

A Eats about the same amount as usual □Eats less than usual □Eats more than usual □Seems to prefer different foods than usual □Other □ □Eats more than usual 3. Over the last few weeks, has your pet (check one) □Lost weight □Gained weight □Stayed about the same weight □Don't know

Please list below A currently eats. Plea	<u>LL</u> pet foods se include th	people food, treats, snace brand, specific product	ck, dental chews, , and flavor so w	rawhides, and a e know exactly w	ny other food ite hat you pet is ea	m that your pet ating.	
Examples are show	vn in the tabl	e – please provide enoug	h detail that we c	could go to the sto	ore and buy the	exact same food	
Food (include	e specific pr	oduct and flavor)	Form	Amount	How often?	Fed since	
Nutro Grain Free C	hicken, Lenti	I, & Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2018	
85% lean hamburg			microwaved	3 oz			
Pupperoni original i	beef flavor		treat	1/2	1x/day	Jan 2015 Aug 2015	
Rawhide		7,000	treat	6 inch twist	1x/week	Dec 2015	
ROYAL CAWII LIVKA TRE CITICHEN LIN	ATS-Hon	CARDIAC 18MADE - JUST CORNEONA		1 14 Cur 1/4 Cur	2× My 2 v My	DGC 2013	
*Any additional diet	information	can be listed on the back	of this shoot				
Do you give any die supplements)? Taurine Carnitine Antioxidants Multivitamin Fish oil Coenzyme Q10 Other (please list):	□Yes □No □Yes □No □Yes □No □Yes □No □Yes □No □Yes □No	nents to your pet (for exar If yes, please list whic Brand/C	h ones and give oncentration	brands and amo	unts:	her unt per day	
How do you adminis I do not give any I put them in my I put them in a Pil	ster pills to your medications y in my pet's dog/cat	our pet? mouth without food food	re's Bounty		500 mg tablet	ts – 1 per day	
□ I put them in food	ls (list foods)	·					

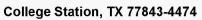




Gastrointestinal Laboratory Dr. J.M. Steiner

Department of Small Animal Clinical Sciences Texas A&M University







website User iD: clinpatn@tuπs.edu				
GI Lab Assigned Clinic ID: 11405				
Dr. Freeman	Phone:	Phone: Fax:		
Tufts University-Clinical Pathology Lab Attn B6	Fax:			
200 Westboro Road North Grafton, MA 01536	Animal I Owner I	B6		
USA	Species	Canine		
	Date Re	ceived:	Apr 04, 2019	
Clinical Pathology Tracking Number: 441842		GI Lab A	ccession B6	
<u>Test</u>	Result	Control Range	Assay Date	
Ultra-Sensitive Troponin I Fasting	B6 ng/mL	≤0.06	04/05/19	
	B6			
Comments:				

Important Notices:

Internal Medicine Conference

Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see http://texasimconference.tamu.edu

Ongoing studies

Cobalamin Supplementation Study- Dogs and cats with cobalamin deficiency with normal PLI, and either normal or low(consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at chchang@cvm.tamu.edu for further information.

Chronic Pancreatitis with Uncontrolled Diabetes Mellitus- Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial(medication provided at no cost). Contact Dr. Sue Yee Lim at slim@cvm.tamu.edu or Dr. Sina Marsilio at smarsilio@cvm.tamu.edu

Dogs with Primary Hyperlipidemia- Prescription diet naïve dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu for more information.

Dogs with Chronic Pancreatitis-Dogs with chronic pancreatitis (cPLi >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu

Chronic enteropathies in dogs-Please fill out this brief form http://tinyurl.com/ibd-enroll to see if your patient qualifies.

Feline Chronic Pancreatitis- Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 μ g/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at pyamkate@cvm.tamu.edu.

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GI Lab Contact Information

 Phone: (979) 862-2861
 Email: gilab@cvm.tamu.edu

 Fax: (979) 862-2864
 vetmed.tamu.edu/gilab

From:	PFR Event <pre><pre>creation@fda.hhs.gov></pre></pre>		
То:	Cleary, Michael *; HQ Pet Food Report Notification; B6		
Sent:	4/22/2019 5:16:54 PM		
Subject:	Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food: B6 EON-385697		
Attachments:	2066104-report.pdf; 2066104-attachments.zip		

A PFR Report has been received and PFR Event [EON-385697] has been created in the EON System.

A "PDF" report by name "2066104-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2066104-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-385697

ICSR #: 2066104

EON Title: PFR Event created for Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry

Dog Food, Blue Buffalo Life Protection Adult Dog Food Natural Chicken & Brown Rice; 2066104

AE Date	B6	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	12 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2066104

Product Group: Pet Food

Product Name: Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue

Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice

Description: Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd **B6** and referred to Tufts

for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice		
Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food		

B6	
USA	
Owner information	
B 6	USA
L	i O D2 3

To	view this PFR Event.	please	click	the	link	belo)W
	B6						

To view the PFR Event Report, please click the link below:	
B6	

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Report Details - EON-	385697		
ICSR:	2066104		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:		reaction or disease associated with the product)	
Reporting Type:	Voluntary	Todatan or disease assessated with the producty	
	2019-04-22 13:04:20 EDT		
Reported Problem:	Problem Description:	Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd: B6 and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF	
	Date Problem Started:	03/17/2019	
	Concurrent Medical Problem:		
	Outcome to Date:	Stable	
Product Information:	Product Name:	Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:		
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:		
	Manufacturer //Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:		
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	38 Kilogram	
	Age:	12 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Yes	

		Information	
		provided:	
		Contact:	Name: B6
			Phone:
			Name: B6 Phone: B6
		Address:	B6 United States
	Harithana Darfaraisaal		
	Healthcare Professional Information:		Tufts Cummings School of Veterinary Medicine
		Contact:	Name: B6
			Phone: B6 Email: B6
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States
		Practice Name:	Tufts University
		Contact:	Name: Lisa Freeman
			Phone: 508-887-4523
			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	В6	
	Address:	North Grafton Massachusetts 01536 United States	
	Contact:	Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	Tufts Medical record	pdf
	Description:	Medical records	
	Туре:	Medical Records	

Cummings Veterinary Medical Center

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client: Address: B6	
----------------------------	--

Patient: **B6**Breed: Golden Retriever DOB: **B6**

Species: Canine
Sex: Male
(Neutered)

Referring	Information
-----------	-------------

	1979				
[B6		
i			 	 	
CIT!	i				
Client:	B6				
	. DO				
Patient:		i			

Initial Complaint:

Cardiology New - possibly going to enroll in DCM study

SOAP Text Apr 17 2019 1:32PM - Rush, John

Disposition/Recommendations

n.	LLIMA	20 1 10		
J	umi	Ш	143	
				l Center
	TUFTS	원투다. 원과원생기		

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client:	B6
Veterinariar	n:
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Golden Retriever
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

CBC, Comprehensive, Sm Animal (Re	4/17/2019 3:28:16 PM	Accession ID: B6	
Test	Results	Reference Range	Units
RDW (ADVIA)		11.9 - 15.2	
MPV (ADVIA)		8.29 - 13.2	fl
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL
PDW		0 - 0	%
MCVR		0 - 0	fl
WBC (ADVIA)		4.4 - 15.1	K/uL
HGB(ADVIA)		13.3 - 20.5	g/dL
HCT(ADVIA)		39 - 55	%
CHR	B6	0 - 0	pg
MCHC(ADVIA)		31.9 - 34.3	g/dL
CHCM		0 - 0	g/dl
PLT(ADVIA)		173 - 486	K/uL
MCH(ADVIA)		21.3 - 25.9	pg
RBC(ADVIA)		5.8 - 8.5	M/uL
MCV(ADVIA)		64.5 - 77.5	fL
RETIC(ADVIA)		0.2 - 1.6	%
PLTCRT		0.129 - 0.403	%

Microscopic Exam of Blood Smear (A	4/17/2019 3:28:16 PM	Accession ID: B6
	3/29	B6
striposoft		

Printed Monday, April 22, 2019

Client: **B6**

Test	Results	Reference Range	Units
WBC MORPHOLOGY		0 - 0	
No Morphologic Abnormalities			
SEGS (AB)ADVIA		2.8 - 11.5	K/ul
SEGS%		43 - 86	%
RBC MORPHOLOGY		0 - 0	
No morphologic abnormalities			
LYMPHS%	B6	7 - 47	%
LYMPHS (ABS)ADVIA	Бо	1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
MONOS%		1 - 15	%
EOS%		0 - 16	%
EOS (ABS)ADVIA		0 - 1.4	K/uL

Research Chemistry Profile - Small A	4/17/2019 3:28:16 PM	Accession ID: B6	
Test	Results	Reference Range	Units
SODIUM		140 - 150	mEq/L
ALT		14 - 86	U/L
UREA		8 - 30	mg/dL
POTASSIUM		3.7 - 5.4	mEq/L
ALK PHOS		12 - 127	U/L
AGAP		8 - 19	
A/G RATIO		0.7 - 1.6	
CREATININE		0.6 - 2	mg/dL
CHLORIDE		106 - 116	mEq/L
TRIGLYCERIDES		30 - 338	mg/dl
ALBUMIN	B6	2.8 - 4	g/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T BILIRUBIN		0.1 - 0.3	mg/dL
GLUCOSE		67 - 135	mg/dL
NA/K		29 - 40	
PHOSPHORUS		2.6 - 7.2	mg/dL
AST		9 - 54	U/L
CK		22 - 422	U/L
AMYLASE		409 - 1250	U/L
GGT		0 - 10	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

4/29 B6

stringsoft

Printed Monday, April 22, 2019

Page 4/29

CHOLESTEROL		82 - 355	mg/dL
tCO2 (BICARB)		14 - 28	mEq/L
CALCIUM2	B6	9.4 - 11.3	mg/dL
GLOBULINS		2.3 - 4.2	g/dL
T. PROTEIN		5.5 - 7.8	g/dL
		ļ	
	5/29	B6	
stringsoft		Printed Monday	. A

Printed Monday, April 22, 2019

RX B6 give Tab 1 in AM, 1/2 in PM

	Ho	Tufts Univers r Hospital for Sn pspital for Large North Grafton, MA	mall Animals)-5395
Patient:				
Owner:		H	36	
Address:				
D PART	TIAL FILL UPON PATIENT	T REQUEST	SECUF	RITY FEATURES ON BACI
		R	3	
		B(Signature	1. Dulan
DEA #:		Be	Signature	sh DVM

Diet Hx B6

				1	В6	
		CARDIOLOGY Please answer the follow			ur nat	
	В6		DC	-		1/17/16
t's name:	<u> </u>	Owner's name :			Today's	date: 4 17 19
How would	d you assess y	our pet's appetite? (mark the po	int on the line	below that bes	t represents yo	ur pet's appetite)
Example:	Poor			-	Excellent	
	Poor	,			Excellent	
	1 001	1			LACCHEIN	
Have you □Eats abo	noticed a chan out the same a	ge in your pet's appetite over the mount as usual	e last 1-2 week than usual	ks? (check all t □Eats more	that apply) than usual	
□Seems t	to prefer differe	ent foods than usual Dother				
	ast few weeks, ight □Gaine	has your pet (check one) d weight Stayed about the	same weight	□Don't know		
Please list currently e	below ALL per eats and that yo	t foods, people food, treats, snar ou have fed in the last 2 years.	ck, dental chev	vs, rawhides, a	and any other fo	ood item that your pet
Please pro	ovide enough d	letail that we could go to the stor	re and buy the	exact same fo	od - examples	are shown in the table
·						
		cific product and flavor) n, Lentil, & Sweet Potato Adult	Form dry	Amount 1 ½ cup	How often?	Dates fed
	hamburger	n, Lentin, & Sweet Fotato Addit	microwaved	3 oz	2x/day 1x/week	Jan 2016-present June -Aug 2016
	i original beef fl	lavor	treat	1/2	1x/day	Sept 2016-present
Rawhide	original book is	470	treat	6 inch twist	1x/week	Dec 2018-present
	uf R	equial turing a chilh	72.1	1/2 (The second contract of the second contract of	2010 - 3 2
Zive P	harden to	grain Free chicken	Dry	11/20	2x das	BULGUENT +0 8
1000	MITALE	grain rest anoun	177	1 - 6	SXMUS	
13/14	Ril - 1.		10.	1/20	2x days	9/2018 - pres
1010		imited ingred dry-chick	019	120	xx (my	1/2018 - Mr. Je
				- 31		
-						
*Any addit	ional diet infer	mation can be listed on the back	of this shoot			
Arry additi	ional diet inion	nation can be listed on the back	or trus sneet			
Do you giv	e anv dietarv s	supplements to your pet (for exa	mole: vitamins	. glucosamine	fatty acids or	any other
supplemen	nts)?	s thro If yes, please list which	ch ones and gi	ve brands and	amounts:	any other
227 19	7 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	Brand/C	oncentration			Amount per day
Taurine		s ONO			_	
Carnitine		s TINO_				
Antioxidan	ts 🗆 Ye	s DNo				
Multivitami	in Live	s DNo			-	
Fish oil Coenzyme	010 010	s DNO				
Other (plea		3 9410			-	
Example: \		Nati	ure's Bounty		500 mg	g tablets – 1 per day
		-				
		-, -			- s 55 <u></u>	
		-				
How do yo	u administer si	ills to your pet?				
	give any medic					
☐ I nut the	em directly in m	y pet's mouth without food				
□ I put the	em in my pet's	dog/cat food				
□ I put the	m in a Pill Poc	ket or similar product				
D put the	m in foods (list	(foods): pick of chill	in			

Research cbc/chem 4-17-2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

DUPLICATE

Name/DOB: B6	Sex: CM	Provider. Dr. John Rush Order Location: Foster Hospital for Small Animal
Phone number:	Age: 12	Sample ID: 1904170138
Collection Date: 4/17/2019 3:28 PM	Species: Canine	Contract to 🍁 to refer the Contract Co
Approval date: 4/17/2019 6:15 PM	Breed: Golden Retreiver	

CBC, Comprehensive, Sm Animal (Research) SMACHUNSKI Ref. Range/Males WBC (ADVIA) 4.40-15.10 K/uL RBC (Advia) 5.80-8.50 M/uL Hemoglobin (ADVIA) 13.3-20.5 g/dL 39-55% Hematocrit (Advia) MCV (ADVIA) 64.5-77.5 fL **B6** MCH (ADVIA) 21.3-25.9 pg CHCM MCHC (ADVIA) 31.9-34.3 g/dL RDW (ADVIA) 11.9-15.2 Platelet Count (Advia) 173-486 K/uL B6 plts per 100x field (estimated count of 90,000-180,000/ul) 6:15 PM B6 Mean Platelet Volume B6 8.29-13.20 fl (Advia) 04/17/19 4:15 PM Platelet clumps (if present) and sample age (greater than 4 hours) can result in a falsely increased MPV. Platelet Crit 0.129-0.403 % Platelet Crit is invalid when clumped platelets are present. 04/17/19 4:15 PM Interpretation of PltCt is unclear in species other than canines. Reticulocyte Count (Advia) 0.20-1.60% Absolute Reticulocyte 14.7-113.7 K/uL **B6** Count (Advia) CHr MCVr Microscopic Exam of Blood Smear (Advia) SMACHUNSKI Ref. Range/Males Seg Neuts (%) 43-86% Lymphocytes (%) 7-47% 1-15% Monocytes (%) 0-16% Eosinophils (%) 2.800-11.500 K/ul Seg Neutrophils (Abs) 1.00-4.80 K/uL Lymphs (Abs) Advia 0.10-1.50 K/uL Mono (Abs) Advia Eosinophils (Abs) Advia 0.00-1.40 K/uL WBC Morphology RBC Morphology

Research Chemistry Profile - Small Animal (Cobas)

Sample ID: 1904170138/1 This report continues... (Final)

Reviewed by: _

Research cbc/chem 4-17-2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

DUPLICATE

Name/DOB: B6	Sex: CM		Dr. John Rush Foster Hospital for Small Animals
Phone number:	Age: 12	Sample ID:	1904170138
Collection Date: 4/17/2019 3:28 PM	Species: Canine		
Approval date: 4/17/2019 6:15 PM	Breed: Golden Retreiver		

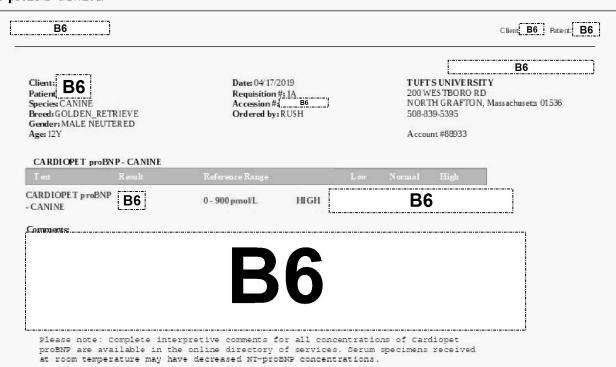
Research Chemistry Profile - Small Animal (Cobas) (cont'd) SMACHUNSKI Ref. Range/Males 67-135 mg/dL Glucose Urea 8-30 mg/dL 0.6-2.0 mg/dL Creatinine Phosphorus 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L Calcium 2 Magnesium 2+ Total Protein 5.5-7.8 g/dL Albumin 2.8-4.0 g/dL Globulins 2.3-4.2 g/dL A/G Ratio 0.7-1.6 140-150~mEq/LSodium Chloride 106-116 mEq/L **B6** Potassium 3.7-5.4 mEq/L 14-28 mEq/LtCO2(Bicarb) AGAP 8.0-19.0 NA/K 29-40 0.10-0.30 mg/dL Total Bilirubin Alkaline Phosphatase 12-127 U/L GGT 0-10 U/L ALT 14-86 U/L AST 9-54 U/L Creatine Kinase 22-422 U/L Cholesterol 82-355 mg/dL Triglycerides 30-338 mg/dl 409-1250 U/L Amylase Osmolality (calculated) 291-315 mmol/L

Sample ID: 1904170138/2

REPRINT: Orig. printing on 4/17/2019 (Final)

Reviewed by: _____ Page 2

Idexx NT-proBNP 4/17/2019



Client: Patient:	B0
,	

Vitals Results

4/17/2019 1:37:54 PM

Weight (kg)

38.0000

В6

4/17/2019 2:29:36 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

4/17/2019 2:29:36 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

В6

4/17/2019 2:32:10 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

4/17/2019 2:34:20 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

B6

4/17/2019 2:34:46 PM

Page 1 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

12 Lead: Standard Placement

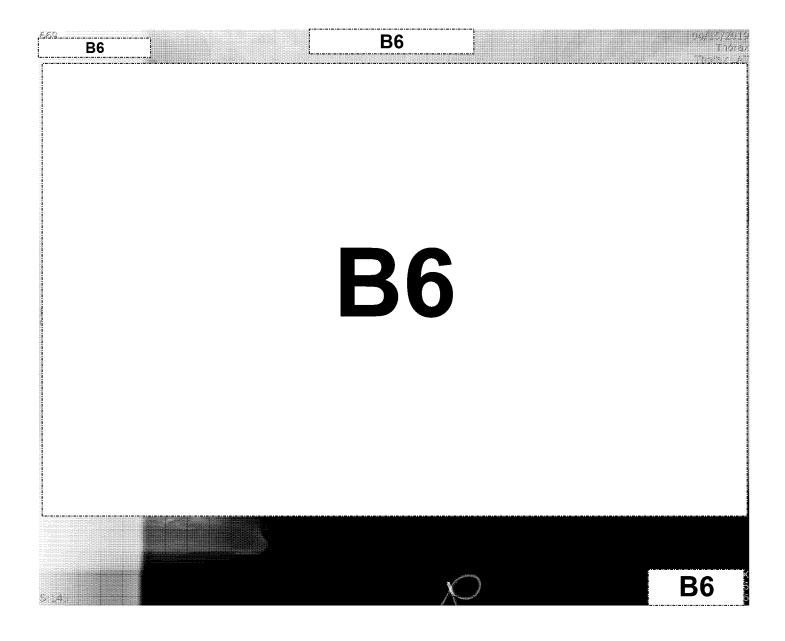
B6

4/17/2019 2:34:46 PM

Page 2 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

4/15/19 rads



Patient History

04/17/2019 01:32 PM	UserForm	
04/17/2019 01:37 PM	Vitals	
04/17/2019 02:00 PM	Treatment	
04/17/2019 02:34 PM	Purchase	
04/17/2019 02:34 PM	Purchase	
04/17/2019 02:34 PM	Purchase	
04/17/2019 02:45 PM	Purchase	
04/17/2019 02:45 PM	Purchase	B 6
		LJU
04/17/2019 03:14 PM	UserForm	
04/17/2019 03:15 PM	Prescription	
04/17/2019 03:16 PM	Prescription	
04/17/2019 03:20 PM	Purchase	
04/17/2019 03:49 PM	Prescription	
04/17/2019 03:51 PM	Email	

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 56 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://wetmed.tufts.edu/

Discharge Instructions

Patient	Owner	
Name B6	Name B6	Patient ID: B6
Species: Canine	Address B6	
Gold Male (Neutered) Golden Retriever	В	
Birthdate: B6		
Attending Cardiologist:		
John E. Rush DVM, MS, DACVIM (Ca	rdiology), DACVECC	
B6		
БО		
_ L		
Cardiology Resident:		
B6		
Cardiology Technician:		
DC		
B6		
	- 	
Student:		
8.4m2 10-1 4/17/2019 1 19-29 INA		

Diagnoses: Chronic valvular disease with mitral regurgitation, Reduced contractile function/myocardial failure, pericardial effusion (small volume), congestive heart failure with pulmonary edema (suspected), atrial and ventricular arrhythmias

Clinical findings:

Discharge Date: 4/17/2019

Your dog has a leak at one of the heart valves, the mitral valve, and this leak has resulted in a heart murmur and enlargement of the heart. This problem with the heart valve is a common one in dogs, due to aging changes to the valve that result in thickening and a subsequent leak of the valve B6 also had reduced contractile function of the heart - this could be just related to end stage heart disease from the leaky valve, or may be in part related to a limited ingredient diet. The heart enlargement has now progressed to the point where fluid is backing up into the lungs causing pulmonary edema, a condition called congestive heart failure. We also found some irregular heart beats but do not seem to be frequent enough to warrant treatment at this time. However, they may eventually lead to collapse (syncope). We will re-assess the addition of this medication at the next recheck appointment.

There is a small amount of fluid around the heart (pericardial effusion) - we suspect this is due to heart failure, and we cannot see a mass that might have cause the fluid, but sometimes there is a small mass we cannot find.

We cannot do anything to change the thickening or leak at the valve, but we can use cardiac medications and some changes to the diet to make B6 comfortable and have him breathing easier. Unfortunately, this is a progressive disease and the treatment options cannot reverse the damage to the valve.

Diagnostic test results:



Monitoring at home:

Recommended Medications:

We would like you to monito; B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The dose of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of bely wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing rate or effort will usually mean that you should give an extra dose of B6 If difficulty breathing is not improved within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that B6 be evaluated by an emergency dinic. There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/). We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination. If you notice an episode of collapse, it is olay to help the dog get back up; however, most dogs will get up on their own in about 20 minutes. If an episode of collapse occurs, we would like to know about it right away.

B6

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many treats, most people foods, and the supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site. In addition, your dog's usual diet may have more sodium than recommended - we want your dog to eat their usual diet for the first 5 to 10 days so we can make sure they are tolerating medications well, but after that time

we would recommend slowly introducing one of the lower sodium diets on the HeartSmart, list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). Hopefully you can find a diet on the list that $\begin{bmatrix} B6 \end{bmatrix}$ likes to eat. Alternatively, you can research the amount of sodium in your dog's current diet to ensure that the sodium content is similar to those on the list. The HeartSmart web site also has some information on supplements such as fish oil, taurine, and other supplements that you might have questions about (http://vet.tults.edu/heartsmart/diet/).

- O The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching B6 sto commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and childpeas.
- O The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVM/Updates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufls.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet) Royal Canin Boser Purina Pro Plan Adult Weight Management Purina Pro Plan Bright Mind Adult Small Breed Formula <u>Canned Food Options:</u> Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with

Exercise Recommendations:

our nutritionists (508-887-4696).

Royal Canin Mature 8+

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walk only is ideal, and short walks to start. Once heart failure is better controlled then slightly longer walks are acceptable. If B6 is lagging behind or needs to stop then this was too long a walk and shorter walks are advised. High energy activities (repetitive ball chasing, running fast off a leash) are generally not advised at this stage of heart failure.

Recheck Visits: A recheck visit is scheduled for $\frac{B6}{B6}$ at April 30th at noon. At this visit we will want to recheck $\frac{B6}{B6}$ breathing effort and heart function, do a blood test to recheck kidney values, and recheck an ECG. A recheck echocardiogram is recommended in 3 months. Your other dog, $\frac{B6}{B6}$ should get a blood test at your local veterinarian's office to check for levels of NT-proBNP. This is a protein that is released by the heart when it is stretched. If this value is normal, there is a low chance that she has a cardiac disease. However, if this value is at least moderately elevated, we might like to take a look at her. Please send us the result when you receive it.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tuits.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/

Prescription Refill Discloimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us,

please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: website: website: Case B6	Owner: B6	Discharge Instructions	_
	\		

Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

Bo		
Patient ID: B6 Canine Years Old Ma	ale (Neutered)	Golden Retrieve

Cardiology Appointment Report ENROLLED IN DCM DIET STUDY

Gold

Date: 4/17/2019

Atte	nding Cardiologist: John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC (primary)
	B6 ·
Carc	iology Resident:
	B6
Carc	liclogy Technician:
	B6

Presenting Complaint:

Presented to rDVM for cough for a month. Went to two vets yesterday. Suspicion of pericardial effusion vs DCM. Took radiographs and showed enlarged heart. Started B6 yesterday.

Concurrent Diseases:

Pretty healthy dog. Occasional vomiting early on in life. Seasonal allergies

General Medical History:

Over last month has been slowing down. Eating less. Does not want to go upstairs with family.

Diet and Supplements:

Blue buffalo limited ingredient for about a year. Blue buffalo for first couple years of his life and started vomiting then switched to grain free. Switched to Blue Buffalo Chicken limited ingredient almost a year ago.

Cardiovascular History:

NO
YES
NO
NO
NO
YES

Shortness of breath or difficulty	Maybe (panting has increased)
breathing?	
Syncope or collapse?	NO
Sudden onset lameness?	NO
Exercise intolerance?	NO
Current Medications Pertinent to CV System:	
Heartgard chew	
Flea and tick is seasonal	
Pimobendan 10mg PO BID	
Cardiac Physical Examination:	
B (0
Muscle condition:	
☑ Normal	Moderate cacheda
Mild musde loss	Marked cachesia
Cardiovascular Physical Exam:	
Murmur Grade:	E
III None III I/VI	☑ IV/VI □ V/VI
□ 1/¥1	VI/VI
₩ III/VI	= *//*:
——————————————————————————————————————	
Murmur location/description: Left apical murmu	r
Jugular vein:	1/2 years the week
Bottom 1/3 of the neck Middle 1/3 of the neck	☐ 1/2 way up the neck☐ Top 2/3 of the neck
E HARRY 13 W DE INCA	in the particular includes
Arterial pulses:	
₩eak	Bounding
Fair .	Pulse deficits
Good	Pulsus paradous
■ Strong	Other:
Arrhythmia:	
None	☐ Bradycardia
Sinus arrhythmia	☐ Tachycardia
Premature beats	
Callana	
Gallop: ☑ Yes	Preneunced
No	Other:
Intermittent	
Pulmonary assessments:	_
☑ Eupneic to	Pulmonary crackles
Mild dyspnea slightly blue hue to the	Wheezes

tongue Marked dyspnea Normal BV sounds	Upper ainway stridor
Abdominal exam: Normal Hepatomegaly Abdominal distension	Mild ascites Marked ascites
<u>Problems</u> : Cardiac murmur, arrhythmia, cough, possible D	DCM vs pericardial disease
Diagnostic plan: ☐ Echocardiogram ☐ Chemistry profile ☐ ECG ☐ Renal profile ☐ Blood pressure	☐ Dialysis profile ☐ Thoracic radiographs ☐ NT-proBNP ☐ Troponin ☐ Other tests:
	B6
Mitral inflow: Summated Normal Delayed relaxation	■ Pseudonormal ■ Restrictive
	36

Interpretation: predominant sinus rhythm with frequent and short episodes of SVT. Occasional monomorphic ventricular bigeminy and occasional isolated LV origin VPCs.

Radiographic findings:

None are available for review at the time of the cardiology exam. SOme recent films were taken and had been requested.

Subsequently available lateral radiograph shows marked cardiomegaly with some pulmonary vein distension and likely mild IS pattern that could be mild pulmonary edema.

Assessment and	recommend	ations

Advanced DVMD with myocardial failure. Large breed dogs are more predispos	ed to have v	vorsening
contractile function when affected by DMVD. However, there may also be a co	mponent of	either DCM or
diet-induced cardiomyopathy, so at this point it is unclear which would be the s	underlying ca	use of the
systolic dysfunction. We believe that B6 is in mild CHF, thus recommend	В6	every
12-24h - depending on clinical signs such as cough, respiratory rate and effort)	and B6	
B6		BID.
Recommend switch diet to one oif the diucts listed in the discharge instruction,	; check with	Dr. Freeman if
the dog will not eat any of these. As some Golden Retrievers with diet-induced	cardiomyop	athy are
taurine deficient and may respond to Taurine supplementation, (750 to 1000m	g BID) Taurir	e should be
started until have the levels results back. Recommend recheck blood work and	ECG in 2 we	eks. The
arrhythmia might not be severe enough to require specific antiarrhythmic treat	tment today,	but it si close,

Final Diagnosis:

- DMVD with severe LA enlargement;
- Decreased contractile function r/o secondary to advanced DMVD vs. concomitant DCM vs. component of diet-induced DCM.

and the dog may be at risk of sudden death. If the arrhythmia is worse then we might star

Heart Failure Classification Score:		
ISACHC Classification:	☑ IIIa	
□ 1b ■ 11	□ IIIb	
ACVIM Classification: A B1 B2	☑ C □ D	
<u>M-Mode</u> IVSd		cm
LVIDd LVPWd		cm
IVSs		cm
LVIDs	B6	cm
LVPWs EDM/Toich)		cm ml
EDV(Teich) ESV(Teich)		mi mi
EF(Teich)		%
erre		, , , , , , , , , , , , , , , , , , ,

SV(Teich)		ml
Max LA	B6	cm
TAPSE	В	cm
EPSS		cm
M-Mode Normalized	, <u>,</u>	
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN	B6	(0.330 - 0.530)
IVSsN	БО	(0.430 - 0.710) !
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)
<u>2D</u>	[
SA IA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teidh)	DC	%
%FS	B6	%
SV(Teich)		ml
LV Major		cm
LV Minor		cm
Sphericity Index		
LVId A4C		cm
LVEDV MOD A4C		ml
LVIs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml
R-R		ms
HR		ВРМ
<u>Doppler</u>		
MRVmax		m/s
MRmaxPG		mmHg
MV E Vel		m/s
MV DecT	DC	ms
MV Dec Slope	B6	m/s
MV A Vel		m/s
MV E/A Ratio		
E		m/s
E/E		

),	
A'		m/s
\$		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax	B6	m/s
PV maxPG	БО	mmHg
PRend Vmax		m/s
PRend PG		mmHg
TR Vmax		m/s
TR maxPG	<u> </u>	mmHg

A PFR Report has been received and Related PFR Event [EON-390198] has been created in the EON System.

2068091-report.pdf; 2068091-attachments.zip

A "PDF" report by name "2068091-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068091-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390198

Attachments:

ICSR #: 2068091

EON Title: Related PFR Event created for Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food Natural Chicken & Brown Rice; 2068091

AE Date	03/17/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	12 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068091

Product Group: Pet Food

Product Name: Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue

Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice

Description: Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O

suspected cough was due to seasonal allergies as patient has a hx of allergies pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd for further evaluation. Diet history: Blue Buffalo chicken limited ingredient a Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contra effusion, ruptured chordae, no obvious heart base mass, no obvious RAA may whole blood taurine levels Submission Type: Followup Report Type: Adverse Event (a symptom, reaction or disease associated with Outcome of reaction/event at the time of last observation: Better/Improve Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1	B6 and reference	erred to Tufts eating Blue pericardial
Product Name	Lot Number or ID	Best By Date
Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice		
Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food		
This report is linked to: Initial EON Event Key: EON-385697 Initial ICSR: 2066104		
Sender information B6		
USA		
Owner information B6 USA		
To view this Related PFR Event, please click the link below: B6		
To view the Related PFR Event Report, please click the link below:		
B6		

This email and attached document are being provided to you in your capacity as a Commissioned Official with

the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-				
ICSR:	2068091			
Type Of Submission:	Followup			
Report Version:		FPSR.FDA.PETF.V.V1		
Type Of Report:	3	reaction or disease associated with the product)		
Reporting Type:	Voluntary			
Report Submission Date:	5 			
Initial Report Date:	04/22/2019			
Parent ICSR:	2066104			
Follow-up Report to FDA Request:	Yes			
Reported Problem:	Problem Description:	Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd B6 and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF Normal plasma and whole blood taurine levels		
	Date Problem Started:	3		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Better/Improved/Recovering		
Product Information:	Product Name:	Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:			
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
	Product Name: Product Type:	Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:			
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:			
	Type Of Species:	1		
	3)	Retriever - Golden		
	Gender:	3		
	Reproductive Status:	1		
	<u> </u>	38 Kilogram		
	3 }	12 Years		
	Assessment of Prior Health:	Excellent		

	Number of Animals Given the Product:	1					
	Number of Animals Reacted:	1					
	Owner Information:	Owner Information provided:	Yes				
		Contact:	Name:	В6			
			Phone:	DU			
			Email:	Е	36		
		Address:	B6 United States				
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine				
	Information:	Contact:		B6	i		
			Phone:	B6	<u>!</u>		
			Email:		<u>:</u> 		
		A -1 -1		(i		
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States				
		Practice Name:	Tufts University				
		Contact:	Name:	Lisa Freeman			
				508-887-4523			
			Email:	lisa.freeman@	tufts.edu		
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States				
		Permission to Release Records to FDA:	Yes				
Sender Information:	Name:	В6					
	Address:	North Grafton Massachusetts 01536 United States					
	Contact:	Phone: Email:	B6 B6				
	Permission To Contact Sender:	·fes					
	Preferred Method Of Contact:	Email					
	Reported to Other Parties:	None					
Additional Documents:							
	Attachment:	At home ECG readings.pdf					
	Description:						
	Туре:	Medical Records	ecords				

	Recheck ECG 4-30-2019.pdf
	Hospital ECG
Type:	Medical Records
Attachment:	Follow-up med records pt 1.pdf
Description:	
	Medical Records
Attachment:	Follow-up med records pt 2.pdf
Description:	
	Medical Records

Patient: B6
Breed/Species Golden / Canine

Recorded: Wednesday, May 8, 2019 at 9:07:06 PM Heart Rate: B6 bpm Duration: 29 s 🖰 AliveCor

Mains filter: ROHz ... Scale: 25mm/s, 1.0mm/ml/

B6

Page 15/34

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Page 1 of 1



Patient: B6
Breed/Species Golden / Canine

Recorded: Thursday, May 9, 2019 at 9:03:43 PM Heart Rate: B6:pm Duration: 39 s





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Page 1 of 2

Patient: B6 | Breed/Species Golden / Canine | Thursday May 9, 2

Recorded: Thursday, May 9, 2019 at 9:03:43 PM
Heart Rate: B6|bpm Duration: 39 s



Mains filter: 60Hz Scale: 25mm/s, 10mm/m//

B6 (d) Copyright 2012, AliveCor Inc, AliveECG Vet v2.1.4.17, Report v2.0.0, UUID: 0B84E004-94F4-4CDE-99C2-74FF245B499E Page 2 of 2



Patient: Breed/Species

B6

Recorded: Heart Rate:

Golden / Canine Eriday, May 10, 2019 at 10:00:45 PM Belopm Duration: 28 s



Mains filter: RDHz. Scale: 25mm/s. 1flmm/ml

B6

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Page 1 of 1

Patient: B6 | Golden / Canine | Recorded: Sunday, May 12, 2019 at 8:06:48 PM | B6 | bpm | Duration: 40 s **B6**

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Page 1 of 2

Patient: Breed/Species

B6 Gölden / Canine Sunday, May 12, 2019 at 8:06:48 PM B6 bpm Duration: 40 s Recorded: Heart Rate:



Mains filter: RDHz ... Scale: 0.5rom/s .1Decolrel/.

B6

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Page 2 of 2



B6 Patient:

Breed/Species Golden / Canine

Monday, May 13, 2019 at 8:43:21 PM B6 bpm Duration: 43 s Recorded:



Mains filter: 60Hz Scale: 25mm/s, 10mm/m//

B6 (d) Copyright 2012, AliveCor Inc, AliveECG Vet v2.1.4.17, Report v2.0.0, UUID: 0F78FCA2-8A74-4533-A153-DDBFB4B6BC08 Page 1 of 2

Patient: B6 Breed/Species Golden / Canine Monday, May 13, 2019 at 8:43:21 PM B6 bpm Duration: 43 s Recorded: Heart Rate:

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Patient: B6
Breed/Species Golden / Canine

Recorded: Wednesday, May 15, 2019 at 9:34:29 PM Heart Rate: B6 bpm Duration: 39 s ∧liveCor

B6

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Page 1 of 2

Patient: B6 Breed/Species Golden / Canine

Recorded: Wednesday, May 15, 2019 at 9:34:29 PM Heart Rate: B6 bpm Duration: 39 s

₩ AliveCor

Meins füher: ROHz. Scale: 35mm/s. 1.flmm/m//.

B6

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Page 2 of 2

Patient: B6
Breed/Species Golden / Canine

Recorded: Sunday, May 19, 2019 at 8:35:18 PM Heart Rate: B6 bpm Duration: 32 s





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Page 1 of 1



Patient: B6 | Golden / Canine | Recorded: Monday, May 27, 2019 at 9.41:45 PM | B6 | bpm | Duration: 36 s



B6

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Page 1 of 2

Patient: Breed/Species

B6 Golden / Canine Monday, May 27, 2019 at 9:41:45 PM B6 bpm Duration: 36 s Recorded: Heart Rate:



Mains filter: 60Hz. Scale: 25mm/s. 10mm/m/...

B6

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Page 2 of 2

 Patient:
 B6

 Breed/Species
 Golden / Canine

 Recorded:
 Sunday, June 9, 2019 at 9:45:27 PM

 Heart Rate:
 B6 bpm Duration: 32 s



... Maios filter: 80Hz... Snale: 75mm/s 10mm/m//...

B6

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Page 1 of 2

В6 Patient: Breed/Species

B6 Golden / Canine
Sunday, June 9, 2019 at 9:45:27 PM
B6 bpm Duration: 32 s Recorded: Heart Rate:



Maios filter: 80Hz Scale: 25mm/s 10mm/m/c



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Page 2 of 2

Recheck chem

B6



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

Name/DOB: Provider. Dr. John Rush **B6** Patient ID: Sex: CM

Phone number: Age: 12

Collection Date: 4/30/2019 12:52 PM Approval date: 4/30/2019 1:33 PM

Species: Canine Breed: Golden Retreiver Order Location: V320559: Investigation into Sample ID: 1904300091

Research Chemistry Profile - Small Animal (Cobas) CSTCYR

Glucose Urea Creatinine Phosphorus Calcium 2 Magnesium 2+ Total Protein Albumin Globulins A/G Ratio Sodium Chloride **B6** Potassium tCO2(Bicarb) AGAP NA/K Total Bilirubin Alkaline Phosphatase GGT ALT AST Creatine Kinase Cholesterol

Ref. Range/Males 67-135 mg/dL 8-30 mg/dL 0.6-2.0 mg/dL 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L 5.5-7.8 g/dL 2.8-4.0 g/dL 2.3-4.2 g/dL 0.7-1.6 140-150 mEq/L 106-116 mEq/L 3.7-5.4 mEq/L 14-28 mEq/L8.0-19.0 29-40 0.10-0.30 mg/dL 12-127 U/L 0-10 U/L 14-86 U/L 9-54 U/L 22-422 U/L 82-355 mg/dL 30-338 mg/dl 409-1250 U/L 291-315 mmol/L

Sample ID: 1904300091/1 END OF REPORT (Final)

Triglycerides

Osmolality (calculated)

Amylase

Reviewed by: ____

	CARDIOLOGY Please answer the follow			ur net		
Pe	's name: B6Owner's name :			Today's	date B6	
1.	How would you assess your pet's appetite? (mark the po Example: Poor			t represents you	ur pet's appetite)	
	Poor		-	Excellent		
2.	Have you noticed a change in your pet's appetite over the □Eats about the same amount as usual □Eats less □Seems to prefer different foods than usual □Other ②	e last 1-2 week than usual Oppetit	ks? (check all f	that apply) than usual mpn) ~ d	since he bego	
3.	Over the last few weeks, has your pet (check one) Lost weight Gained weight Stayed about the				"Cas	
1.	Please list below ALL pet foods, people food, treats, snar currently eats and that you have fed in the last 2 years. Please provide enough detail that we could go to the store.	include	histry / as	t usit s	Bod here.	
	Food (include specific product and flavor)	Form	Amount	How often?	Dates fed	
	Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2016-present	
	85% lean hamburger	microwaved	3 oz	1x/week	June -Aug 2016	
	Pupperoni original beef flavor	treat	1/2	1x/day	Sept 2016-present	
	Rawhide	treat	6 inch twist	1x/week	Dec 2018-present	
	Pro Arina Pro Plan weight management-	Nn	11/2 C	ax day	Started 4/22- preser	
	few Bit size PC Chieven	boiled	few oc.	2x daly	7 - present	
	milkbore brand Sm. dus bisants	Danced	138 pc -	3x dul	2 - present	
	THITTING TO WIND SITE OF THE OPENING		3	32 000	- 1000	
	*Any additional diet information can be listed on the back	of this sheet				
2.	Do you give any dietary supplements to your pet (for exa supplements)? Yes No If yes, please list which Brand/O	ch ones and gi	ve brands and	amounts:	any other Amount per day	
	Taurine □Yes □No <u>3ℓℓ f, tø</u> Carnitine □Yes □No	_				
	Antioxidants			-		
	Multivitamin					
	Fish oil Yes ONO					
	Coenzyme Q10					
	Other (please list):					
					tablets – 1 per day	
		. Vitaliiii G				
				_		
3.	How do you administer pills to your pet? ☐ I do not give any medications ☐ I put them directly in my pet's mouth without food ☐ I put them in my pet's dog/cat food					
	☐ I put them in a Pill Pocket or similar product					
	put them in foods (list foods): Small picch o	of Chicken	N			

Amino Acid Lab taurine panel 4/17/19

29882 OWB

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616 Telephone: 530-752-5058, Fax: 530-752-4698

Email: ucd.aminoacid.lab@ucdavis.edu

www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

	B6
1	B6 3:54 PM SHIP W ICE PACKS TAURINE
	PANEL Lithium Heparin
	LuxH

Veterinarian Cont	tact: B6	j						
Clinic/Company N	lame: Tufts Cummir	ngs School of Vet. Me	ed Clinical Patholog	y Laboratory				
Address: 200 Wes	stboro Road, North Gr	rafton MA 015369						
Email: Clinpath(⊚tufts.edu caro	diovet@tufts	. e d u					
Telephone:508-	887-4669		508-839-7936					
Billing Contact:	B6	Emai	I; B6					
Billing Contact Pho	one: B6	Tax II	D:					
Patient Name:	B6	Spec	ies: <u>Canin</u>	<u></u>				
Breed: Gold	en Ret.	Owne	er's Name: B	6				
Current Diet :	Blue Buf	alo Cuic	wen LID					
Sample type: (Plasma Whole	Blood Urine	Food Other _					
Test: Taurine	Complete Amin	o Acids Other:						
Taurine Resul	ts (lab use only)	,						
Plasma: B6	Whole Blood:		e: F	ood:				
	a> B6							
	Plasma (nMol/ml) Whole Blood (nMol/ml)							
	Normal Range	No known risk	Normal Range	No known risk				
		for deficiency		for deficiency				
Cat	80-120	>40	300-600	>200				
Dog	60-120	>40	200-350	>150				

^{*} Please note with the recent increase in the number of dogs screened for taurine deficiency, we are seeing dogs with values within the reference ranges (or above the "no known risk for deficiency range") yet are still exhibiting signs of cardiac disease. Veterinarians are welcome to contact our laboratory for assistance in evaluating your patient's results.



Troponin 5/31/2019



Gastrointestinal Laboratory

Dr. J.M. Steiner

Department of Small Animal Clinical Sciences

Texas A&MUniversity

4474 TAMU

College Station, TX 77843-4474

Result

Website User ID: lisa.freeman@tufts.edu OF B6 @tufts.edu

GI Lab Assigned Clinic ID: 23523

Dr. Rush Tufts Cummings School of Vet Med - Cardiology/Nutrition 200 Westboro Road North Grafton, MA 01536 USA

Animal Name: Owner Name: Species: Date Received:

Phone:

Fax:

Canine

508 887 4696

May 30, 2019

Tufts Cummings School of Vet Med -Cardiology/Nutrition Tracking Number: 444016 GI Lab Accession:

Reference Interval

≤0.06

B6

444016 Test

Ultra-Sensitive Troponin I Fasting B6 ng/mL

Assay Date

05/31/19

Comments:

GI Lab Contact Information

Phone: (979) 862-2861 Fax: (979) 862-2864 Email: gilab@cvm.tamu.edu vetmed.tamu.edu/gilab

Cummings Veterinary Medical Center

these findings indicate that we should do a recheck examination.

Foster Hospital for Small Animals 56 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://vetmed.tufts.edu/

Discharge Instructions Cardiology Technician Appointment - ENROLLED IN DCM DIET STUDY

			/=
Name B6	Maine: B6		Patient ID: B6
Species: Canine	Addres	DC	
Gold Male (Neutered) Golden Retriever		B6	
Birthdate B6	i	i	
Attending Cardiologist:	Contained Digita	-	
John E. Rush DVM, MS, DACVIM (.aronology), DAC VEO	_	
B6			
Cardiology Resident:	i		
<u> </u>	36		
Cardioloev Technician:			
B6			
Discharge Date: B6			
Clinical Findings: B6 came in today to recheck bloodwork medications well. The ECG still showed and monitor 2) Do a 24 hour holter monitor 3) antiarrhythmic. At this time, it was decided to purchase the There are also directions attached to the divect and if he feels an additional medications.	hythmia (VPCs). Wed Purchase the Kardia e Alivecor/Kardia dev ischarges. I will send	discussed a few options ECG and send us at ho rice. We went over the the readings to Dr Rus	s of the next steps: 1) Continue to me ECG readings 4) start an edevice and how to use it in the room. h for review when he is back next
Monitoring at home: We would like you to monitor B6 bread of drugs will be adjusted based on the bread controlled have a breathing rate at rest of amount of belly wall motion used for each rate or effort will usually mean that you shimproved within 30-60 minutes after giving and/or that B6 be evaluated by an emerkeep track of breathing rate and drug dose (http://vet.tufts.edu/heartsmart/at-home)	thing rate and effort ess than 35 breaths breath, is fairly mini ould give an extra do gB6	t. In general, most dog per minute. In addition mal if heart failure is on se of B6 nen we recommend th re instructions for mor	s with heart failure that is well n, the breathing effort, noted by the introlled. An increase in breathing If difficulty breathing is not at a recheck exam be scheduled
We also want you to watch for weakness o		ın in appetite, worseni	ing cough, or distention of the bely as

if you notice an episode of collapse, it is olay to help the dogget back up; however, most dogs will get up on their own in about 20 minutes. If an episode of collapse occurs, we would like to know about it right away. Medications: **B6** Recheck Visits: A recheck has been scheduled for Thursday, July 18th at 1:00 pm with Dr. John Rush Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tults.edu for scheduling and non-emergent questions or concerns. B6 was such a good boy today. Kind Regards CVT, VTS (Cardiology) Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/ Prescription Refill Dischoiner: For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications. Ordering Food: Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval. Clinical Trials: Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a

promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/dinical-studies

Owner:

B6

Discharge Instructions

Casse B6

В6

4/30/2019 11:53:50 AM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

4/30/2019 11:54:19 AM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

4/30/2019 11:54:41 AM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

4/30/2019 11:55:39 AM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

4/30/2019 11:58:37 AM

Tufts University Tufts Cummings School of Vet Med Cardiology

B6

4/30/2019 12:00:51 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement

From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>
То:	Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent:	4/29/2019 8:12:57 PM
Subject:	PureVita Venison & Red Lentils Grain-Free Dry Dog Food: B6 - EON-386301
Attachments:	2066404-report.pdf; 2066404-attachments.zip

A PFR Report has been received and PFR Event [EON-386301] has been created in the EON System.

A "PDF" report by name "2066404-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2066404-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-386301

ICSR #: 2066404

EON Title: PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource

Adult Chicken and Rice formula; 2066404

AE Date	03/01/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	American Pit Bull Terrier		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2066404

Product Group: Pet Food

Product Name: PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and

Rice formula

Description: Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on **B6** Taurine levels prior to supplementation was WNL.

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NutriSource Adult Chicken and Rice formula		
PureVita Venison & Red Lentils Grain-Free Dry Dog Food		

Sender information		
B6		
USA		
Owner information		
B6 USA		
To view this PFR Event, pleas	se click the link below:	
B6	se ener the link below.	
i	. <u></u>	
To view the PFR Event Repor	t, please click the link below:	
	B6	

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Report Details - EON-	386301			
ICSR:	2066404			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom,	reaction or disease associated with the product)		
Reporting Type:	Voluntary			
	2019-04-29 16:02:28 EDT			
Reported Problem:	Problem Description:	Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on B6 [Taurine levels prior to supplementation was WNL.		
	Date Problem Started:	03/01/2019 u		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	NutriSource Adult Chicken and Rice formula		
	Product Type:			
	Lot Number:			
	UPC:	9B15P 18581		
	Package Type:	BAG		
	Package Size:	30 Pound		
	Possess Opened	Yes		
	Product:			
	Product Use Information:			
	Manufacturer /Distributor Information:			
	Purchase Location			
	Information:			
	Product Name:	PureVita Venison & Red Lentils Grain-Free Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:			
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	American Pit Bull Terrier		
	Gender:	Male		
	Reproductive Status:	Neutered		
	52. Norman (1980)	32 Kilogram		
		B6 Years		
	Assessment of Prior Health:			
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Yes		

		Contact:	Name: Phone: Email:	B6		
		Address:	B6			
	Healthcare Professional	Practice Name:		s School of Veterinary Medicine		
	Information:	Contact:		B6		
		Address:	200 Westboro North Grafton Massachusetts 01536 United States			
			Tufts University	,		
		Contact:		Lisa Freeman		
				(508) 887-4523		
				lisa.freeman@tufts.edu		
		Type of Veterinarian Veterinarian:				
		Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6				
	Address:	200 Westboro Road North Grafton Massachusetts 01536 United States				
	Contact:	Phone:	В6			
		Email:	В6			
	Permission To Contact Sender:	Yes				
	Preferred Method Of Contact:	Email				
	Reported to Other Parties:	None				
Additional Documents:						
		Med records pt 2.pdf				
		Medical Records				
		Medical Records				
	Attachment:	Medical Boards	9-2019.pdf			
		Medical Records Medical Records				
	туре.					

Research cbc/chem 4/26/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

Name/DOB: B6	Sex: CM	Provider. Dr. Lisa Freeman Order Location: Foster Hospital for Small Animals
Phone number:	Age: 2	Sample ID: 1904260155
Collection Date: 4/26/2019 4:57 PM	Species: Canine	50 00 10 · · · · · · · · · · · · · · · ·
Approxim1 date: 4/26/2010 5:57 PM	Breed: Dit Buill	

CBC, Comprehensive, Sm Animal (Research) SMACHUNSKI Ref. Range/Males WBC (ADVIA) 4.40-15.10 K/uL RBC (Advia) 5.80-8.50 M/uL Hemoglobin (ADVIA) 13.3-20.5 g/dL 39-55% Hematocrit (Advia) MCV (ADVIA) 64.5-77.5 fL **B6** MCH (ADVIA) 21.3-25.9 pg CHCM MCHC (ADVIA) 31.9-34.3 g/dL RDW (ADVIA) 11.9-15.2 Platelet Count (Advia) 173-486 K/uL platelets per 100x field (estimated count of 200,000-500,000/ul) 04/26/19 5:54 PM Mean Platelet Volume **B6** 8.29-13.20 fl (Advia) 04/26/19 5:30 PM Platelet clumps (if present) and sample age (greater than 4 hours) can result in a falsely increased MPV. Platelet Crit 0.129-0.403 % 04/26/19 5:30 PM Platelet Crit is invalid when clumped platelets are present. Interpretation of PltCt is unclear in species other than canines. Reticulocyte Count (Advia) 0.20-1.60% Absolute Reticulocyte 14.7-113.7 K/uL **B6** Count (Advia) CHr MCVr Microscopic Exam of Blood Smear (Advia) SMACHUNSKI Ref. Range/Males Seg Neuts (%) 43-86% Lymphocytes (%) 7-47% Monocytes (%) 1-15% Eosinophils (%) 0-16% 2.800-11.500 K/ul Seg Neutrophils (Abs) 1.00-4.80 K/uL Lymphs (Abs) Advia 0.10-1.50 K/uL Mono (Abs) Advia Eosinophils (Abs) Advia 0.00-1.40 K/uL WBC Morphology RBC Morphology Research Chemistry Profile - Small Animal (Cobas)

Sample ID: 1904260155/1 This report continues... (Final) Reviewed by:

Research cbc/chem 4/26/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

Name/DOB: Patient ID: Phone number:

B6

Collection Date: 4/26/2019 4:57 PM

Approval date: 4/26/2019 5:57 PM

Sex: CM Age: 2 Species: Canine Breed: Pit Bull Provider. Dr. Lisa Freeman

Order Location: Foster Hospital for Small Animals

Sample ID: 1904260155

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

SMACHUNSKI Glucose Urea Creatinine Phosphorus Calcium 2 Magnesium 2+ Total Protein Albumin Globulins A/G Ratio Sodium Chloride **B6** Potassium tCO2(Bicarb) AGAP NA/K Total Bilirubin Alkaline Phosphatase GGT ALT AST Creatine Kinase Cholesterol Triglycerides Amylase

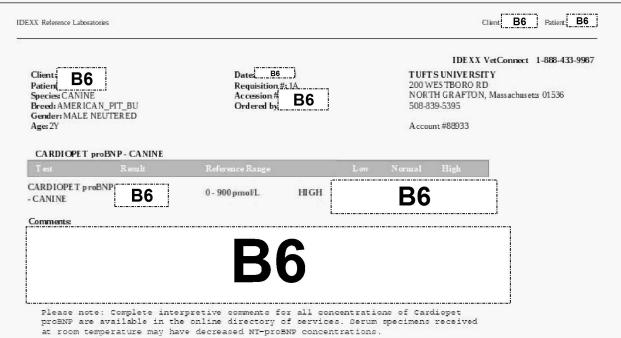
Ref. Range/Males 67-135 mg/dL 8-30 mg/dL 0.6-2.0 mg/dL 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L 5.5-7.8 g/dL 2.8-4.0 g/dL 2.3-4.2 g/dL 0.7-1.6 140-150 mEq/L 106-116 mEq/L 3.7-5.4 mEq/L 14-28~mEq/L8.0-19.0 29-40 0.10-0.30 mg/dL 12-127 U/L 0-10 U/L 14-86 U/L 9-54 U/L 22-422 U/L 82-355 mg/dL 30-338 mg/dl 409-1250 U/L 291-315 mmol/L

Sample ID: 1904260155/2 END OF REPORT (Final)

Osmolality (calculated)

Reviewed by: ______Page 2

Idexx NT-proBNP 4/26/2019



Diet Hx 4/26/2019

		CARDIOLOGY	DIET HISTOR	OV EODM	₽ B6	<u> </u>
	Please	answer the follow			ur net	
		distroit the follower		is about yo		ا ، ا م
et's name:	B6	Owner's name :	Bb	Ĺ	Todav's	date: 4 26 19
l				j		-
How would	you assess your pet's ar	petite? (mark the po	int on the line I	below that bes	t represents yo	our pet's appetite)
Example:	Poor			1	Excellent	
				1		
	Poor			1	Excellent	
	70			(-2.005/7307007	
many and the same of the same	oticed a change in your patterns the same amount as uprefer different foods that					cause of switching
	t few weeks, has your p nt Gained weight	et (check one) Stayed about the				M Control of
Please list b	elow ALL pet foods, pec	ple food, treats, sna	ck, dental chev	vs, rawhides, a	and any other fo	ood item that your pet
currently ea	s and that you have fed	in the last 2 years.				
Please prov	ide enough detail that w	e could go to the sto	re and buy the	exact same fo	od - examples	are shown in the table
=						
	include specific produ		Form	Amount	How often?	Dates fed
	Free Chicken, Lentil, &	Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2016-present
85% lean ha			microwaved	3 oz	1x/week	June -Aug 2016
	riginal beef flavor		treat	1/2	1x/day	Sept 2016-present
Rawhide			treat	6 inch twist	1x/week	Dec 2018-present
MUTTON SON	TCE PURVITA VENT	SON + RedLANTILS	Dry	2 LUPS	2 X 24 X	Aug 2018-Mar 2019
	GLANCE UENISIN +		CAN CAN	376LS,	24 day	AUY 2014 -MY 201
MUTURILI	salunce venison +	Sweet PITUNO	Treat	6 Treuts/Buy	6 Aday	Augzoir - Marzo
Natural Bo	LYNC SWEET POTA	to + Fish	Treat	11:54ME	6 A day	AUY 2018- Mar 20
	rce chilken + Rice	· Formula	DVAR	1,5 CWS	27 dax	Mur 2014 - fresa
- 11 ,	- 11		Ca~	1,57665	24241	MUMZUIG-Presi
BOBELOW	204 Trats		+reuT	1/2	1xduy	Mur 2019 - 18185.
MILKBON	: Smull morero		Trait	4	14 244	MUN 2014 -12/05A
Viyeurs			Freut	1	1 x week	M47 2014 - Proje
Frmur +	- knucky Bone		Trat		1 y MONTL	Mu- 2014 - Presh
*Any addition	nal diet information can	be listed on the back	of this sheet	-		
•						
Do you give	any dietary supplement	s to your pet (for exa	mple: vitamins	glucosamine.	fatty acids, or	any other
supplement)?	f yes, please list whi	ch ones and giv	ve brands and	amounts:	
	_ /	_ Brand/C	Concentration			Amount per day
Taurine	Yes DNo	GNL				00 M4
Carnitine	Yes No					,
Antioxidants	□Yes □No					
Multivitamin	□Yes □No					
Fish oil	LIYES LINO					
Coenzyme (ZIU LITES LINO					
Other (pleas	e list):				-	F6: Wall 65: V
Example: Vi	amin C	Nat	ure's Bounty		500 mg	g tablets – 1 per day
·				00		
W						,
-						
Llaw de c	administer pills to your p	pet?				
☐ I do not g	ve any medications	المحادث والقرارة والقرار والقرار				
☐ I do not g	directly in my pet's mou	uth without food				
l do not g put them		d				

rDVM Cardiology report 3/14/2019

artifology Teport 3/14/2017	
Dear Doctors,	
Please see the accompanying cardiology report for our mutual patient. Thank you for the referral and your continued support of B6 Please contact me if you need any more information regarding this patient. As I am only at B6 once to twice per month, email (see below) is the best mode of communication for me.	
B6	
Consulting Cardiologist: B6	

rDVM Cardiology report 3/14/2019

Patient DC	2yo MN pit bul	1)					
Examination	Date: 3/14/19					- 35	
- CARDIOLO	GY EXAMINATION	ON					
HISTORY: C	ough x 2 weeks, de	creased appetite.	. Admitted yeste	erday for monitori	ng/echo. Started o	B6	
(rDVM) 50m	g SQ q 8 h B	Taurine	drawn/not yet s	ubmitted. ECG 10	00 bpm NSF. TFA	ST suspect	
	rads in record.						
MEDICATIO							
	ree pork and pea						
WEIGHT: 27	kg						
PHYSICAL	EXAMINATION:						
Sedate. BCS	4/9. Adequate hydra	ation					
Mm color: pii	nk, CRT: 1.5 sec						
	nation: normal						
	0/minute. Rhythm:		460 [100 1 650 160 1				
	ade III/VI left apica	l systolic mumu	I				
	요리 이렇게 하면 없는데 모르는데 그리다						
	scultation: clear						
Femoral pulse	iscultation: clear e quality: moderate.	, synchronous	r by Sadatad mit	B6 3	ma/ka W with are	st affact	
Femoral pulse Other Comme ECHOCARI Two-dimensic	scultation: clear e quality: moderate, ents: Moderate diffi DIOGRAM mal description:	ise muscle atroph	F 084 76 80	er e dece	mg/kg IV with grea		
Femoral pulse Other Comme ECHOCARI Two-dimension The left atrium ventricular che valve leaflets of the right he Cardiac rhyth 2-D measurer LA (cm) M-mode meas IVSd (cm)	equality: moderate, ents: Moderate difficents: Moderate difficents: Moderate difficents: Moderate difficents: moderately to sumber is severely deant appears normal and during study appoint and the companion of	severely enlarged filated with norm normal. The righ . No masses or e leared regular. LA/Ao LVFWd (cm)	d. The mitral vai nal to thin walls ht atrium and rig ffusions noted.	lve leaflets are no and significantly	ormal thickness. The	ne left on. The aortic	
Femoral pulse Other Comme ECHOCARI Two-dimension The left atrium ventricular che valve leaflets of the right he Cardiac rhyth 2-D measurer LA (cm) M-mode meas IVSd (cm)	equality: moderate, ents: Moderate difficents: Moderate difficents: Moderate difficents: Moderate difficents: moderately to summer is moderately to and aortic root are eart appears normal and during study appoints: Ao (cm) B6 surements:	severely enlarged filated with norm normal. The righ . No masses or e seared regular.	d. The mitral vainal to thin walls ht atrium and rightsions noted.	lve lea flets are no and significantly ght ventricle are n	ormal thickness. The reduced wall moti- noderately enlarged	ne left on. The aortic d. Remainder	
Femoral pulse Other Comme ECHOCARI Two-dimension The left atrium ventricular che ventricular c	equality: moderate, ents: Moderate difficents: Moderate difficents: Moderate difficents: Moderate difficents: Moderate difficents: mis moderately to suamber is severely defend and aortic root are eart appears normal and during study appoints: Ao (cm) B6 Surements: LVIDd (cm) LVIDs (cm) B6	severely enlarged filated with norm normal. The righ . No masses or e leared regular. LA/Ao LVFWd (cm)	d. The mitral vainal to thin walls ht atrium and rightsions noted.	lve lea flets are no and significantly ght ventricle are n	ormal thickness. The reduced wall moti- noderately enlarged	ne left on. The aortic d. Remainder	
Femoral pulse Other Comme ECHOCARI Two-dimension The left atrium ventricular che ventricular c	scultation: clear e quality: moderate, ents: Moderate diffi DIOGRAM mal description: m is moderately to search appears normal and aortic root are eart appears normal im during study app Ments: Ao (cm) B6 Surements: LVIDd (cm) LVIDs (cm) B6	severely enlarged tilated with norm normal. The right. No masses or eleared regular. LA/Ao LVFWd (cm)	d. The mitral vainal to thin walls ht atrium and rightsions noted.	lve lea flets are no and significantly ght ventricle are n	ormal thickness. The reduced wall moti- noderately enlarged	ne left on. The aortic d. Remainder	
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rDVM Cardiology report 3/14/2019



ECHOCARDIOGRAPHIC DIAGNOSIS:

- Dilated cardiomyopathy (severe left atrial and left ventricular enlargement; moderate right atrial and right ventricular enlargement; severely reduced left ventricular wall motion)
- 2. Mild mitral and trace tricuspid regurgitations likely from annular stretch secondary to #1

RADIOGRAPHIC FINDINGS: 2 view thorax, rDVM: The cardiac silhouette is severely and globally enlarged. The pulmonary vasculature is moderately dilated. There is a moderate to severe bilateral caudodorsal interstitial pattern consistent with congestive heart failure.

**** FINAL REPORT *****

FINAL DIAGNOSIS:

- Dilated cardiomyopathy (severe left atrial and left ventricular enlargement; moderate right atrial and right ventricular enlargement; severely reduced left ventricular wall motion) – R/O nutritional (taurine deficiency or secondary to grain free/pork based diet) vs familial vs hypothyroidism
- 2. Mild mitral and trace tricuspid regurgitations likely from annular stretch secondary to #1
- 3. Congestive heart failure (pulmonary edema), 3/13/19

DIG.,OSTE RE	B6	
THERAPEUTIC F	ECOMMENDATIONS:	*
	B6	
FOLLOW UP SCI		

FOLLOW UP SCHEDULE:

10-14 days for recheck exam, renal panel, CXR.

3 months for echocardiogram

*There is a chance that some of B6 cardiac disease may be reversible if this is secondary to nutritional cause. However, even some patients with diet-induced DCM can have irreversible cardiac changes. Thus, prognosis is variable and will be determined based on followup testing.

Consulting Cardiologist: B6

Consulting Cardiologist: B6

rDVM Cardiology report 3/14/2019 В6 Consulting Cardiologist:

While many dogs with primary hypothyroidism have elevated cTSH concentrations, up to one third of affected dogs have normal or low cTSH concentrations, for reasons that are unclear. In those cases where TSH concentrations are normal and hypothyroidism is still strongly suspected, consider performing a free T4 and/or thyroglobulin autoantibodies.

Page 1 FINAL For online lab results please visit online B6

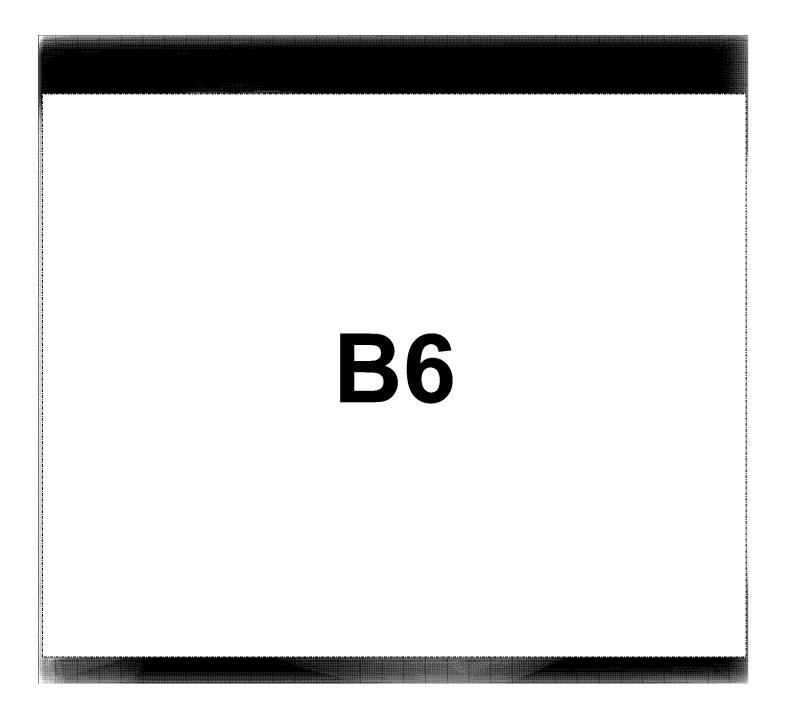
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V	'ita	le	Res	ulte
v	11a	13	IXCS	unto

4/26/2019 2:52:48 PM

Weight (kg)

32.0000



Medical Record Image

Medical Record Image



12 Lead; Standard Placement

ECG from Cardio

B6

4/26/2019 4:27:10 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

4/26/2019 4:27:45 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

12 Lead: Standard Placement

B6

4/26/2019 4:28:13 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://wetmed.tufls.edu/

Discharge Instructions

<u>Patient</u>	Owner	
Name: B6	Mame B6	Patient ID: B6
Species: Canine	Address B6	L
Mahogany Male (Neutered) Pit Bull	В	
Birthdate: B6		
Attending Cardiologist: John E. Rush DVM. MS. DACVIM (Ca	rdioloevi. DACVECC	
Cardinloov Resident	·	
B6		
Cardiology Technician:		
B6		
Student: B6 V19		
Admit Date: 4/26/2019 2:17:55 PM Discharge Date: 4/26/2019		

Diagnoses: Dilated cardiomyopathy (DOM) with history of congestive heart failure

Case summary

B6 was diagnosed with a heart muscle disease called dilated cardiomyopathy (DOM) in March. He was started on several cardiac medications at that time as well as a change in diet since he had been on a grain-free diet. Since then, he has shown improvement in his appetite and weight; however, he is still coughing and experiencing some exercise intolerance. On physical examination today, he is very bright and alert. We could hear a small Grade II/VI heart murmur that was noted previously.

We performed an echocardiogram (ultrasound of the heart) which confirmed B6 still has DCM. This disease is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart B6 has a leak at his mitral valve (valve between his left atrium and ventricle) which is the cause of his murmur. His mitral valve is slightly thickened as well so he could also have a component of a congenital mitral valve disease. The medications he is currently on are the same medications we would be using to treat anymitral valve disease. An ECG was performed to evaluate his heart rhythym which showed normal rhythym today. We also took chest x-rays to determine if he still has evidence of fluid in his lungs that could be contributing to his cough. His x-rays are improved compared to those taken previously by his primary care veterinarian but his lungs still have residual fluid. Because of this, we made adjustments to his medications as detailed below. Finally, we also collected blood to ensure his kidneys are tolerating his cardiac medications and for cardiac biomarkers useful for monitoring his disease progression and for the research study. We will call you with the results of this bloodwork.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest.
 The doses of drugs will be adjusted based on the breathing rate and effort.
- O in general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- O An increase in breathing rate or effort will usually mean that you should give an extra close of B6 difficulty breathing is not improved by within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- O There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications. B6

Diet suggestions:

Dogs with heart failure accumulatemore fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (heartsmart/diet/). Unfortunately, the pigs ears and pupperoni treats are high in sodium so should be avoided.

Your dog's usual diet may also have more sodium than recommended – we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50.50, etc.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

 The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those

containing exotic ingredient or aregrain-free. Therefore, we are currently recommending that dogs do not eat. We recommend switching B6 to commercial diet made by a well-established company that is not grain-free. and does not contain any exotic ingredients, such as langaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas. The FDA issued a statement regarding this issue. (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/uom613385.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vebrutrition.tufls.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-ex otic-ingredients/). Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease. Dry Food Options: Royal Canin Early Cardiac (veterinary diet) Royal Canin Boxer Purina Pro Plan Adult Weight Management Purina Pro Plan Bright Mind Adult Small Breed Formula Carmed Food Options: Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew Royal Canin Mature 8+ We think Royal Canin Boxer or the Royal Canin Early Cardiac diets would be good choices for Deater. We have sent you home with a sample of the Royal Carin Boxer diet. If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696). Exercise Recommendations: For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure. Recheck Visits: Arecheck visit is scheduled for Friday, May 3rd at 11:00 AM to recheck his bloodwork to see if he is tolerating the changes to his medicatoins. Additionally, recheck visits at 3 months and 6 months are needed for monitoring and would be covered. by the DOM study. Thank you for entrusting us with B6 care; he is a very sweet boy! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tults.edu for scheduling and non-emergent questions or concerns. Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/ Prescription Refill Discloimer: For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications. Ordering Food: Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval. Clinical Triple:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a

B6

promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/dinical-studies

Owner:

Case B6

Discharge Instructions

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Te lephone (508) 839-5395 Fax (508) 839-7951 http://vetmed.tufts.edu/

Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:

- Most other dog treats are high in sodium.
- If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

Product	Calories per treat
Dogs	
Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat	8
Hill's Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat	34
Hill's Science Diet Soft Savories Peanut Butter & Banana, Beef & Cheddar, or Chicken & Yogurt Dog Treat	25-27, depending on flavor
Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots, Duck & Pumpkin, or Beef & Sweet Potato Dog Treat	12-13, depending on flavor
Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken & Barley	27-29, depending on flavor
Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb or beef, bacon, cheese, peanut butter)	16
Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)	58
Royal Canin Original Canine treat	5
Cats	
Royal Canin Original Feline treat	2
Fancy Feast Duos Natural Rotisserie Chicken Cat treat	2
Fancy Feast Duos Tuna with Accents of Parsley Cat treat	2

Taste enhancers to can make your pet's food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes:

- 1. All foods in this list should be prepared without salt
- These taste enhancers should be added in small amounts. If your pet eats too much of them, they will unbalance the diet and increase your pet's risk for nutritional deficiencies

Dogs

- Honey or maple syrup
- Homemade chicken, beef, or fish broth (made without salt; avoid all delimeats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- Sugar (brown or white) Domino pourable light brown sugar is a good option
- Vanilla or fruit yogurt One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
- Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- Applesauce (be sure they have less than 50 mg sodium per serving)
- Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico's no salt added)
- Frosted Mini Wheats Original these can be crumbled on his food
- Lean meats, cooked (chicken, turkey, beef, or fish) not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- ▼ Eggs, cooked



Dogs (continued)

- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium).
 Avoid all canned soups unless labeled as no salt added
- Low-salt breakfast cereal the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- Low sodium canned dog foods

Cats

- Lean meats, cooked (chicken, turkey, beef, or fish) not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- Eggs, cooked
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- Low sodium canned cat foods

Foods to avoid

- Fatty foods (meat trimmings, cream, ice cream)
- Baby food
- Pickled foods
- ▼ Bread
- Pizza
- Condiments (ketchup, soy sauce, barbecue sauce, etc unless they are unsalted or no salt added)
- Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- Rotisserie chicken
- Most cheeses, including "squirtable" cheeses
- Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- ♥ Canned vegetables (unless "no salt added")
- Potato chips, packaged popcorn, crackers, and other snack foods
- Soups (unless homemade without salt)
- Most commercial pet treats

Tips for administering medications

Foods commonly used to administer your pet's pills can provide a large amount of additional salt to your pet's diet. Preferable ways to give medications include:

- Have one of our staff show you how to give medications without using food
- Insert medications into one of the following foods:

Dogs or cats

- Low-sodium canned pet food
- Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
- Whipped cream (Reddi Wip)
- Marshmallows
- Greenies Pill Pockets
 - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
 - Avoid grain-free duck and pea which is high in sodium
 - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
 - Caution: Not all similar products from other companies are low in sodium.

Dogs

- Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
- Peanut butter (only if labeled as "no salt added") examples include Smucker's Natural Creamy
 Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
- Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol).
 Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting)

You may find our Petfoodology post called, "Pill-popping pets" helpful for additional ideas: http://vetnutrition.tufts.edu/2018/09/foods for giving pills/

Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

Date: 4/26/2019

B6	
Patient ID: B6 B6 Canine B6 Years Old Mak	e (Neutered) Pit Bui

Cardiology Appointment Report DCM STUDY

Attending Cardiologist: John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC Cardiology Resident: Cardiology Technician: **B6** Student: Presenting Complaint: DCM Concurrent Diseases: None General Medical History: Diagnosed with DCM in March. In March, owners noticed he was coughing alot and had labored breathing, rDV<u>M did x-</u>ray and showed enlarged heart. Also treated for potential kennel cough at that time. Referred to B6 (emergency room) where they did cardiac workup which showed DCM. He was immediately started on cardiac medications and diet change. Since starting meds and changing diet, still coughing but gaining weight. Coughing in the middle of the night, after exercise/excitement; roughly 10 times per day. Owner trying to limit exercise, but B6 has always had good energy. After exercise sometimes seems to have trouble

Diet and Supplements:

diagnosis but has improved since starting meds.

Previous diet: Venison and red lentils (Pure Vida), canned food- natural balance venice and sweet potatoe; treats- natural balance venison and fish

catching his breath. Owner has not been counting RR at home. Appetite has been decreased prior to DCM

Current Diet: Nutri Source Chicken and Rice (dry and canned), treats, cooked chicken. Cardiovascular History: Prior CHF diagnosis? Yes Prior heart murmur? Y Grade II/VI left sided Prior ATE? N Prior arrhythmia? Monitoring respiratory rate and effort at home? Effort increased during exercise, not mointoring rate. Cough? Yes Shortness of breath or difficulty breathing? After exercise Syncope or collapse? No Sudden onset lameness? No Exercise intolerance? Tires easier because of cough Current Medications Pertinent to CV System: **B6** Cardiac Physical Examination: Muscle condition: Mormal. Moderate cachexia Mildmuscle loss Marked cachexia Cardiovascular Physical Exam: Murmur Grade: None **□** IV/VI **□** I/VI **□** ν/νι **□** ₩/₩

Murmur location/description: focal left apical systolic

Jugular vein:

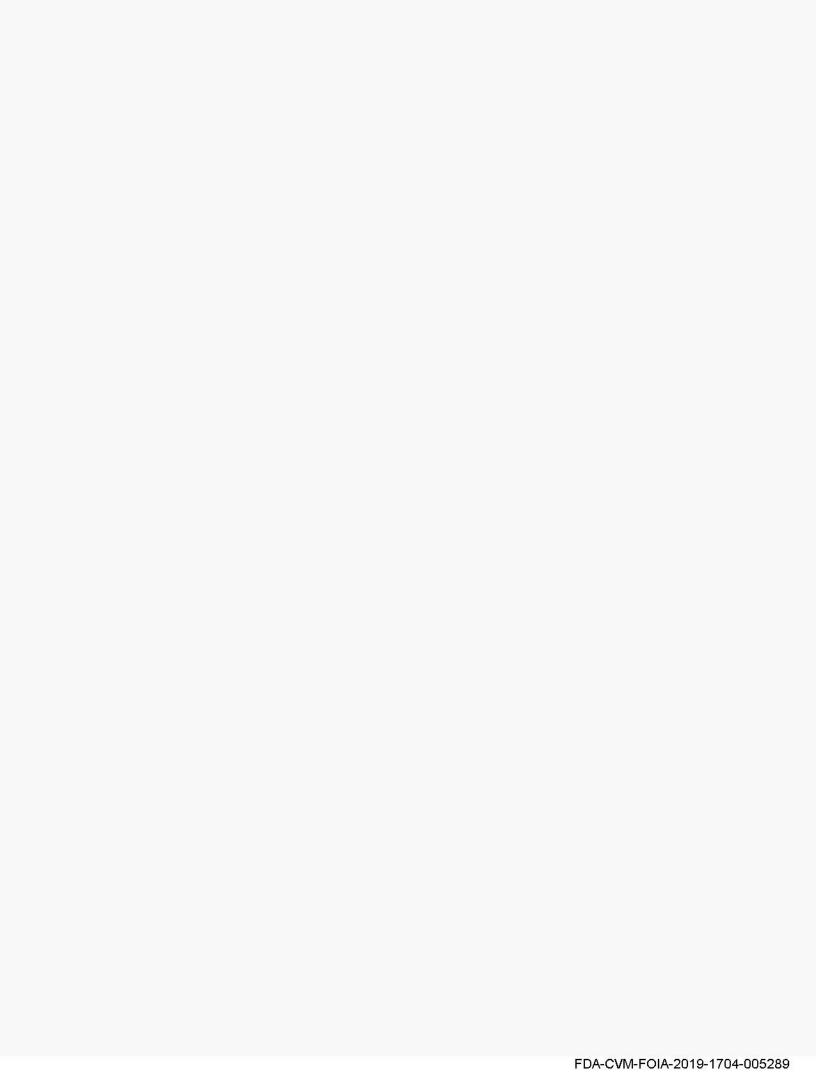
III/VI

■ Bottom 1/3 of the neck■ Middle 1/3 of the neck	☐ 1/2 way up theneck ☐ Top 2/3 of theneck
Arterial pulses: Weak Good Strong	■ Bounding ■ Pulse deficits ■ Pulsus paradoxus ■ Other:
Arrhythmia: None Sinus arrhythmia Premature beats	☐ Bradycardia ☐ Tachycardia
Gallop: ☐ Yes ☑ No ☐ intermittent	Pronounced Other:
Pulmonary assessments: Eupneic Mild dyspnea Marked dyspnea Normal BV sounds	Pulmonary crackles Wheezes Upper airway stridor
Abdominal exam: Normal Hepatomegaly Abdominal distension	Mild ascites Marked ascites
<u>Problems and Differential Diagnoses:</u> History of DCM: R/O- diet-associated vs. taurir Cough: R/O- secondary to DCM vs. less likely in	
Diagnostic plan: ✓ Echocardiogram ✓ Chemistry profile ✓ ECG ☐ Renal profile ☐ Blood pressure Echocardiogram Findings:	☐ Dialysis profile ☑ +/- Thoracic radiographs ☑ NT-proBNP ☐ Troponin I ☐ Other tests: DCM Study-taurine
	B6
Mitral inflow: Summated Normal	Pseudonormal Restrictive

ECG findings: sinus arrhythmia			
Radiographic findings: Enlarged cardiac silhoutte. The amount of intellimproved from rDVM rads. However, there is s	-		
Assessment and recommendations: The patient is still in mild CHF based on radiogr B6 normal at that time, we will increase B6 enrolled in the DCM diet study. We recommendate that the DCM diet study.	Recheck rena o BID. Rechect d switching the	al values :kechoc	in 1-2 weeks. If renal values are ardiogram in 3 months. Patient
DCM with LCHF. R/O diet-induced, primary, to: +/- mitral valve dysplasia	ân		
Heart Failure Classification Score: ISACHC Classification: la lb ll ACVIM Classification:	☑ IIIa ☑ IIIb ☑ C		
■ B1 ■ B2	■ D		
M-Mode IVSd LVIDd LVPWd IVSs LVIDs LVPWs EDV(Teich) ESV(Teich) EF(Teich) Ao Diam LA Diam LA/Ao Max LA TAPSE EPSS		В6	cm cm cm cm cm mi mi % % mi cm cm cm

Delayed relaxation

M-Mode Normalized	[·
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVS=N	B6	(0.430 - 0.710)
LVIDsN	30	(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)
Ao Diam N		! (068.0 - 086.0)
LA Diam N		(0.640 - 0.900) !
<u>2D</u>		
SALA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs	DC	cm
ESV(Teich)	B6	ml
EF{Teich}		%
%FS		%
SV(Teich)		ml
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml
<u>Doppler</u>	[
MR Vmax		m/s
MR maxPG		mmHg ,
MV E Vel		m/s
MV DecT		ms ,
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio	B6	
E'	БО	m/s
E/E'		
A'		m/s
s'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
P V maxPG		mmHg



Cummings Veterinary Medical Center



B6 Male (Neutered)
Canine Pit Bull Mahogany
Patient ID: B6

Outside Prescription Log



2. Date:

Clinician: Prescription:

Pharmacy sent to:

Completed by: Origin of request:

3. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

4. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

5. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

6. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

7. Date:

Clinician: Prescription: Pharmacy sent to: Completed by: Origin of request:

8. Date:

Clinician: Prescription: Pharmacy sent to: Completed by: Origin of request:

9. Date:

Clinician: Prescription: Pharmacy sent to: Completed by: Origin of request:

10. Date:

Clinician: Prescription: Pharmacy sent to: Completed by: Origin of request:

Cummings Veterinary Medical Center



Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://wetmed.tufts.edu/

B6	Male (Neutered)
Canine P B6	it Bull Mahogany

4/29/2019			
Dear B6			
Thank you for referring	В6	with their pe	t B6
If you have any question	s, or concer	ns, please conta	nd us at 508-887-498
Thank you,			
B6			

From:	Related PFR Event <pre>cpfrsignificantactivitycreation@fda.hhs.gov></pre>		
То:	Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification; B6		
Sent:	6/10/2019 2:56:47 PM		
Subject:	PureVita Venison & Red Lentils Grain-Free Dry Dog Food: B6 - EON-390031		
Attachments:	2067992-report.pdf: 2067992-attachments.zip		

A PFR Report has been received and Related PFR Event [EON-390031] has been created in the EON System.

A "PDF" report by name "2067992-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2067992-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390031

ICSR #: 2067992

EON Title: Related PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food,

NutriSource Adult Chicken and Rice formula; 2067992

AE Date	03/01/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	American Pit Bull Terrier		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2067992

Product Group: Pet Food

Product Name: Pure Vita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and

Rice formula

Description: Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related.

Patient was placed on B6 Submission Type: Followup Report Type: Adverse Event (a symptom, reaction or disease Outcome of reaction/event at the time of last observation: Number of Animals Treated With Product: 1		
Number of Animals Reacted With Product: 1		
Product Name	Lot Number or ID	Best By Date
NutriSource Adult Chicken and Rice formula		
PureVita Venison & Red Lentils Grain-Free Dry Dog Food		
Initial EON Event Key: EON-386301 Initial ICSR: 2066404 Sender information B6 USA Owner information B6 USA		
To view this Related PFR Event, please click the link below: B6	U	
To view the Related PFR Event Report, please click the link b	elow:	

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-	390031	
ICSR:	2067992	
Type Of Submission:	Followup	
Report Version:	FPSR.FDA.PETF.V.V1	
		reaction or disease associated with the product)
Type Of Report:	74 77	reaction of disease associated with the product)
Reporting Type: Report Submission Date:	Voluntary	
	:3 :3	
Initial Report Date:	04/29/2019	
Parent ICSR:	2066404	
Follow-up Report to FDA Request:	Yes	
Reported Problem:	Problem Description:	Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on B6 Taurine levels prior to supplementation was WNL.
	Date Problem Started:	03/01/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering
Product Information:	Product Name:	NutriSource Adult Chicken and Rice formula
	Product Type:	<u> </u>
	Lot Number:	
		9B15P 18581
	Package Type:	
	Package Size:	2
	Possess Opened Product:	
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	PureVita Venison & Red Lentils Grain-Free Dry Dog Food
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use	
	Information: Manufacturer	
	/Distributor Information: Purchase Location	
A	Information:	
Animal Information:	Name:	B6
	Type Of Species:	
		American Pit Bull Terrier
	Gender:	
	Reproductive Status:	1 man nitara nit
	-	32 Kilogram
	2 }	B6 Years
	Assessment of Prior Health:	Excellent

	Number of Animals Given the Product:	1			
	Number of Animals Reacted:	1			
	Owner Information:	Owner Information provided:	Yes		
		Contact:		В6	
			Phone: Email:	B6 B6]
		Address:	B6 United States		<u></u>
	Healthcare Professional	Practice Name:	Tufts Cumming	s School of Vete	erinary Medicine
	Information:	Contact:		В6	,
			Phone:	В6]
			Email:	B6_	
		Address:	200 Westboro North Grafton Massachusetts 01536 United States		
		Practice Name:	Tufts University		
		Contact:	Name:	Lisa Freeman	
				(508) 887-4523	
				lisa.freeman@t	ufts.edu
		Veterinarian:	Referred veteri	narian	
		Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	В6			
		200 Westboro Road North Grafton Massachusetts 01536 United States			
	Contact:	Phone:	В6		
		Email:	B6		
	Permission To Contact Sender:	Yes			
	Preferred Method Of Contact:	Email			
	Reported to Other Parties:	None			
Additional Documents:					
		Diet Hx 5-3-2019.pd	f		
	Description:				
	Type:	Medical Records			
		Recheck chem 21 5-	-3-2019.pdf		
	Description:				
	Туре:	Laboratory Report			

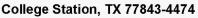
Attachment:	В6	roponin 5-30-2019.pdf
Description:	Lab work	
Туре:	Laboratory Re	eport



Comments:

Gastrointestinal Laboratory

Department of Small Animal Clinical Sciences





Website User ID: **B6** GI Lab Assigned Clinic ID: 23523 Phone: 508 887 4696 **B6** Tufts Cummings School of Vet Med - Cardiology/Nutrition Fax: 200 Westboro Road **Animal Name:** North Grafton, MA 01536 Owner Name: USA Species: Canine Date Received: May 30, 2019 Tufts Cummings School of Vet Med -GI Lab Accession: **B6** Cardiology/Nutrition Tracking Number: 444116 <u>Test</u> Result Reference Interval **Assay Date** B6 ng/mL **Ultra-Sensitive Troponin I Fasting** ≤0.06 05/31/19

GI Lab Contact Information

Email: gilab@cvm.tamu.edu Phone: (979) 862-2861 Fax: (979) 862-2864 vetmed.tamu.edu/gilab

CARDIOLOGY DIET HISTORY FORM

	Please answer the following of the second of	B6	low that bes	Today's o	late: <u>5[3][9</u> ur pet's appetite)
	Poor		·	Excellent	
2.	Have you noticed a change in your pet's appetite over the Eats about the same amount as usual Seems to prefer different foods than usual Other	e last 1-2 week than usual	s? (check all t ■Eats more		_
3.	Over the last few weeks, has your pet (check one) Lost weight Gained weight Stayed about the s	same weight I	□Don't know		
1.	Please list below <u>ALL</u> pet foods, people food, treats, snac currently eats and that you have fed in the last 2 years.	ck, dental chew	vs, rawhides, a	and any other fo	ood item that your pet
	Please provide enough detail that we could go to the stor	re and buy the	exact same fo	od - examples	are shown in the table
ſ	Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
	Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2016-present
-	85% lean hamburger	microwaved	3 oz	1x/week	June -Aug 2016
	Pupperoni original beef flavor	treat	1/2	1x/day	Sept 2016-present
1	Rawhide	treat	6 inch twist	1x/week	Dec 2018-present
	20492 Canin Boxer	1	3/4	27/244	APril 2019 - Present
		94	2 TBLS	2//24/	
	Sclerul diet 7+ Bet F + Barley	C9~		\(\frac{7}{4} \frac{1}{4} \frac{1}{2} \)	AMIL 2014 - Prese-
	HILLS & Clorice CLET SOFTS AVOITES PRANUT + BONDA	Treat	41/2	64 50 %	APRIL 2014 - Presa
	ALPO VIARIETY SMUPS BLAKBITES	trat	1/4	6 4 dyx	APAIL 2019-Pres
	<u> </u>				
ļ	*Any additional diet information can be listed on the back	of this sheet			
	Any additional distribution out so holds on the sack	cor uno onoot			
2.	Do you give any dietary supplements to your pet (for exa	mole: vitamins	glucosamine	fatty acids, or	any other
۷.	supplements)?	ch ones and di	ve brands and	amounts:	any outer
		Concentration	vo brando ana		Amount per day
				20	00 Mg
	7.00 - 1.0				
	Carnitine				
	Antioxidants				
	Multivitamin			_	
	Fish oil			_	-
	Coenzyme Q10			_	
	Other (please list):			=00	
	Example: Vitamin C Nat	ure's Bounty		500 m	g tablets – 1 per day
				_	
				_	
3.	How do you administer pills to your pet?				
	□ I do not give any medications				
	I put them directly in my pet's mouth without food				
	put them in my pet's dog/cat food				
	put them in a Pill Pocket or similar product				
	□ I put them in foods (list foods):				

Tufts Cummings School Of Veterinary Medicine



200 Westboro Road North Grafton, MA 01536

Name/DOB: B6		Provider: B6
Patient ID:	Sex: CM	Order Location: Foster Hospital for Small Animals
Phone number:	Age: 2	Sample ID: 1905030068
Collection Date: 5/3/2019 11:51 AM	Species: Canine	•
Approval date: 5/3/2019 12:55 PM	Breed: Pit Bull	

Research Chemistry Profile - Small Animal (Cobas)

DNOYES Glucose Urea Creatinine Phosphorus Calcium 2 Magnesium 2+ **Total Protein** Albumin Globulins A/G Ratio Sodium Chloride Potassium tCO2(Bicarb) **AGAP** NA/K **Total Bilirubin**

Alkaline Phosphatase GGT ALT AST Creatine Kinase Cholesterol Triglycerides Amylase Osmolality (calculated) Comments (Chemistry) **B6**

Ref. Range/Males 67-135 mg/dL 8-30 mg/dL 0.6-2.0 mg/dL 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L 5.5-7.8 g/dL 2.8-4.0 g/dL 2.3-4.2 g/dL 0.7 - 1.6140-150 mEq/L 106-116 mEq/L 3.7-5.4 mEq/L 14-28 mEq/L 8.0-19.0 29-40 0.10-0.30 mg/dL 12-127 U/L 0-10 U/L 14-86 U/L 9-54 U/L 22-422 U/L 82-355 mg/dL 30-338 mg/dl 409-1250 U/L 291-315 mmol/L

Sample ID: 1905030068/1 END OF REPORT (Final) Reviewed by: _____

From:	PFR Event <pre><pre>creation@fda.hhs.gov></pre></pre>
То:	Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent:	5/28/2019 7:41:41 PM
Subject:	Bil Jac Picky No MoreSmall Breed-Persnickety Recipe w/ chicken liver: B6 - EON-388960
Attachments:	2067506-report.pdf; 2067506-attachments.zip

A PFR Report has been received and PFR Event [EON-388960] has been created in the EON System.

A "PDF" report by name "2067506-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2067506-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-388960

ICSR #: 2067506

EON Title: PFR Event created for Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver;

2067506

AE Date	05/17/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Spaniel - Cocker American		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2067506

Product Group: Pet Food

Product Name: Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver

Description: Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermmitent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided

heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver		

B6	
USA	
Owner information	ì
B6	USA
i	JUSA

To view this PFR Event, please click the link below:	
В6	

To view the PFR Event Report, please click the link below:

B 6	

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<u>v.z</u>	388960							
ICSR:	2067506							
Type Of Submission:	Initial							
Report Version:	FPSR.FDA.PETF.V.V1							
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)					
Reporting Type:	Voluntary							
Report Submission Date:	2019-05-28 15:31:05 EDT	19-05-28 15:31:05 EDT						
Reported Problem:	Problem Description:	Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermmitent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.						
	Date Problem Started:	05/17/2019						
	Concurrent Medical Problem:	Yes						
	Pre Existing Conditions:	Previously diagnosed (Jan 2019) with with a 1-2/6 heart murmur - asymptomatic, rDVM rec rechecking in 1 year.						
	Outcome to Date:	Stable						
Product Information:	Product Name:	Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver						
	Product Type:	Pet Food						
	Lot Number:							
	Package Type:	BAG						
	Product Use Information:							
	Manufacturer /Distributor Information:							
	Purchase Location Information:							
Animal Information:	Name:							
	Type Of Species:	Dog						
	Type Of Breed:	Spaniel - Cocker American						
	Gender:	Female						
	Reproductive Status:	Neutered						
	4	14 Kilogram						
	Age:	B6 Years						
	Assessment of Prior Health:							
	Number of Animals Given the Product:							
	Number of Animals Reacted:							
	Owner Information:	Owner Information provided:	Yes					
	1	Contact:	Name: DC					
		Address:	Phone: B6					
			В В В В В В В В В В В В В В В В В В В					
	Healthcare Professional	Address:	Phone: B6					

	Information:	Contact:	Name: Phone:	B6		
			Email:	B6	r i	
		Address:	200 Westboro North Grafton Massachusetts 01536 United States	Road		
		Practice Name:	Tufts University Cummings School of Veterinary Medicine			
		Contact: Type of Veterinarian:	Name:	Lisa Freeman		
				508 887 4696		
			Referred veteri	narian		
		Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	В6				
	Address:	North Grafton Massachusetts 01536 United States				
	Contact:	Phone:	В6			
		Email:	B6			
	Permission To Contact Sender:	Yes				
	Preferred Method Of Contact:					
	Reported to Other Parties:					
Additional Documents:						
		Med Rec pt 1.pdf				
		Medical Records				
		Medical Records				
		Med Rec pt 2.pdf				
		Medical Records				
	Type:	Medical Records				

Cummings Veterinary Medical Center

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

All Medical Records

Client:	Patient: B6		
Address: B 0	Breed: Cocker Spaniel		Canine
<u> </u>	DOB: B6	Sex:	Female (Spayed)
Home Phone: B6			(Spayed)
Home Phone: B6 Work Phone: ()			
Cell Phone: B6			
Referring Information			
В	36		
Client: B6			
Patient: D			
Initial Complaint:			
Emergency			
;=	·		
SOAP Text May 18 2019 12:21PM - B6			
C. Maritan			
Subjective			
NEW VISIT (ER)			
Doctor: B6 Student: B6 20			
\			
Presenting complaint B6 CHF			

HISTORY:

Referral visit? Y

Chem/SDMA - all WNL

Signalment: 10 yo SF Cocker Spaniel

Diagnostics completed prior to visit:

Current history: O noted that in August of 2018, O+P moved from B6 and into an apartment. At this time, O noted anxiety and a cough. O noted that vet in B6 mentioned P had a heart murmur, but O had not noticed a cough until August. O noted that P is on a medication for anxiety but could not remember which medication. O noted that the last 3 months, the cough has gotten a lot worse. It is a constant cough that happens every 1.5 hours and throughout

Radiograph - Severe cardiomegaly with dorsal displacement of the trachea and left mainstem bronchi compression. Pulmonary vessels are increased in diameter and lung lobar veins are bigger than the arteries. There is patchy

interstitial pattern in the perihilar area. Caudal liver lobes look enlarged.

Client: B6	
	d that P has become exercise intolerant and cannot walk very far without becoming short of erDVM vesterday, 05/17/19 and the vet noted that P is in CHF and has a very enlarged heart and referrred P here for an echocardiogram. No S/V/D/PU/PD.
Current medications:	B6
Diet: Bill Jack Persnickety	ntà Rin
	tick preventative use: UTD per O, f/t/hw prevention per O
Travel history: moved from	B6 August 2018
EXAM:	
LAAWI.	
	B6
C/V: Grade IV/VI heart mu	ırmur ausculated. Arrhythmia appreciated. Fair femoral pulses.
	B6
ASSESSMENT:	
	rmur with arrhythmia and increased respiratory effort - CHF (due to advanced DMVD with
active left sided CHF, mod	and supraventricular arrhythmias
A3:	
A4: B6	
	<u></u> j
PLAN:	
P1: Cardio consult	
	with active L- CHF
Moderate PHTN	
	ılar and supraventricular arrhythmias
P2:	
P3: P4:	B6
г т .	

Page 2/70

Client: Patient: B6
B6
P5: iSTAT: B6
Client communication:
B6
Deposit & estimate status:
Resuscitation code (if admitting to ICU):
SOAP approved (DVM to sign): B6
Initial Complaint: Recheck B6 - consult thru ER (DMVD/DCM study?)
Disposition/Recommendations

Cummings Veterinary Medical Center

AT TUFTS UNIVE	RS	IΤ
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Client:	B6
Veterinarian:	
Patient ID:	В6
Visit ID:	

Lab Results Report

stringsoft

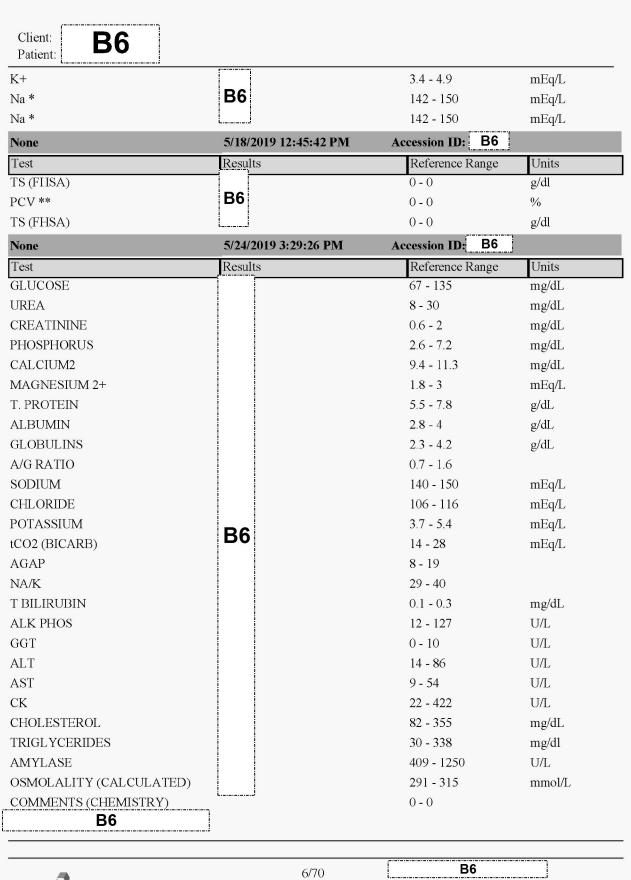
Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Patient:	B6
Species:	Canine
Breed:	Cocker Spaniel
Sex:	Female (Spayed)
Age:	B6 Years Old

None	5/18/2019 12:44:43 PM	Accession ID: B6	
Test	Results	Reference Range	Units
AGAP (i-STAT)		8 - 25	mmol/L
AGAP (i-STAT)		8 - 25	mmol/L
Hb		12 - 17	g/dL
Hb		12 - 17	g/dL
HCT		35 - 50	%
HCT		35 - 50	%
Creat		0.5 - 1.3	
Creat		0.5 - 1.3	
BUN		10 - 26	mg/dL
BUN		10 - 26	mg/dL
K+	B6	3.4 - 4.9	mEq/L
Glucose (i-STAT)		60 - 115	mg/dL
Glucose (i-STAT)		60 - 115	mg/dL
iCa		1.12 - 1.4	mmol/L
TCO2		17 - 25	mmol/L
TCO2		17 - 25	mmol/L
iCa		1.12 - 1.4	mmol/L
iCa		1.12 - 1.4	mmol/L
Cl-		106 - 127	mEq/L
Cl-		106 - 127	mEq/L
K+		3.4 - 4.9	mEq/L
	5/70	B6	

Printed Tuesday, May 28, 2019



Printed Tuesday, May 28, 2019

stringsoft

Client: B6 Patient:

B6 Records

		Patie	nt History Re	port		
Client: Phone: Address:	B		Patient: Species: Cat Age: Color: Bla	B6 nine B6		aniel, Cocker ayed Fernale
Date Type	Staff	History				
5/18/2019 TC	B6	pc from owner	she is going to call	Tuffs and try	to get in today -	TENTATIVE
at present dose ui her children take t	ntil evalual heir pets. Itact us so	results (all wnl). ed by cardiologis I stressed need we can get get ir	s and recommendat She feels like B t. She will pursue cardiologist and if nfo to a referral in	6 jis doina.b e echo at they do not	etter advise o B6 have one a <u>vail</u>	ontinus B6 jwhere able within several B6 today, or
5/17/2019 C	В6	B6 BI	ank Document - FIN	IAL 05/17/201 Veterinariai	9 - Check B6 n B6	DVM 5/17/201 Patient Name: B6
E Commu		ï	echnician: B6			
Reason for Visit:	cough					
12/10/2 10:39 Å Vital Sign		5/17/2019 3:35 PM				
	i. Milmage case:	s, P. Prescription, PA PVL A	Dibliagnosis, DH: Declined Accepted, PB:problems, PP			-
B6			Page 1 of 4	Date	: 5/18/2019 10:0	00 AM

			Patie	ent History F	Report	
Cllent	:			Patlent:	B6	
Phone	. 1	K		Species: _C		Breed: Spaniel, Cocker
Address	•		•	Age: [B6 lack/Tan	Sex: Spayed Female
	i		!		ineracia i manici	
Date	Туре	Staff	History			
Weight	26 pound	Š	29 pounds			
o contact with her last v	with other isit. O s	er dogs. (ays that h	D says that Ter appetite is n	_B6had to	ld her that he	ounds like a hacking cough. She ha er heart murmer could cause a coug slightly looser stools. O says that s
acting ve	ry leth ar	gic Tem	p 101.4			
ardiac mum ateral thora .: Cough, lor	nur; som x: genera ng standi	e arrythmi dized card ng murmu	as ascultated. Mi liomyopathy, dors ir, evidence of ge	ld dypnea; color a al caudal increase neralized heart enl	nd CRT wnl. d interstitial pa argement and	CHF
: Discussec dministered	į.		ar. Emphasizad s	R6	and need for	cardiac evaluation. Ωbem drawn: Advise ech
onsult ASAI						
5/17/2019	TC	B6	B6 Technicia	an History - TENTA	ATIVE	
				Technician: E	<u> </u>	
eason for	Visit:	cough				
	12/10/201	8	5/17/2019			
Vital Sign	10:39 AM	B6	3:35.PM			
Weight	26 pound	s	29 pounds			
D reports t	hat B6	_has had	a cough f <u>or ab</u>	out a month now	. O says it so	ounds like a hacking cough. She ha er heart murmer could cause a coug
o contact i t her last v	with other isit. O s	ar dogs. v ays that h	o says mai: ner appetite is n	ormal but that sh	e does have	er neart murmer could cause a coug slightly looser stools. O says that s
acting ve						
Departing instr. L	Labresulf, I	M:Image cases		rs, D:Diagnosis, DH:Declin Accepted, PB:problems, F		
			The second secon	Page 2 of 4	Ďa	te: 5/18/2019 10:00 AM
В	U	1			20	responding to the contract of

Client: **B6** Patient:

B6 Records

Patient History Report

Cllent: Phone: Address:

Patlent: B6 Species: Canine Age: E В6 Color: Black/Tan

Breed: Spaniel, Cocker Sex: Spayed Female

Staff History

5/17/2019 L

Date Type

B6

Chemistru results from IDEXX Reference Laboratory Requisition B6 ID: Posted Final Test Reference Range Reference F 2.7 - 3.9 5 - 160 18 - 121 337 - 1469 11 - 26 16 - 55 13 - 27 ALB ALKP ALT AMYL ANION GAP AST BICARB 9 - 31 8.4 - 11.8 108 - 119 131 - 345 0.5 - 1.5 0.0 - 0.1 BUN/UREA Chloride CHOL CREA DBIL GGT 0 - 130 - 13 63 - 114 0.0 - 0.2 138 - 755 2.5 - 6.1 4.0 - 5.4 0.0 - 0.3 GLU IBIL LIPA PHOS Potassium TBIL 5.5 - 7.5 142 - 152 0.7 - 1.5 TP Sodium A/G Ratio B/C Ratio Na/K Ratio 28 - 37 2.4 - 4.0 10 - 200 GLOB CK 0 - 14SDMA Ascn.: В6

RE: B6 HEMOLYSIS INDEX N
Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

RE: B6 LIPEMIA INDEX N

Index of N, 1+, 2+ exhibits no significant effect on

chemistry values.

BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates

B6

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr. L:Lab result, M:Image cases, P:Prescription, PA.PVL Accepted, PB:problems, PP.PVL Performed, PB:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medi note, V:Vital signs.

B6

Page 3 of 4

Client: Patient: B6

B6 Records

Patient History Report

Phone:
Address:

 Patient:
 B6

 Species:
 Canine

 Age:
 B6

 Color:
 Black/Tan

Breed: Spaniel, Cocker Sex: Spayed Female

Date Type

Staff

History

B.Billing, C.Med note, CB.Call back, CK.Check-in, CM.Communications, D.Diagnosis, DH.Declined to history, E.Examination, ES:Estimates, I.Departing instr. L.Lab result, M.Image cases, P.Prescription, PA.PVL Accepted, PB.problems, PP.PVL Performed, PR.PVL Recommended, R.Comespondence, T.Images, TC:Tentative medinate, V.Vitatisigns

B6

Page 4 of 4

RDVM B6 medical records 5/17/19-5/18/19

B6

Records **B6** Patient History Report Client: Patient: Phone: Species: Canine Breed: Spaniel, Cocker Sex: Spayed Female Address: Age: **B**6 Color: Black/Tan Date Type History Staff 5/18/2019 TC В6 pc from owner - she is going to call Tufts and try to get in today - TENTATIVE 5/18/2019 TC B6 P.C. lab results and recommendations - TENTATIVE

Called B6 with Chem results (all wnl). She feels like B6 is doing better advise continue Eurosemide at present dose until evaluated by cardiologist. She will pursue echo at B6) where B6 her children take their pets. I stressed need cardiologist and if they do not have one available within several days, she can contact us so we can get get info to a referral institution of her choice.

B6 or Tufts next week.) 5/17/2019 C B6 ****** B6 Blank Document - FINAL B6 Check cough DVM 5/17/2019 Patient Name: **B6** Technician: **B6** Reason for Visit: cough 12/10/2018 5/17/2019 3:35 PM В6 B-Billing, C: Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr. L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medi note, V:Vitalsigns

Page 1 of 4

RDVM

В6

medical records 5/17/19-5/18/19

B6 Records		
	Patient History R	eport
Cllent: Phone: Address: B6	Patient: Species: Ca Age: Color: Bi	B6 Breed: Spaniel, Cocker B6 Sex: Spayed Female
Date Type Staff Histor	у	
Weight 26 pounds 29 pounds	nds	
no contact with other dogs. O says th	nat B6 had tok	O says it scunds like a hacking cough. She has d her that her heart murmer could cause a cough e does have slightly looser stools. O says that she
cardiac murmur; some arrythmias ascult. Lateral thorax: generalized cardiomyopat A: Cough, long standing murmur, evidence	ated. Mild dypnea; color ar hy, dorsal caudal increased ce of generalized heart enla	interstitial pattern
consult ASAP.		
5/17/2019 TC B6 B6	echnician History - TENTA Technician: B	:
Reason for Visit: cough		
12/10/2018 5/17/20 10:39 AM 3:35 PI Vital Sign B6 Weight 26 pourids 29 pour	и 	
no contact with other dogs. O says the	nat B6 had told	O says it sounds like a hacking cough. She has dher that her heart murmer could cause a cough does have slightly looser stools. O says that she
B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Corl:Departing instr. L:Lab result, M:Image cases, P:Prescripti R:Correspondence, T:Images, TC:Tentative medinote, V:N	on, PA:PVL Accepted, PB:problems, PF	
B6	Page 2 of 4	Date: 5/18/2019 10:00 AM

Client: **B6**

RDVM B6 medical records 5/17/19-5/18/19

B6 Records

Patient History Report

Client: Phone: Address: B6
Species: Canine Breed: Spaniel, Cocker Sex: Spayed Female

Color: Black/Tan

Date Type Staff History

5/17/2019 L B6

Reference Laboratory Final
Reference Range
2.7 - 3.9
5 - 160
18 - 121
337 - 1469
11 - 26
16 - 55
13 - 27
9 - 31
8.4 - 11.8
108 - 119
131 - 345
0.5 - 1.5
0.0 - 0.1
0 - 13
63 - 114
0.0 - 0.2
138 - 755
2.5 - 6.1
4.0 - 5.4
0.0 - 0.3
5.5 - 7.5
142 - 152
0.7 - 1.5 Chemistry results from IDEXX Reference Laboratory Requisition ID: B6 Test ALB Posted Result ALKP ALT AMYL ANION GAP BICARB BUN/UREA Ca Chloride CHOL DBIL GLU IBIL PHOS Potassium TBIL TP Sodium A/G Ratio B/C Ratio Na/K Ratio 28 - 37 2.4 - 4.0 10 - 200 0 - 14 GLOB CK SDMA 0 - 14

Ascn: B6 B6 HEMOLYSIS INDEX N

Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

RE: B6 LIPEMIA INDEX N

Index of N, 1+, 2+ exhibits no significant effect on chemistry values. SDMA BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates

which indicates B6

B.Billing, C.Med note, CB.Call back, CK.Check-in, CM.Communications, D.Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, t.Departing instr. L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, T:C:Tentative mediinote, V:Vitalisigns

B6

Page 3 of 4

RDVM

B6

medical records 5/17/19-5/18/19

B6 Records

Patient History Report

Client: Phone: Address:

Date Type

B6

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker Sex: Spayed Female

Staff History

B. Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, l:Departing instr. L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medinate, V:Vitalsigns

В6

Page 4 of 4



Chem 5/24/2019



Comments (Chemistry)

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

DUPLICATE

Name/DOB: B6	Sex: SF	Provider. B6 Order Location: V320539: Investigation into
Phone number:	-' Age: 10	Sample ID: 1905240076
Collection Date: 5/24/2019 3:29 PM	Species: Canine	20 march 4
Approval date: 5/24/2019 4:18 PM	Breed: Cocker Spaniel	

Research Chemistry Profile - Small Animal (Cobas) CSTCYR Ref. Range/Females 67-135 mg/dL Glucose Urea 8-30 mg/dL 0.6-2.0 mg/dL Creatinine Phosphorus 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L Calcium 2 Magnesium 2+ Total Protein 5.5-7.8 g/dL 2.8-4.0 g/dL Albumin Globulins 2.3-4.2 g/dL A/G Ratio 0.7-1.6 140-150~mEq/LSodium Chloride 106-116 mEq/L Potassium 3.7-5.4 mEq/L **B6** tCO2(Bicarb) 14-28 mEq/L AGAP 8.0-19.0 NA/K 29-40 0.10-0.30 mg/dL Total Bilirubin Alkaline Phosphatase 12-127 U/L GGT 0-10 U/L ALT 14-86 U/L AST 9-54 U/L Creatine Kinase 22-422 U/L Cholesterol 82-355 mg/dL Triglycerides 30-338 mg/dl 409-1250 U/L Amylase Osmolality (calculated) 291-315 mmol/L

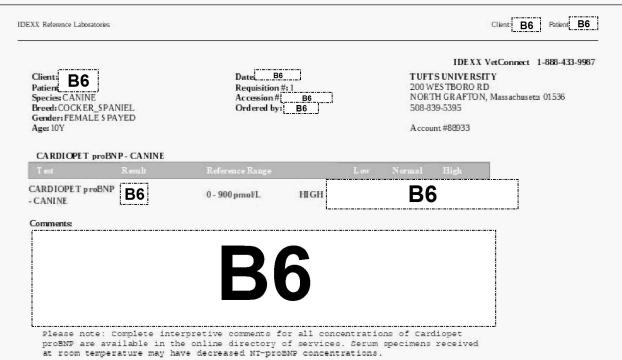
Sample ID: 1905240076/1 Reviewed by: _______
END OF REPORT (Final)

В6

Diet Hx 5/24/2019

	36	Owner's name	B			date: <u>5- 24-20</u>
	ssess your oor	pet's appetite? (mark the po	oint on the line	pelow that bes	t represents yo	our pet's appetite)
Р	oor				_Excellent	
				,		
■Eats about the s	same amou	n your pet's appetite over th unt as usual ■Eats less oods than usual Other	ne last 1-2 week than usual	s? (check all Eats more		
Over the last few Lost weight	weeks, has IGained w	s your pet (check one) eight Stayed about the	same weight	□Don't know		
currently eats and	that you h	ods, people food, treats, sna ave fed in the last 2 years.				
Please provide en	ough detai	I that we could go to the sto	ore and buy the	exact same fo	od - examples	are shown in the table
		product and flavor)	Form	Amount	How often?	Dates fed
		entil, & Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2016-present
5% lean hambur			microwaved	3 oz	1x/week	June -Aug 2016
upperoni origina	beef flavo	r	treat	1/2	1x/day	Sept 2016-present
Rawhide			treat	6 inch twist	1x/week	Dec 2018-present
		D / BLUE JAC	D Ry	1/2 cups	2x/day	July 2018- pre
Chieren	to a		BoLLED	,	1 0	/ /
RICE						
MILK BOW	E SOF	TREATS	TREAT	<u></u>	ADAY	
Any additional die	et informati	on can be listed on the bac	k of this sheet			
o you give any dupplements)?	ietary supp □Yes E		ich ones and giv	glucosamine e brands and	, fatty acids, or a	any other
aurine	□Yes □		Concentration			Amount per day
arnitine	□Yes □					
ntioxidants	□Yes □				-	
lultivitamin	□Yes □					
ish oil		INo			-	
oenzyme Q10	□Yes □					
other (please list)		793	3 5 5 3			15 7-
example: Vitamin	С	Nai	ture's Bounty		500 mg	tablets – 1 per day
		(
low do you admir	ister oills t	o your pet?				
low do you admir I I do not give an	y medicatio	ons				
I do not give an	y medication tly in my pe	ons et's mouth without food				

Idexx - NTproBNP 5/25/2019

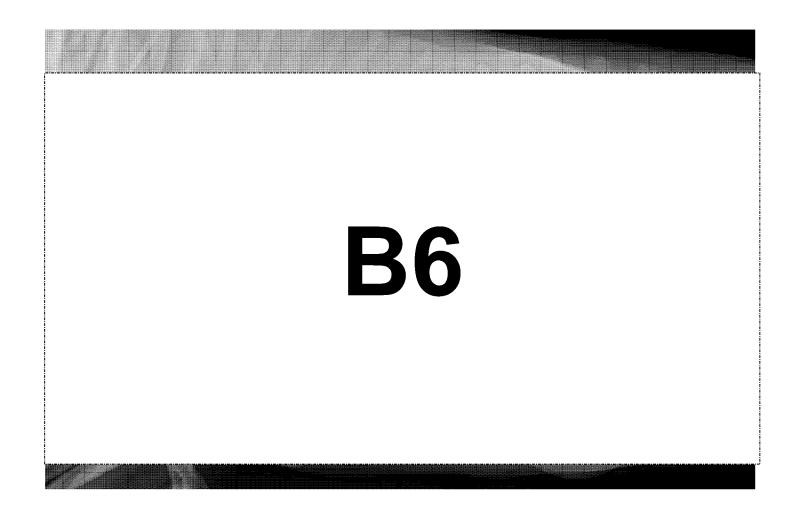


Client:	DC
Patient:	DO

Vitals Results

5/18/2019 11:14:07 AM	Heart Rate (/min)	
5/18/2019 11:14:08 AM	Respiratory Rate	
5/18/2019 11:14:09 AM	Temperature (F)	
5/18/2019 11:14:10 AM	Weight (kg)	
5/18/2019 12:43:53 PM	Lasix/Furosemide treatment note	
5/18/2019 12:54:58 PM	Sedation	B6
5/18/2019 1:33:08 PM	Heart Rate (/min)	
5/18/2019 1:33:09 PM	Temperature (F)	
5/18/2019 1:33:10 PM	Respiratory Rate	
5/18/2019 1:33:11 PM	Weight (kg)	
5/18/2019 3:08:13 PM	Eliminations	
5/18/2019 4:11:00 PM	Lasix/Furosemide treatment note	
5/24/2019 12:04:05 PM	Weight (kg)	

Client: Patient: **B6** CXR - 5/17/2019



B6

5/18/2019 12:42:53 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

5/18/2019 12:44:32 PM

Page 1 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

EKG from cardio

В6

5/18/2019 12:44:32 PM

Page 2 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

5/18/2019 12:44:37 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

12 Lead; Standard Placement

EKG from cardio

В6

5/18/2019 12:44:59 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

EKG from cardio

B6

5/18/2019 12:45:43 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

...12_lead:_Standard_Placement....

EKG from cardio

В6

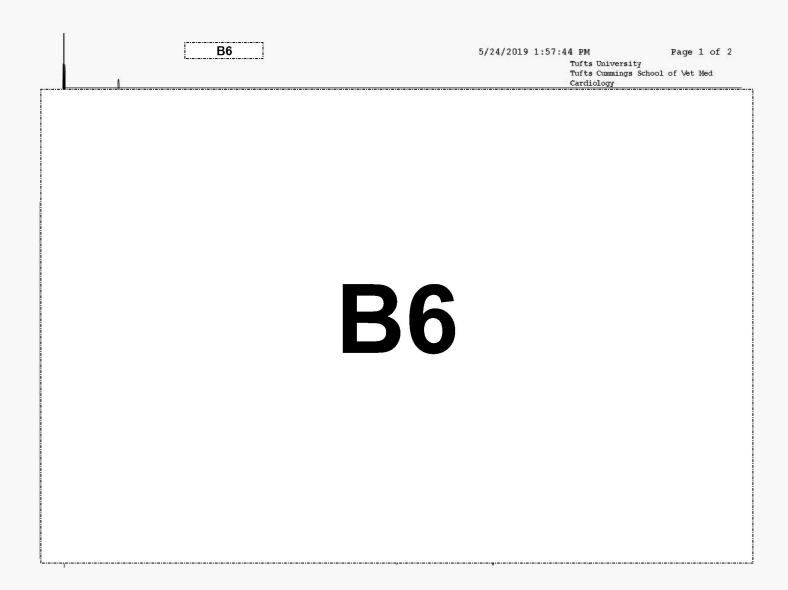
5/18/2019 12:45:55 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

B6

5/24/2019 1:57:20 PM

Tufts University Tufts Cummings School of Vet Med Cardiology



B6

5/24/2019 1:57:44 PM

Page 2 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

B6

5/24/2019 1:57:50 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

5/24/2019 1:57:50 PM

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Tufts University Tufts Cummings School of Vet Med Cardiology

Patient History

05/18/2019 11:14 AM	Vitals	
05/18/2019 11:14 AM	Vitals	
05/18/2019 11:14 AM	Vitals	
05/18/2019 11:14 AM	Vitals	
05/18/2019 11:14 AM	Vitals	
05/18/2019 11:17 AM	UserForm	
05/18/2019 11:17 AM	Email	
05/18/2019 11:43 AM	Purchase	
05/18/2019 11:43 AM	Purchase	
05/18/2019 12:25 PM	UserForm	
05/18/2019 12:33 PM	Treatment	
05,16,2019 12.55 111	Troutment	
05/18/2019 12:43 PM	Vitals	
05/18/2019 12:45 PM	Labwork	
05/18/2019 12:45 PM	Labwork	
05/18/2019 12:54 PM	Vitals	
05/18/2019 12:55 PM	Purchase	
05/18/2019 12:55 PM	Purchase	
05/18/2019 01:07 PM	Purchase	
05/18/2019 01:33 PM	Vitals	
05/18/2019 01:33 PM	Vitals	
05/18/2019 01:33 PM	Vitals	B6
05/18/2019 01:33 PM	Vitals	
05/18/2019 02:35 PM	Appointment	
03/10/2019 02.33 1 141	прошини	
05/18/2019 02:39 PM	Treatment	
05/18/2019 02:49 PM	Prescription	
05/18/2019 02:50 PM	Prescription	
05/18/2019 02:50 PM	Prescription	
05/18/2019 02:54 PM	Purchase	
05/18/2019 03:05 PM	Treatment	
05/18/2019 03:06 PM	Vitals	
05/18/2019 03:06 PM	Vitals	
05/18/2019 03:08 PM	Vitals	
05/18/2019 03:09 PM	UserForm	
05/18/2019 03:00 PM	Treatment	
05/18/2019 04:11 PM	Vitals	
05/18/2019 04:11 PM	Treatment	
05/18/2019 04:11 PM 05/18/2019 06:46 PM	Treatment	
05/18/2019 06:46 PM 05/21/2019 09:29 AM		
03/21/2019 09:29 AIVI	Appointment	
05/24/2019 12:00 PM	UserForm	
05/24/2019 12:04 PM	Vitals	
00,5 (/2017 15.0T 1 IVI	. 10010	<u> </u>

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F	
Client: Patient:	B6

Patient History								
05/24/2019 12:20 PM	Treatment							
05/24/2019 01:27 PM	UserForm							
05/24/2019 01:53 PM	Purchase							
05/24/2019 01:58 PM	Purchase							
05/24/2019 02:01 PM	Prescription				B	b		
05/24/2019 02:39 PM	Appointment	ta				V		
05/24/2019 02:44 PM	Appointment							
Patient Account History	Description		Qty	price	Extended	Disc	Pmt	

Client: **B6**

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 Ap 11:43	ppointment: Emergency Room Vi	sit 1.000	B6	B6 0.0000	0.0000

Client: **B6**

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 11:43	B6 (0 To 6 hrs)	В6	В6	B6 0.0000	0.0000

Client: **B6**Patient:

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 12:45	В6	1.000	В6	B6 0.0000	0.0000

Patient Account History Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 B6 - FHSA 12:45	1.000		B6 0.0000	0.0000

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 12:55	B6	1.000	:	B6 0.0000	0.0000

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 12:55	B6	1.000		B6 0.0000	0.0000

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 [B6	1.000		B6 0.0000	0.0000

Client: **B6**Patient:

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 [14:49	B6 tablets - FHSA	В6		B6 0.0000	0.0000

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 14:50 VF	B6 tablets	90.000		B6 0.0000	0.0000

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 [B6 Tablets - FHSA	. 100.000) []	B6 0.0000	0.0000

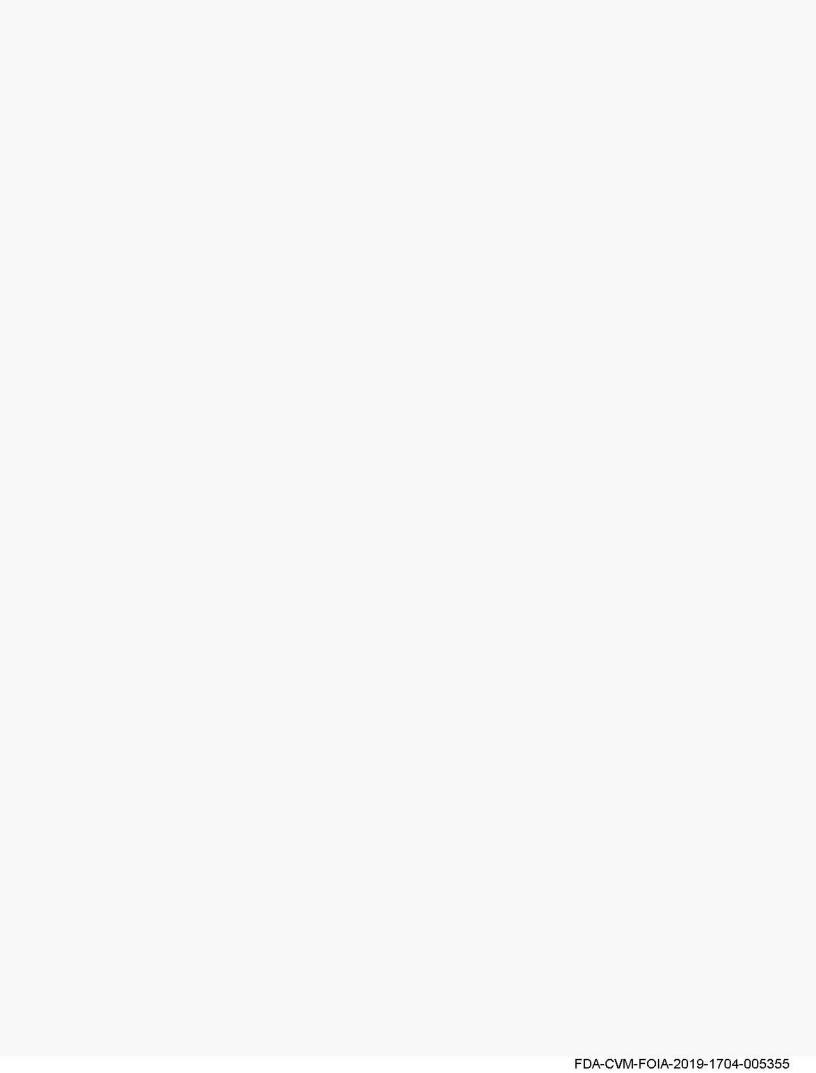
Patient Account History Description	Qty	price	Extende	ed Disc	Pmt
Saturday, 18 May 2019 Pharmacy Finished 14:54	1.000	0.000	0.0000	0.0000	0.0000

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Saturday, 18 May 2019 [B6 (ECC STOCK) B6	0.600	Е	0.0000	0.0000

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 [B6 (ECC STOCK) B6	0.600	В	6	0.0000	0.0000

Patient Account Histo	ory Description	Qty	price	Extende	d Disc	Pmt
Friday, 24 May 2019 13:53	Appointment: Cardiology Study	1.000	0.000	0.0000	0.0000	0.0000

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Friday, 24 May 2019	B6 Tablets - FHSA	30.000	: -	36 0.0000	0.0000



Cummings Veterinary Medical Center

B6

B6 Fermale (Spayed)
Camine Cocker Spaniel Black
Patient ID: B6

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tults University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly adknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) nowlenown or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 1.6% applied to the average daily balance outstanding, with a minimum fee of \$.50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above agreed upon time of payment or payments, the entire balanceshall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name:	В6	Date: E	36	
Owner's address:		B6		
	B6			B6

If the individual admitting the arimal is someone other than the legal owner, please complete the portion below:

The owner of the animal, owner to pay the veterinary described above	B6 medical se		nted me authority to obtain medical treatment and to bind this ded at Cummings School pursuant to the terms and conditions
Authorized Agent - Please Pr	int .		Agent's Signature
Street Address			Date
Town/City Stat	e	Zip	

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://wetmed.turks.edu/

Discharge Instructions

Owner Name: Address:	B6	
L		
ive heart failure witl	n pulmonary edema	•
mmon one in dogs, art enlargement has a condition called co an use cardiac medic	due to aging chang now progressed to ongestive heart fail ations and some ch	es to the valve the point re. We cannot ranges to the
6		
	ive heart failure with his leak has resulted mmon one in dogs, art enlargement has a condition called on an use cardiac medic	ive heart failure with pulmonary edema is leak has resulted in a loud heart mur mmon one in dogs, due to aging chang art enlargement has now progressed to a condition called congestive heart failure use cardiac medications and some changes. Unfortunately, this is a progressive dis

Monitoring at home:

We would like you to monito: B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted

 by the amount of belly wall motion used for each breath, is fairly minimal if heart 	failure is contr	colled. An increase in
breathing rate or effort will usually mean that you should give an extra dose of	B6	difficulty breathing is
not improved within 30-60 minutes after giving extra furosemide then we recom	mend that a re	check exam be scheduled
and/or tha B6 be evaluated by an emergency clinic.		
There are instructions for monitoring breathing, and a form to help keep track of		
Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring		
 weakness or collapse, a reduction in appetite, worsening cough, or distention of the should do a recheck examination. 	he belly as the	se findings indicate that we
snowd do a recheck examination.		
Recommended Medications:		
B6		
Diet suggestions: Continue feeding B6 current diet until her recheck appointment.		
Exercise Recommendations:		
For the first 7 to 10 days after starting medications for heart failure, we recommo		
only is ideal, and short walks to start. Once the heart failure is better controlled,		
However, if you find that B6 is lagging behind or needs to stop on a walk then		_
are advised in the future. Repetitive or strenuous high-energy activities (repetitiv	e ball chasing,	running fast off-leash, etc.)
are generally not advised at this stage of heart failure.		
Recheck/Follow-up:		
A recheck has been scheduled for B6 on		
Friday, May 24th at 12:00pm with B6		
a completely area of the secondaria and a DC	i	
Thank you for entrusting us with B6 care.		
Prescription Refill Disclaimer:		
For the safety and well-being of our patients, your pet must have had an examination	by one of our	veterinarions within the past
year in order to obtain prescription medications.		

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us,

Ordering Food:

FDA-CVM-FOIA-2019-1704-005359

please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Cummings Veterinary Medical Center

Month of: Heart Failure Monitoring Worksheet

Day	Respiratory	В6	Dose		Appetite			
	Rate/Minute	AM	PM					
Sam	ple 32	1 tab (12.5mg)	1/2 tab (6.25mg)	Excellent	Good	Fair	Poor	Notes:Breathing better
1 :				Excellent	Good	Fair	Poor	Notes
2 :				Excellent	Good	Fair	Poor	Notes
3 :				Excellent	Good	Fair	Poor	Notes
4:				Excellent	Good	Fair	Poor	Notes
5:				Excellent	Good	Fair	Poor	Notes
6 :				Excellent	Good	Fair	Poor	Notes
7 :				Excellent	Good	Fair	Poor	Notes
8:				Excellent	Good	Fair	Poor	Notes
9:				Excellent	Good	Fair	Poor	Notes
10:				Excellent	Good	Fair	Poor	Notes
11:				Excellent	Good	Fair	Poor	Notes
1 2 :				Excellent	Good	Fair	Poor	Notes
13:				Excellent	Good	Fair	Poor	Notes
14:				Excellent	Good	Fair	Poor	Notes
15:				Excellent	Good	Fair	Poor	Notes
16:				Excellent	Good	Fair	Poor	Notes
17:				Excellent	Good	Fair	Poor	Notes
18:				Excellent	Good	Fair	Poor	Notes
19:				Excellent	Good	Fair	Poor	Notes
20:				Excellent	Good	Fair	Poor	Notes
21:				Excellent	Good	Fair	Poor	Notes
22 :				Excellent	Good	Fair	Poor	Notes
23:				Excellent	Good	Fair	Poor	Notes

24	Excellent Good	Fair	Poor N	lotes
25:	Excellent Good	Fair	Poor N	lotes
26:	Excellent Good	Fair	Poor N	lotes
27:	Excellent Good	Fair	Poor N	lotes
28:	Excellent Good	Fair	Poor N	lotes
29:	Excellent Good	Fair	Poor N	lotes
30:	Excellent Good	Fair	Poor N	lotes
31:	Excellent Good	Fair	Poor N	lotes

Respiration Rate: Count the number of breaths for 30 seconds and multiply times 2 to get the respiratory rate per minute. In dogs, obtain the respiratory rate when they are at rest and not panting. In cats, get the respiratory rate at rest when they are not purring. In animals with well controlled heart failure, the breathing rate is often less than 35-40 breaths per minute. When the breathing rate is dimbing, or when there is more effort to the chest wall or belly muscles during breathing, then fluid is likely accumulating in the lungs and more furosemide may be indicated. Please bring this sheet with you to your next veterinary exam.

Please visit our HeartSmart Website for further information http://vet.tuits.edu/heartsmart/at-home monitoring/

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Te lephone (508) 839-5395 Fax (508) 839-7951 http://vetmed.tufts.edu/

Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:

- Most other dog treats are high in sodium.
- If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

Product	Calories per treat
Dogs	
Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat	8
Hill's Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat	34
Hill's Science Diet Soft Savories Peanut Butter & Banana, Beef & Cheddar, or Chicken & Yogurt Dog Treat	25-27, depending on flavor
Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots, Duck & Pumpkin, or Beef & Sweet Potato Dog Treat	12-13, depending on flavor
Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken & Barley	27-29, depending on flavor
Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb or beef, bacon, cheese, peanut butter)	16
Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)	58
Royal Canin Original Canine treat	5
Cats	
Royal Canin Original Feline treat	2
Fancy Feast Duos Natural Rotisserie Chicken Cat treat	2
Fancy Feast Duos Tuna with Accents of Parsley Cat treat	2

Taste enhancers to can make your pet's food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes:

- All foods in this list should be prepared without salt
- These taste enhancers should be added in small amounts. If your pet eats too much of them, they will unbalance the diet and increase your pet's risk for nutritional deficiencies

Dogs

- ▼ Honey or maple syrup
- Homemade chicken, beef, or fish broth (made without salt; avoid all delimeats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- Sugar (brown or white) Domino pourable light brown sugar is a good option
- Vanilla or fruit yogurt One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yog
- calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
 Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- Applesauce (be sure they have less than 50 mg sodium per serving)
- Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico's no salt added)
- Frosted Mini Wheats Original these can be crumbled on his food
- Lean meats, cooked (chicken, turkey, beef, or fish) not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- Eggs, cooked



Dogs (continued)

- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium).
 Avoid all canned soups unless labeled as no salt added
- Low-salt breakfast cereal the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- Low sodium canned dog foods

Cats

- Lean meats, cooked (chicken, turkey, beef, or fish) not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- Eggs, cooked
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- Low sodium canned cat foods

Foods to avoid

- Fatty foods (meat trimmings, cream, ice cream)
- Baby food
- Pickled foods
- ▼ Bread
- Pizza
- Condiments (ketchup, soy sauce, barbecue sauce, etc unless they are unsalted or no salt added)
- Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- Rotisserie chicken
- Most cheeses, including "squirtable" cheeses
- Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- ♥ Canned vegetables (unless "no salt added")
- Potato chips, packaged popcorn, crackers, and other snack foods
- Soups (unless homemade without salt)
- Most commercial pet treats

Tips for administering medications

Foods commonly used to administer your pet's pills can provide a large amount of additional salt to your pet's diet. Preferable ways to give medications include:

- Have one of our staff show you how to give medications without using food
- Insert medications into one of the following foods:

Dogs or cats

- Low-sodium canned pet food
- Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
- Whipped cream (Reddi Wip)
- Marshmallows
- Greenies Pill Pockets
 - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
 - Avoid grain-free duck and pea which is high in sodium
 - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
 - Caution: Not all similar products from other companies are low in sodium.

Dogs

- Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
- Peanut butter (only if labeled as "no salt added") examples include Smucker's Natural Creamy
 Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
- Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol).
 Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting)

You may find our Petfoodology post called, "Pill-popping pets" helpful for additional ideas: http://vetnutrition.tufts.edu/2018/09/foods for giving pills/

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY Cardiology Liaison: 508-887-4696

Date: 5/18/2019

Patient ID: B6

B6 Canine

Years Old Female (Spayed) Cocker

Spanie!

Black BW: Weight (kg) 14.40

Cardiology Consultation

Weight Weight (kg) 14.40
Requesting Clinician: B6
Attending Cardiologist John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC B6
Cardiology Resident:
B6
Thoracic radiographs available for review? Yes - in SS Yes - in PACS No Yes in ECC email
Patient location: ER
Presenting complaint and important concurrent diseases: Enlarged heart on rDVM radiographs, cough
Current medications and doses:
B6
At-home diet: (name, form, amount, frequency) Bill Jack Persnickety - BID
Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.) Murmur and enlarged heart on radiographs, cough
Is your consult time-sensitive ? (e.g., anesthesia today, owner waiting, trying to get biopsy today) ☑ Yes (explain): O waiting ☑ No

STOP - remainder of form to be filled out by Cardiology

Physical Examination			
	36		
Muscle condition:			
Normal Normal	Moderate cachexia		
Mild muscle loss	Marked cachexia		
Cardiovascular Physical Exam			
Murmur Grade:			
None	☑ IV/VI		
□ I /V I	□ v/v i		
□ II /v I	□ vi/vi		
□ III /v I			
Murmur location/description: left apical, s	ystolic		
Jugular vein:			
■ Bottom 1/3 of the neck	■ Top 2/3 of the neck		
Middle 1/3 of the neck	■ 1/2 way up the neck		
Arterial pulses:			
₩eak	■ Bounding		
✓ Fair	Pulse deficits		
Good	Pulsus paradoxus		
Strong	Other (describe):		
5			
Arrhythmia:	_		
None None	Bradycardia		
Sinus arrhythmia	■ Tachycardia		
Premature beats			
Gallop:			
Yes	Pronounced		
☑ No	Other:		
Intermittent			
Pulmonary assessments:			
Eupneic	☑ Pulmonary Crackles		
Mild dyspnea	Wheezes		
✓ Marked dyspnea	Upper airway stridor		
Normal BV sounds	Other auscultatory findings:		
Abdominal exam:	at desired discussion		
Normal	Abdominal distension		
Hepatomegaly	Mild ascites		
Echocardiogram Findings:			

	B6
Mittal inflow: Summated Normal	☐ Pseudonormal ☑ Restrictive
Delayed relaxation	= IVERIBLINE
ECG findings:	
Assessment and recommend	B6
Findings consistent with adva	nced DMVD with active left-sided CHF. Despite patient having received 3 t 18h (less than 2mg/kg each dose), there is still significant CHF. Since
hospitalization is not possible B6 every 4 hours.	recommend There is moderate PHTN, but LCHF should be adressed first. Reduced
contractile function is not rou	tinely seen in DMVD, but there very frequent arrhythmias and BEG diet may
contribute. B6 grain-based low sodium diet a echocardiogram in 3 months.	ND for 1 week (and then decrease to every 24h) and switching to a re recommended. Recommend recheck bloodwork and EKG in 1 week and
Treatment plan:	
	B6

B6

Final Diagnosis:

Advanced DMVD with active L-CHF;

Moderate PHTN;

Frequent ventricular and supraventricular arrhythmias.

Heart Failure Classification Score:

ISACHC Classification:

la la	🗷 Illa
■ lb	IIIb
III	

ACVIM CHF Classification:

■ A	∠ C
■ B1	■ D
■ B2	

M-Mode	
MI-MIDUE	
IVSd	
LVIDd	
LVPWd	
I V Ss	
LVIDs	
LVPWs	
EDV(Teich)	
ESV(Teich)	
EF(Teich)	
%FS	
SV(Teich)	
Ao Diam	
LA Diam	

B6

cm cm cm cm cm ml ml % % ml cm cm ms **BPM** I/min l/minm cm

cm

cm

cm

M-Mode Normalized

IVSdN LVIDdN

LA/Ao Max LA

Time

CO(Teidh)

CI(Teich)

HR

IVSd

EPSS

TAPSE

B6

(0.290 - 0.520) (1.350 - 1.730) !

LVPWdN IVSsN LVIDsN LVPWsN Ao Diam N LA Diam N	B6	(0.330 - 0.530) (0.430 - 0.710) (0.790 - 1.140) ! (0.530 - 0.780) (0.680 - 0.890) (0.640 - 0.900) !
2D SA IA Ao Diam SA IA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs ESV(Teich) EF(Teich) %FS SV(Teich) LV Major LV Major LV Minor Sphericity Index LVLd A4C LVEDV MOD A4C LVESV MOD A4C LVEF MOD A4C SV MOD A4C SV MOD A4C	B6	cm cm cm cm cm cm cm cm cm cm cm cm cm c
Doppler MR Vmax MR maxPG MV E Vel MV DecT MV Dec Slope MV A Vel MV E/A Ratio AV Vmax AV maxPG PV Vmax PV maxPG TR Vmax TR maxPG	B6	m/s mmHg m/s ms m/s m/s mMHg m/s mmHg m/s

Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://webmed.tufts.edu/

Discharge Instructions

<u>atient</u>	Owner	,
aune: B6	Maine: B6	Patient ID: B6
pecies: Canine	Address: B6	
ack Female (Spayed) Cocker Spaniel irthdate: B6		
TUBS (D0)		
ttending Cardiologist:		
John E. Rush DVM, MS, DACVIM	(Cardiology), DACVECC	
B6		
DU		
ardiology Resident:	j	
	36	
ardiology Technician:		
DC		
B 6		
<u> </u>		
tudent: B6		
L		
dmit Date: 5/24/2019 11:54:53 AM		
Discharge Date: 5/24/2019		
Commence Charminusky day discours with	mitral regurgitation, congestive heart fail	harry weith, our depressors and reserve
agnos. Circincyavuar usese with	innianegugiauur, cungswenear rai	ше житринина у еизта.

Clinical findings: Thank you for bringing B6 in for a recheck of her recent diagnosis of chronic valvular disease with mitral regurgitation and congestive heart failure with pulmonary edema. Since her last appointment, you report that she has been coughing, has had a decreased appetite, and you've had some difficulties giving her medication. Her respiratory (breathing) rate at rest, however, has been comfortable with no effort.

On physical examination, B6 is bright, alert, and responsive B6 has a slower heart rate today and has little to no arrythmias which is excellent news! While it is difficult to assess her breathing rate here due to her stress and anxiety, you indicate that she does start to pant much more frequently when out on a walk. Her tongue is a little blue today, which indicates she is still having issues fully oxygenating, and she coughed occasionally during the exam.

Her arrythmias have dramatically decreased and seems to be pretty well controlled from her anti-arrythmias. Other findings were consistent with her previous echocardiogram. While she has not fully recovered, B6 seems to be doing much better comparatively to her initial presentation this past Saturday.

Monitoring at home:

We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of bely wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing

rate or effort will usually mean that you should give an extra dose of improved within 30-60 minutes after giving extra furosemide then we and/or that B6 be evaluated by an emergency clinic. There are instrace track of breathing rate and drug doses, on the Tufts HeartSmart v (http://vet.tufts.edu/heartsmart/at-home-monitoring/). We also want in appetite, worsening cough, or distention of the belly as these finding	recommend th uctions for mo web site you to watch	at a recheck exam be scheduled nitoring breathing, and a form to help for weakness or collapse, a reduction
B6		

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many treats, most people foods, and the supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site. In addition, your dog's usual diet may have more sodium than recommended - we want your dog to eat their usual diet for the first 7 to 14 days so we can make sure they are tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). Hopefully you can find a diet on the list that $\begin{bmatrix} B_0 \end{bmatrix}$ likes to eat. Alternatively, you can research the amount of sodium in your dog's current diet to ensure that the sodium content is similar to those on the list. The HeartSmart web site also has some information on supplements such as fish oil, taurine, and other supplements that you might have questions about (http://vet.tufts.edu/heartsmart/diet/).

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- Werecommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- O The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVM/Updates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://wetnutrition.tufls.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Option:

Royal Canin Early Cardiac (veterinary diet)

Correct	l Food Oations:
12000	

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew Royal Canin Mature 8+

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise Recommendations:

Please continue limiting B6 activity and avoiding any strenuous exercise when possible.

Recheck Visits: We want to recheck her in 10-14 days (06/07/19). At this visit we will want to check B6 breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram and/or chest radiographs (x-rays) are recommended in 3 months.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tults.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

http://vet.tufts.edu/heartsmart/

Prescription Refill Discloimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Tripls:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case: B6	Owner: B6	Discharge Instructions	

Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

Date: 5/24/2019

 B6
Patient ID: B6 B6 Canine Canine Years Old Female (Spayed) Cocker Spanie

Cardiology Appointment Report

Attending Cardiologist:	
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC	
B6	
Cardiology Resident:	
B6	
Cardiology Technician:	
B6	
Student: B6 V20	
<u>Presenting Complaint:</u> Recheck for hx of advanced DMVD with active left sided CHF on	В6

Concurrent Diseases: None

<u>General Medical History</u>: Still coughing and doing a lot of panting. When sleeping, has to splay on the ground on a cold surface. When walking any tiny bit, she will start panting. She hasn't been really eating. Having a hard time giving her medication and tries to grind it into her food but P is not really eating much of her food.

Diet and Supplements:

Bill Jack Persnickety - BID

Cardiovascular History:

Prior CHF diagnosis? Y
Prior heart murmur? Y
Prior ATE? N
Prior arrhythmia? Y
Monitoring respiratory rate and effort at home? N
Cough? Y
Shortness of breath or difficulty breathing? Y

Exercise intolerance? Y Current Medications Pertinent to CV System: **B6** Cardiac Physical Examination: **B6** Muscle condition: Normal Moderate cachecia Mildmuscleloss Marked cachecia Cardiovascular Physical Exam: Murmur Grade: None ₩ rv/vi I/VI ■ v/vi Murmur location/description: left apical systole Jugular vein: Bottom 1/3 of the neck 1/2 way up the neck Middle 1/3 of the neck Top 2/3 of the neck Arterial pulses: Weak Bounding Pulse deliaits Fair Good 🔲 Pulsus paradoxus Strong Other: Arrhythmia:

Syncope or collapse? Has not collapsed since last Saturday during her last incident.

Sudden onset lameness? N

NoneSinus arrhythmiaPremature beats	■ Bradycardia ■ Tachycardia	
Gallop: ☐ Yes ☑ No ☐ Intermittent	Pronounced Other:	
Pulmonary assessments: Eupneic Mild dyspnea Marked dyspnea Normal BV sounds	Pulmonary crackles Wheezes Upper airway stridor	
Abdominal exam: Normal Hepatomegaly Abdominal distension	Mild ascites Marked ascites	
<u>Problems</u> : CHF with advanced DMVD Pulmonary hypertension		
Diagnostic plan: Echocardiogram Chemistry profile ECG Renal profile Blood pressure Echocardiogram Findings:	☐ Dialysis profile ☐ Thoracic radiographs ☐ NT-proBNP ☐ Troponin I ☐ Other tests:	
B6		
	active left-sided CHF. Heart rhythm is better com	
rare ventricular arrhythmias were seen today. Patient still has some respiratory effort, but seems brighter and alert. Reduced contractile function is not routinely seen in DMVD, but since there were very frequent		
	t, these factors should also be considered. Reco	-
give	B6	Recheck
in 7 days.		

Reduced Contractile function.		
Heart Failure Classification Score:		
ISACHC Classification:		
🔲 la	🗹 Illa	
□ lb	🔲 IIIb	
□		
ACVIM Classification:		
□ A	∠ C	
□ B1	D D	
□ B2		

Final Diagnosis:

From: To: CC: Sent: Subject:	Freeman, Lisa <lisa.freeman@tufts.edu> Jones, Jennifer L Peloquin, Sarah; Guag, Jake 7/2/2019 1:45:01 PM RE: B6 euthanized</lisa.freeman@tufts.edu>
Hi Jen	know. I'll update her primary care vet
	nary Nutritionist TM Veterinary Medicine utrition Science and Policy nslational Science Institute
Sent : Tuesday, July 0 To: Freeman, Lisa <l< td=""><td>isa.Freeman@tufts.edu> <saarah.peloquin@fda.hhs.gov>; Guag, Jake <jake.guag@fda.hhs.gov></jake.guag@fda.hhs.gov></saarah.peloquin@fda.hhs.gov></td></l<>	isa.Freeman@tufts.edu> <saarah.peloquin@fda.hhs.gov>; Guag, Jake <jake.guag@fda.hhs.gov></jake.guag@fda.hhs.gov></saarah.peloquin@fda.hhs.gov>
Currently, we are not	late about B6 m sorry to hear that she passed away. collecting more tissues for DCM histopathology except on a case-by-case basis. We will blogy or tissue for B6 case.
Jennifer Jones, DVM Veterinary Medical Offic Tel: 240-402-5421	er
Sent: Monday, July 0	< <u>Jennifer.Jones@fda.hhs.gov</u> >; Peloquin, Sarah < <u>Sarah.Peloquin@fda.hhs.gov</u> >; Guag,
contractility) and that	ne dogs in our study (Cocker Spaniel with heart failure, mitral valve disease but reduced we reported to you, was euthanized on B6 The RDVM is holding the body in case at I wasn't sure if it would be too autolyzed at this point. Can you let me know either way date the vet?

Lisa M. Freeman, DVM, PhD, DACVN

Board Certified Veterinary NutritionistTM
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification;

B6

6/10/2019 8:20:57 PM Sent:

Subject: Fromm Game Bird Recipe Dog - Four-Star - Dry -Grain-Free formula: **B6**

EON-390092

Attachments: 2068038-report.pdf; 2068038-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390092] has been created in the EON System.

A "PDF" report by name "2068038-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068038-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390092

ICSR #: 2068038

EON Title: Related PFR Event created for Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula;

2068038

AE Date	04/16/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Hound (unspecified)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068038

Product Group: Pet Food

Product Name: Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula

Description: Patient presented to rDVM for evaluation of abdominal distension x 5 weeks and increase in respiratory rate and effort. FAST scan revealed moderate ascites. Patient was referred to Tufts for further evaluation. Findings consistent with advanced DMVD with suspect L-CHF and poor contractile function.

Considering LA enlargement and severity of MR and AI, we would expect a better systolic function.

B6 10mg BID is recommended. Mild respiratory effort and occasional b-lines vote in favor to L-CHF. There is enough cardiac changes to justify L and R CHF. Since patient is on a BEG diet, it is unclear whether diet is playing a role on decreased contractile function. Recommend transition to a grain-based, low sodium diet and consider Taurine supplementation. Abdominocentesis was performed (5 liters of serous sanguineous fluid) and analysis is recommended. Recommend hospitalization, patient on telemetry monitoring and respiratory watch. Fluid check in the morning and kidney values daily while in the hospital. Since patient is on a BEG diet, recommend transition to a grain-based, low sodium diet.

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product) **Outcome of reaction/event at the time of last observation:** Better/Improved/Recovering

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula		

This report is linked to:

Initial EON Event Key: EON-388971

Initial ICSR: 2067510

Sender information

B6

Owner information

B6

To view this Related PFR Event, please click the link below:

https://eon.fda.gov/eon//browse/EON-390092

To view the Related PFR Event Report, please click the link below:

https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=407364&parentIssueTypeId=12

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-	390092			
ICSR:	2068038			
Type Of Submission:	Followup			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	7.00 	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary			
Report Submission Date:				
Initial Report Date:	05/28/2019			
Parent ICSR:	2067510			
Follow-up Report to FDA Request:	Yes			
Reported Problem:	Date Problem Started: Concurrent Medical Problem: Pre Existing Conditions:	2		
	Outcome to Date:	Better/Improved/Recovering		
Product Information:	Product Name:	Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula		
	Product Type:	}		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:			
	Manufacturer			
	/Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:			
	Type Of Species:			
	3	Hound (unspecified)		
	Gender:			
	Reproductive Status:	3		
		38.9 Kilogram		
		B6 Years		
	Assessment of Prior Health:			
	Number of Animals	1		

	Given the Product:			
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name: B6	
		Address:	B6 United States	
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine	
	Information:	Contact:		
			Email:	
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States	
		Practice Name:	Tufts University Cummings School of Veterinary Medicine	
		Contact:	Name: Lisa Freeman	
			Phone: (508) 887-4696	
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States	
		Permission to Release Records to FDA:	Yes	
Sender Information:	Name:		B6	
	Address:	200 Westboro Road North Grafton Massachusetts 01536 United States		
	Contact:	Phone: Emai	B6	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
	Reported to Other Parties:	None		
Additional Documents:				
	Attachment:	Complete amino acid analysis 5-29-2019.pdf ption: Lab work		
	Description:			
	Type:	ype: Laboratory Report		
	Attachment:	troponin 5-30-2019.pdf		
		ption: Lab work		
		Type: Laboratory Report		
	- 7	7		

Attachment:	Follow-up medical records.pdf
	Medical Records
Туре:	Medical Records
	-1

B6

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Ve	terina	ry M	edio	al	Center
	TUFTS				

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client:	В6	
Veterinariar	1:	
Patient ID:	В6	
Visit ID:		

Patient:	B6
Species:	Canine
Breed:	Treeing Walker Coonhound
Sex:	Male (Neutered)
Age:	B6

Lab Results Report

Chemistry 21 (Cobas)	6/7/2019 2:48:19 PM	Accession ID: B6	
Test	Results	Reference Range	Units
PHOSPHORUS		2.6 - 7.2	mg/dL
GLUCOSE		67 - 135	mg/dL
A/G RATIO		0.7 - 1.6	
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
CALCIUM2		9.4 - 11.3	mg/dL
ALBUMIN		2.8 - 4	g/dL
AST		9 - 54	U/L
POTASSIUM	B6	3.7 - 5.4	mEq/L
ALK PHOS		12 - 127	U/L
CHOLESTEROL		82 - 355	mg/dL
UREA		8 - 30	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
NA/K		29 - 40	
COMMENTS (CHEMISTRY)		0 - 0	
CREATININE		0.6 - 2	mg/dL
ALT		14 - 86	U/L
T BILIRUBIN		0.1 - 0.3	mg/dL

stringsoft

3/12 **B6**

Printed Monday, June 10, 2019



Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://vetmed.tufts.edu/

Discharge Instructions

Patient	Owner	,	
Name: B6	Name	B6	Patient II): B6
Species: Canine	Address:	B6	
Tricolor Male (Neutered) Treeing Walker		В	
Coorhound			
Birthdate: B6			
Attending Cardiologist: John E. Rush DVM, MS, DACVIM (C	ardiology), l	DACVEOC	
B6			
Cardiology Resident:			
В	6		
Cardioloev Technician:	1		
B6			
Student: B6			
Admit Date: 6/7/2019 1:52:55 PM Discharge Date: 6/7/2019			
Diagnoses: Chronic valvular disease with m and ascites.	itral regurgi	tation, history of congestive	heart failure with pulmonary edema
Clinical Findings: Thank you for bringing Bostill had residual fluid in his abdomen during has been eating wonderfull since last visit! Y	g his last visi	it. You report he has been to	olerating his medications very well and
On physical exam today, B6 was bright and last visit. His pulses were good today. We to (ascites). B6 ascited has almost completely	ook a quick l	ook at B6 belly with the ul	trasound to check for fluid in his abdomer
We have submitted a chemistry panel to re You should hear back with these results in t the frequency of the B6 o twic		_	
Monitoring at Home:			

*You can evaluate the fluid in his belly by using a malleable measuring tape around the same part of his abdomen every other day. If you notice significant increases in size, this may also mean that you should give an extra dose of

furoserride. * Please let us know if additional doses are given.

We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well
controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by
the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. <u>An increase in</u>
breathing rate or effort will usually mean that you should give an extra dose of B6 If difficulty
breathing is not improved within 30-60 minutes after giving extra B6 then we recommend that a recheck earn be
scheduled and/or that 86 be evaluated by an emergency clinic. There are instructions for monitoring breathing, and a
form to help keep track of breathing rate and drug doses, on the Tults HeartSmart web site (http://vet.tults.edu/heartsmart/at-home-monitoring/).
Turtely was rough and an amount and the second and an amount and the second and an amount and the second and a
We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as
these findings indicate that we should do a recheck examination.
THE INCHES INDICATE AND MERICAN COLORS CONTINUES.
Diet Suggestions: Continue B6 on his early cardiac diet. He is on the thinner side right now so we recommend increasing
his food from 4 cups a day to 5 cups a day.
Recommended Medications:
B6
Recheck Visits: B6 has an appointment recheck scheduled <u>for the study</u> he is participating in at <u>2pm on August 23rd</u> with
B6
Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at
cardioxet@tults.edu for scheduling and non-emergent questions or concerns.
Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/
Prescription Refill Dischoiner:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past
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year in order to obtain prescription medications. Ordering Food: Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval. Clinical Trials: Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a
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Cummings Veterinary Medical Center

Foster Hospital for Small Animals 55 Willard Street North Grafton, MA 01536 Te lephone (508) 839-5395 Fax (508) 839-7951 http://vetmed.tufts.edu/

Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:

- Most other dog treats are high in sodium.
- If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

Product	Calories per treat
Dogs	
Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat	8
Hill's Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat	34
Hill's Science Diet Soft Savories Peanut Butter & Banana, Beef & Cheddar, or Chicken & Yogurt Dog Treat	25-27, depending on flavor
Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots, Duck & Pumpkin, or Beef & Sweet Potato Dog Treat	12-13, depending on flavor
Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken & Barley	27-29, depending on flavor
Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb or beef, bacon, cheese, peanut butter)	16
Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)	58
Royal Canin Original Canine treat	5
Cats	
Royal Canin Original Feline treat	2
Fancy Feast Duos Natural Rotisserie Chicken Cat treat	2
Fancy Feast Duos Tuna with Accents of Parsley Cat treat	2

Taste enhancers to can make your pet's food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes

- All foods in this list should be prepared without salt
- These taste enhancers should be added in small amounts. If your pet eats too much of them, they will
 unbalance the diet and increase your pet's risk for nutritional deficiencies

Dogs

- Honey or maple syrup
- Homemade chicken, beef, or fish broth (made without salt; avoid all deli meats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- Sugar (brown or white) Domino pourable light brown sugar is a good option
- Vanilla or fruit yogurt One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
- Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- Applesauce (be sure they have less than 50 mg sodium per serving)
- Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico's no salt added)
- Frosted Mini Wheats Original these can be crumbled on his food
- Lean meats, cooked (chicken, turkey, beef, or fish) not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- Eggs, cooked



Dogs (continued)

- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium).
 Avoid all canned soups unless labeled as no salt added
- Low-salt breakfast cereal the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- Low sodium canned dog foods

Cats

- Lean meats, cooked (chicken, turkey, beef, or fish) not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- Eggs, cooked
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- Low sodium canned cat foods

Foods to avoid

- Fatty foods (meat trimmings, cream, ice cream)
- Baby food
- Pickled foods
- ▼ Bread
- Pizza
- Condiments (ketchup, soy sauce, barbecue sauce, etc unless they are unsalted or no salt added)
- Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- Rotisserie chicken
- Most cheeses, including "squirtable" cheeses
- Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- ♥ Canned vegetables (unless "no salt added")
- Potato chips, packaged popcorn, crackers, and other snack foods
- Soups (unless homemade without salt)
- Most commercial pet treats

Tips for administering medications

Foods commonly used to administer your pet's pills can provide a large amount of additional salt to your pet's diet. Preferable ways to give medications include:

- Have one of our staff show you how to give medications without using food
- Insert medications into one of the following foods:

Dogs or cats

- Low-sodium canned pet food
- Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
- Whipped cream (Reddi Wip)
- Marshmallows
- Greenies Pill Pockets
 - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
 - Avoid grain-free duck and pea which is high in sodium
 - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
 - Caution: Not all similar products from other companies are low in sodium.

Dogs

- Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
- Peanut butter (only if labeled as "no salt added") examples include Smucker's Natural Creamy
 Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
- Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol).
 Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting)

You may find our Petfoodology post called, "Pill-popping pets" helpful for additional ideas: http://vetnutrition.tufts.edu/2018/09/foods for giving pills/

Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

B6

Patient D: | B6 | Kris Canine | B6 | Male (Neutered) Treeing Walker Coorhound Trirolor

Cardiology Appointment Report

Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Cardiology Technician:

<u>Presenting Complaint</u>: Recheck. DMVD with decreased contractile function and recent history of CHF (5/22/19). Persistent mild to moderate ascites during last visit 5/29/19.

Concurrent Diseases:

Blindness- unknown etiology (saw optho but declined further diagnostics)

General Medical History:

Appetite back to normal, taking medications no problem, less restless, belly seems less distended than last visit. Looks thinner than he was prior to CHF

History of splenic hematoma.

Had loose bowel movements recently but also had change in diet.

Flaky skin

Student

Rind

Diet and Supplements:

Royal canin early cardiac- 4 cups a day

Cardiovascular History:

Prior CHF diagnosis? Y Prior heart murmur? Y-III Prior ATE? N

Prior arrhythmia? N Monitoring respiratory rate and effort at home? Yaveraging 33 Cough? N Shortness of breath or difficulty breathing? N Syncope or collapse? N Sudden onset lameness? N Exercise intolerance? N **Current Medications Pertinent to CV System: B6** Cardiac Physical Examination: **B6** Muscle condition: ■ Normal Moderate cachecia Mild muscle loss Marked cachecia Cardiovascular Physical Exam: Murmur Grade: ■ None ועעו 🜌 🗷 III/YI Murmur location/description: left apical systolic Jugular vein: Bottom 1/3 of the neck 1/2 way up the neck

III Middle 1/3 of the neck	■ 1op 2/3 of the neck
Arterial pulses:	
Weak	☐ Bounding
□ vreak. □ Fair	Pulse deficits
☑ Good	Pulsus paradoxus
☐ Strong	Other:
= 30 or B	= vuki.
Arrhythmia:	
None	■ Bradycardia
Sinus arrhythmia	■ Tachycardia
Premature beats	•
Gallop:	
■ Yes	Pronounced
₩ No	Other:
Intermittent	
Pulmonary assessments:	
Eupneic	Pulmonary crackles
Mild dyspnea	Wheezes
Marked dyspnea	Upper ainway stridor
Mormal BV sounds	
Abdominal exam:	
Abouminal exam:	Mild assites
Hepatomegaly	Marked axites
Abdominal distension	maker auto
Problems:	
CMVD;	
Hx of CHF:	
Hx of ascites;	
rix or asches,	
Diagnostic plan:	
Echecardiogram	Dialysis profile
Chemistry profile	Theracic radiographs
ECG	NT-proBNP
Renal profile	Troponin I
■ Blood pressure	Other tests: fluid check
•	
Echocardiogram Findings:	
General/2-D findings: *fluid check*	
There is very mild ascites visualized. No pericare	dial effusion or h-lines seen.
THE CITY OF THE GENERAL TO BE REAL	
Assessment and recommendations:	
	on abdominal fluid and, since patient is clinically better
-	nd maintain current medications doses and frequency.
Since blood work revealed increase in kidney va	
■	a week and keep counting respiratory rate. Recommend
-	a. Recheck kidney values and echocardiogram in 2
months, sooner it clinical signs occur such as de	creased appetite, lethargy, abdominal distension, or

DMVD with PHTN;	
Reduced contractile function.	
Heart Failure Classification Score:	
SACHC Classification:	
🔲 la	📝 Illa
■lb	🔲 IIIb
■ II	
ACVIM Classification:	
■A	₩ C
■ B1	■ D
□ B2	

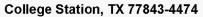
Final Diagnosis



Gastrointestinal Laboratory Dr. J.M. Steiner

Department of Small Animal Clinical Sciences Texas A&M University

4474 TAMU





GI Lab Assigned Clinic ID: 23523

Dr. Freeman Tufts Cummings School of Vet Med - Cardiology/Nutrition 200 Westboro Road North Grafton, MA 01536 USA

Phone: 508 887 4696 Fax:

Animal Name: Owner Name:

Species: Canine Date Received: May 30, 2019

Tufts Cummings School of Vet Med -Cardiology/Nutrition Tracking Number: 309861

Ultra-Sensitive Troponin I Fasting

GI Lab Accession:

B6

Reference Interval Assay Date ≤0.06 05/31/19

Result

Comments:

Phone: (979) 862-2861 Fax: (979) 862-2864

<u>Test</u>

GI Lab Contact Information

Email: gilab@cvm.tamu.edu vetmed.tamu.edu/gilab

From: To: CC: Sent: Subject: Attachments:	Jones, Jennifer L Palmer, Lee Anne; Rotstein, David; Palmer, Lee Anne; Queen, Jackie L Ceric, Olgica; Nemser, Sarah; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' 5/9/2018 10:53:13 AM RE: Zignature Kangaroo Formula: 800.261- EON-351031- B6 MRx.pdf
·	ith low Taurine we recently tested (per feline AAFCO minimum Tau).
Golden Retriever with leading B6 responsive	ow blood taurine and a persistent history of arytenoid dysfunction, possible B6 Since 9 months old
appetite for 2 days, usubut discontinued becaud DCM & L-CHF, tentative eating ok, increased legumes in the diet like on Zignature Kangaroo he ate Acana Ranch Laàno supplements were restless at night but PE 2/23: { B6 Labs: 2/23 Wholest	2/23/2018: CHF possible, consult; tachycardia, last 3 days dyspneic, no cough, poor lally ravenous, decreased energy level, on B6 over a year, tried B6 se it wasn't helping; long history of a panting and swallowing disorder à diagnosed w/ e pulmonary edema à start B6 à 2/27 breathing better, B6 for gagging à 3/1 Tau low, dog still on Zignature Kangaroo diet à vet said by prevent Met & Cys absorption à switched to Royal Canin Kangaroo & Oat; the dog was last 2-3 years, eats milkbones and baked dog treats from a bakery; before the Zignature, amb, Natural Balanace Bison & SP, Natural Balanace Fish & SP, Zignature Trout & Salmon taken before the DCM diagnosis à by 3/13 dog was eating Royal Canin Kangaroo à 3/22 B6 try B6 gallop, panting; at rest/lying down still tachypneic Blood Tau: B6 dilated LV w/ poor systolic function, LA enlarged, mod MR & TR, dec aortic and
	Вб
Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 DA U.S. FOOD & DRUG	
Cc: Rotstein, David <d< th=""><th></th></d<>	
Thanks, Lee Anne. No,	I wasn't expecting it, but I can start with MRx!

FDA U.S. FOOD & DRUG

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

From: Palmer, Lee Anne

Sent: Thursday, April 12, 2018 1:39 PM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>

Cc: Rotstein, David < David.Rotstein@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >

Subject: FW: Zignature Kangaroo Formula: B6 - EON-351031

Hi Jen – were you expecting this one? Thx - LA

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]

Sent: Thursday, April 12, 2018 1:36 PM

To: Cleary, Michael * < Michael. Cleary@fda.hhs.gov>; HQ Pet Food Report Notification

<hacherolation | Subject: Zignature Kangaroo Formula: | B6 | - EON-351031

A PFR Report has been received and PFR Event [EON-351031] has been created in the EON System.

A "PDF" report by name "2045676-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-351031

ICSR #: 2045676

EON Title: PFR Event created for Zignature Kangaroo Formula; 2045676

AE Date	02/22/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	6 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2045676

Product Group: Pet Food

Product Name: Zignature Kangaroo Formula

Falls for tachypnea. He was diagnosed with dilated cardiomyopathy and left side congestive heart failure. Whole

blood taurine level was B6 At the time, patient consuming Zignature

Kangaroo Formula and was advised to change.

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature Kangaroo Formula		

Sender information
B6
USA

<u>Owner</u>	<u>information</u>	
	B6	USA

To view this PFR Event, please click the link below:

To view the PFR	R Event Report, please click the link below:	
	B6	
B6		

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Patient History Report Client: Patient: Phone: Species: Canine Breed: Retriever, Golden Age: Address: Sex: Neutered Male Color: Blonde Date Type Staff History 4/12/2018 C MEDICAL COMMENTS ***ADDENDUM 4/20/2018 4/12/2018 13:26 FDA Safety Reporting Portal - Individual Case Safety Report Number (ICSR) ADDENDUM on 4/20/2018 at 08:34:23 from **B6** permission signed and returned to CS 3/24/2018 P B6 3/24/2018 C PHARMACY NOTE TTO. Meds have been refilled **B6** 3/24/2018 P **B6** 3/22/2018 C COMMUNICATIONS WITH CLIENT 3/22/2018 13:03 dog is restless at night, making breathing sound, but sRR is consistently at 22 brpm, so i do not think do has pulmonary edema, will try B6 recheck in end of april B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

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B6

FDA-CVM-FOIA-2019-1704-005399

Date: 4/20/2018 5:17

Patient History Report

Client: Phone: Address:

В6

B6

Patient: B6
Species: Canine
Age: B6
Color: Blonde

Breed: Retriever, Golden Sex: Neutered Male

Date Type	Staff	History
Í		
3/13/2018 C		COMMUNICATIONS WITH CLIENT 3/13/2018 10:36 SWO - Owner consented to reporting B6 case to the FDA. He has been on the Zignature Kangaroo for the past 2-3 years. Treats include Milkbones and baked dog treats from pet bakery. Prior to the Zignature Kangaroo, he consumed the Acana Ranch Lamb, Natural Balance Sweet Potato and Bison, Natural Balance Sweet Potato and Fish, Zignature Trout & Salmon. He was receiving no supplements prior to his DCM diagnosis. Owner will forward me a copy of her most recent Chewy.com receipt for the Zignature. She does not have the bag anymore. I will email her for additional information. She is now feeding the Royal Canin Kangaroo and Oats.
3/1/2018 D		Taurine Deficiency Final
3/1/2018 C	В6	COMMUNICATIONS WITH DOCTOR 3/1/2018 13:22 i called vet, to let them know taurine is low, she is still on kangaroo diet from Zignature, rec to change diet. The legumes in diet are most likely preventing methionine and cystine absorption, should switch to Royal Canin kangaroo and oats, i originally Im and he called back. he said he would call owner
3/1/2018 C		COMMUNICATIONS WITH CLIENT 3/1/2018 13:20 i called client to let her know taurine is low, she is still on kangaroo diet from Zignature, rec she talk to her vet at last appt, and she did to day at a recheck, and told her to wait. The legumes in diet are most likely preventing methionine and cystine absorption, should switch to Royal Canin kangaroo and oats, I will call her vet.
2/27/2018 C		COMMUNICATIONS WITH CLIENT 2/27/2018 11:03 i called owner, dog is breathing better, eating fine, getting sRR 18-26, did have throat issues, does gagging, pred helped, increased pred again, continue as planned, waiting on taurine level. if normla will start B6
2/24/2018 L		Miscellaneous results from B4, B6
	, M:Image cases	k-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, nedl note, V:Vital signs

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FDA-CVM-FOIA-2019-1704-005400

Date: 4/20/2018 5:17

Patient History Report **B6** Client: Patient: Phone: Breed: Retriever, Golden Species: Canine Address: **B6** Sex: Neutered Male Age: Color: Blonde Date Type Staff History B6 (East) Requisition ID: Posted Final Profile: Taurine RE: 16759 Taurine B6 B6 Normal Values (nmols/ml) Normal Range Critical Level Cat Plasma 60-120 Less than 40 Whole Blood 300-600 Less than 200 60-120 Dog Plasma Less than 40 Whole Blood 200-350 Less than 150 TEST PERFORMED AT **B4**, **B6** LABORATORY 2/23/2018 C PHARMACY NOTE **B6 B6** Pulmonary Edema Tentative 2/23/2018 D 2/23/2018 D Taurine Deficiency Tentative Date Diagnosis made final: 03/01/18 Dilated Cardiomyopathy Tentative 2/23/2018 D 2/23/2018 I Cardiology Discharge Instructions **B6** 2/23/2018 A cardiologist has evaluated B6 and has diagnosed her with Dilated Cardiomyopathy (DCM). DCM means your pet has poor muscle contraction of the heart. This means the heart muscle does not pump as well as a normal dog. The heart has enlarged due to the poor muscle contraction. The change in the heart has caused fluid to form in the lungs, causing increased respiratory rate.

Please take a sleeping respiratory rate rate (sRR) at home. WHILE YOUR PET IS SLEEPING, count the number of times they breathe in over 15 seconds. Your pet should have 8 breathes or less over 15 seconds while sleeping. Do this once a day over the next 3 days, then 2 times a week thereafter.

The free app software for iPhone and Google Play that can help with this is Cardalis

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

Page 3 of 30

Date: 4/20/2018 5:17

Patient History Report Client: Patient: Phone: Species: Canine Breed: Retriever, Golden Address: Age: B6 Sex: Neutered Male Color: Blonde Date Type Staff History I have submitted blood for a taurine level. The result may not return for 2 weeks. In the mean time, please start Taurine at home, 2 gram two times a day with food. This can be purchased at any health food store. I will call in about 2 weeks with a taurine level. **MEDICATIONS: B6** Watch for the following clinical signs and call a veterinarian if you see any of these: Excessive panting or wheezing Restlessness, unable to get comfortable Decreased appetite Lethargy/weakness, less interactive or hiding Collapse or fainting Sudden rear leg or front leg lameness Open-mouth breathing It has been a pleasure meeting you and caring for your B6 Thank you for entrusting us with her care. If you have any further questions or problems, don't hesitate to call. **B6** 2/23/2018 P B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

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B6

FDA-CVM-FOIA-2019-1704-005402

Date: 4/20/2018 5:17

		Pati	ent History	Report		
Client: Phone: Address:	B	3	Patient: Species: Age: Color:	Canine	Breed: Retriever, Golden Sex: Neutered Male	_
Date Type	Staff	History				<u> </u>
2/23/2018 P	В6		E	86		
2/23/2018 C		CARDIAC EV	ALUTION - CLO	SED 02/24/201	8 - Cardiac Evaluation	
Date of evaluation:	Friday, Fe	bruary 23, 2018				
CHIEF COMPLAIN	NT: tachy	onea				
usually ravenous.	Energy le	vel seems dowr	n. No cardiac r	nedications	Appetite has been poor last 2 day B6 for over y panting and swallowing disorder.	ear,
PHYSICAL EXAM	: [В6		
			B6			
ECHOCARDIOGRA	M 2/23/18:	B6	36			
COMMENTS: dila TR. Reduce aortic					nent. Large EPSS. Moderate MR	and
DIAGNOSIS/PRO	BLEM LIS	T: dilated card	iomyopathy (D	CM), left side	congestive heart failure (LCHF)	
personal communi	cations ar	nongst cardiolo	gist of a rash o	f cases of Go	rine deficiency. There have been lden Retrievers on grain free and/ a whole blood level taurine today as below. If taurine deficiency	/or
B:Billing, C:Med note, CB:Cal I:Departing instr, L:Lab result, R:Correspondence, T:Images	M:Image cases	, P:Prescription, PA:PVL	ns, D:Diagnosis, DH:De _ Accepted, PB:problem	clined to history, E:E) s, PP:PVL Performed	kamination, ES:Estimates, I, PR:PVL Recommended,	_
B6		Pag	ge 5 of 30	Dat	e: 4/20/2018 5:17 PM	

		Patie	nt History Re	port		
Client: Phone: Address:	B	3	Patient:	B6		Retriever, Golden Neutered Male
Date Type	Staff	History				
						s, but dog may feel bette level in 2 weeks. They
		B6				
2/23/2018 V		Feb 23, 2018 	: 01:06 PM Staf	f: B6 kilograms		
2/23/2018 CK 2/23/2018 CB		Callback - Call C	: Consult ecked Out: 02/23/18 Dlient Back (CB)			
		Note from Called Wedgew	B6 on 2 ood Pharmacy, spo B	2/23/ <u>2018 at</u> bke td B6 36	15:51:32 on	2/23/2018 at 15:06:34
	B6			B6		
2/22/2018 TC		RECORDS FRC 2/22/2018 14:	(see attachme s attached		
3/10/2017 C		COMMUNICATI 3/10/2017 10:	ONS WITH CLIEN	T		
				B6		
3/8/2017 L	7	Endocrinolog (East) Requi	y results from sition ID: 31	5958	B4, B Posted	6 Final
B:Billing, C:Med note, CB:Ca :Departing instr, L:Lab result. R:Correspondence, T:Images	, M:Image cases,	P:Prescription, PA:PVL Ad				
B6		Page	6 of 30	Date:	4/20/2018 5: F	17 PM

Patient History Report B6 Client: Patient: Phone: Breed: Retriever, Golden Species: Canine Address: **B6** Sex: Neutered Male Age: Color: Blonde Date Type Staff History Result Test Reference Range TSH 0 - 0.60Profile: TSH Ascn: **B6 B6** RADIOLOGY REVIEW - CLOSED 03/08/2017 3/7/2017 C B6 This review was written by: 3/7/2017 V Weight : 41.40 kilograms **B6** 3/7/2017 CK recheck for ESO Reason for Visit: Recheck Date Patient Checked Out: 03/07/17 Practice TF **B6** 3/7/2017 C IM PHYSICAL EXAM NEW 3/7/2017 10:10 Chief Complaint: reevaluation of hard swallowing; upper airway noise History: B6 was originally evaluated in 2015 for hard swallowing, gagging. A laryngeal exam at that time revealed a nodule on the larynx which was biopsied as granulomatous. He has been on low dose prednisone since. Owner still notices hard swallowing and sometimes regurgitation. He also has upper airway noise when sleeping- breathes through nose and no nasal disharge. Occasional hoarse bark. No diarrhea, no pu/pd. He has gained weight. In 2015 a myasthenia titer was negative. Diet includes zignature kangeroo, unsure of current dose of pred 1 tab in morning and sometimes 1/2 tab at night unsure what strength Previous Medical Problems: B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, l:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs Page 7 of 30 Date: 4/20/2018 5:17 **B6** PM

Client: Phone: Address:	B		ent History Patient: Species: Age: Color:	B6	Retriever, Golden Neutered Male
Date Type	Staff	History			
		Medications/Su	upplements:		
		Current Diet:			
				B	
		Diagnostics:	bolow		
			. 1. D=M.118(B6	
		Problems/Diffe	rential Diagnose	es/Assesssment	
				DG	
				B 6	

Page 8 of 30

В6

Date: 4/20/2018 5:17

ΡМ

Patient History Report Patient: Client: Phone: Breed: Retriever, Golden Species: Canine В6 Address: Age: Sex: Neutered Male Color: Blonde Date Type Staff History Plan/Recommendations: **B6** 3/7/2017 L Hematology results from Requisition ID: 315958 Final Posted Test Reference Range Result HCT 36 - 6012.1 - 20.3 HGB MCHC 30 - 38 WBC 4.0 - 15.50 - 3Bands 4.8 - 9.3RBC MCV 58 - 79 19 - 28MCH 0 - 150ABS BASO 170 - 400Platelet C Platelet E 60 - 77 12 - 30 Neutrophil Lymphocyte 3 - 10 Monocytes 2 - 10Eosinophil Basophils 0 - 1 Absolute N 2060 - 10600 690 - 4500Absolute L Absolute M 0 - 840Absolute E 0 - 1200Profile: Complete Blood Count Ascn: **B6** Platelet count reflects the minimum number due to platelet clumping. 3/7/2017 L Chemistry results from **B6** Requisition ID: 315958 Posted Final Test Result Reference Range 2.7 - 4.4ALB ALKP 5 - 131 12 - 118 ALT 290 - 1125 AMYL 15 - 66 6 - 31 AST

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

BUN/UREA

Chloride

Ca

CK CREA

GGT

CHOL

B6

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Date: 4/20/2018 5:17

8.9 - 11.4

102 - 120

92 - 324

59 - 895

1 - 12

0.5 - 1.6

B6 Patient: Client: Phone: Breed: Retriever, Golden Species: Canine Address: Age: Sex: Neutered Male Color: Blonde Date Type Staff History 70 - 138GLU 1.5 - 2.5Mg PHOS 2.5 - 6.03.6 - 5.5Potassium 139 - 154 Sodium 0.1 - 0.3TBIL 5.0 - 7.4 ΤP TRIG 29 - 291 1.6 - 3.6GLOB A/G Ratio 0.8 - 2.0B/C Ratio 4 - 27 27 - 38Na/K Ratio B4, B6 3/7/2017 L Endocrinology results from B4, B6 Requisition ID: 315958 Posted Final Test Result Reference Range B6 ug/dL L Т4 0.8 - 3.5B6 Profile: Total T4 Ascn: The Total T4 result is less than 1.0 mcg/dl. A Free-T4 by equilibrium dialysis may be helpful in supporting the diagnosis of hypothyroidism in patients demonstrating clinical signs compatible with hypothyroidism.Please contact Customer Service for this additional testing. 3/7/2017 L Miscellaneous results from B4, B6 B4, B6 Requisition ID: 315958 Posted Final B6 Profile: Superchem **B6** 3/6/2017 C COMMUNICATIONS WITH CLIENT 3/6/2017 12:55 sto confirmed appt w/B6@ 330 on 3/7 B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

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B6

Patient History Report

Date: 4/20/2018 5:17

Patient History Report B6 Client: Patient: Phone: Breed: Retriever, Golden Species: Canine Address: Age: Sex: Neutered Male Color: Blonde Date Type Staff History 2/26/2017 C COMMUNICATIONS WITH CLIENT 2/26/2017 10:15 LMOM to confirm 3:30 pm ESO appt tomorrow 2/23/2017 TC RECORDS FROM RDVM/LDVM (see attachment) - TENTATIVE 2/23/2017 20:36 Records from **B6** Áttachment(s) 2/23/2017 C COMMUNICATIONS WITH DOCTOR 2/23/2017 17:18 **B6** to request updated records from 5/3/15 forward be faxed RECEPTION ACTIONS NOTE 2/20/2016 C faxed ref letters and labs to B6 per o's req 9/28/2015 C OUTSIDE PHARMACY RX ***ADDENDUM 10/2/2015 - Closed Sep 30/2015 Is this medication a controlled substance?

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

Patient History Report								
Client: Phone: Address:	B 6	S _F	Patient: [pecies: Age: [Color:	B6		etriever, Golden eutered Male		
Date Type	Staff	History						
		Additional Comments: 1 ADDENDUM on 10/1/2		1:11:18 from [:=:=:=:::::::::::::::::::::::::::::::::			
9/28/2015 C		COMMUNICATIONS W 9/28/2015 13:29 B6 was good for 2 mor months. last time, we d we can repeat abx trea dual treatment for B6	nths, thei liscussed tment as	n small flair up I repeat abx t	reat may not be he	elpful. discussed that		
6/1/2015 C	В6	OUTSIDE PHARMACY		osed Jun 04/2	2015			
	M:Image cases, I	in, CM:Communications, D:Diagno P:Prescription, PA:PVL Accepted, P idl note, V:Vital signs						
B6		Page 12 of 3	0	Da	te: 4/20/2018 5:17 PM			

Patient History Report Client: Patient: **B6** Species: Canine Phone: Breed: Retriever, Golden Address: Age: **B6** Sex: Neutered Male Color: Blonde Date Type Staff History 6/1/2015 C COMMUNICATIONS WITH CLIENT 6/1/2015 16:05 within the last 3 days stopped doing the neck movement/episodes that he was having. still sounds congested. when he barks there sounds like there is something in there, would continue B6 unless we are planning to rescope him. owner needs refill of B6 will touch base in 1-2 wks. **B6** 5/17/2015 C COMMUNICATIONS WITH CLIENT 5/17/2015 10:26 swo and asked how B6; is doing, owner said she started ab's yesterday and so far he is doing well, owner will recheck in one week 5/15/2015 C OUTSIDE PHARMACY RX - Closed May 17/2015 **B6** 5/15/2015 C **OUTSIDE PHARMACY RX B6** B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs Date: 4/20/2018 5:17 Page 13 of 30 **B6**

Patient History Report Patient: Client: **B6** Phone: Species: Canine Breed: Retriever, Golden Age: B6 Address: Sex: Neutered Male Color: Blonde Date Type Staff History Prescribing doctor: **B6 B6** 5/15/2015 C COMMUNICATIONS WITH CLIENT ***ADDENDUM 5/15/2015 **B6** 5/15/2015 16:27 **B6 B6** 5/12/2015 C COMMUNICATIONS WITH CLIENT 5/12/2015 14:50 B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

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B6

Date: 4/20/2018 5:17

Patient History Report								
Client: Phone: Address:	Patient: B6 Species: Canine Age: B6 Color: Blonde	Breed: Retriever, Golden Sex: Neutered Male						
Date Type Staff	History							
	В	36						
5/12/2015 C B6	IM TREATMENT NEW 5/12/2015							
i	Internal Medicine Assessment:	B6 j						
	В	36						
5/8/2015 L	Report RE: 7801 History:	B4, B6 B Posted Final Histopathology, Full Written						
	k-in, CM:Communications, D:Diagnosis, DH:Declined to histo P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Penedl note, V:Vital signs							
B6	Page 15 of 30	Date: 4/20/2018 5:17 PM						

Client:			Patient:	B6		
Phone:			Species:	Canine	Breed:	Retriever, Golden
Address:	DU		Age:	B6	Sex:	Neutered Male
			Color:	Blonde		
L		!				
Date Type	Staff	History				
		-				
				B		
		L				
		Received	d: Multiple frag	ments - all	processed.	•
		RE: 601	Blopsy TION/MICROSCOPIC	FINDINGS/C	OMMENTS	
		DESCRIPT				
					_	
		-				
				B		
			•			
		i				i
		MICROSCO	OPIC FINDINGS:		В6	
		В	6			
		D '				
		PROGNOSI	S: Good			
		COMMENT:		В6		
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		PATHOLOG	SIST:			
		PATHOLOG	SIST:	B6		nunununununun
		email:		B6		i
F/7/0045	DC	-	alla antala IIII	a a factoria de 17	the end of the	Wassan and B
5/7/2015 I	B6	For your p	et's safety, he/she wa	as intubated for	the anesthetic	c. You may notice
B:Billing, C:Med note, CB:Call	back, CK:Check	:-in, CM:Communi	ications, D:Diagnosis, DH:Dec	clined to history, E:Exa	mination, ES:Estima	ites,
Departing instr, L:Lab result,	M:Image cases,	P:Prescription, PA	A:PVL Accepted, PB:problems			
R:Correspondence, T:Images	10.Temative me	sui note, v:Vital Si	ıyı ıs			
B6		I	Page 16 of 30	Date	e: 4/20/2018 5:	17
		'	. 490 10 01 00	Daic		PM

Patient History Report

Patient: Client: Species: Canine Phone: Breed: Retriever, Golden Address: Age: B6 Sex: Neutered Male Color: Blonde Date Type Staff History 5/7/2015 I **B6** 5/7/2015 I **B6** 5/7/2015 C COMMUNICATIONS WITH CLIENT 5/7/2015 14:10 called owner post procedure. discussed scope findings. and discussed possible causes for findings. no treatment recommended until results available. okay to d/c at 5 pm. 5/7/2015 C **ENDOSCOPIC EVALUATION B6** Lower Gastrointestinal: Bronchoscopy: Rhinoscopy: Cystoscopy: B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, l:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs **B6** Page 17 of 30 Date: 4/20/2018 5:17

Patient History Report

Client: Phone: Address:	B	5	Patient: Species: Age: Color:	B6 Canine B6 Blonde		Retriever, Golden Neutered Male
Date Type	Staff	History				
		Other:				
		Biopsies:	E	36		
		Culture/Sensitivi Visual Inspection B6			B6	
		Initial Recomme B6	ndations:		В6	
5/7/2015 C	B6	IM TREATMENT 5/7/2015	NEW			
į		Internal Medicine	e Assessment:		В6	
				B	3	
		Treatment: no tr	eatment today			
		Recommended B6	Follow-up Care):[B6	
5/7/2015 C	В6	IM PHYSICAL E Chief Complaint				
		History:		В6]
				B	6	
					U	
			<u></u>	·····		
Billing, C:Med note, CB:Call eparting instr, L:Lab result, N Correspondence, T:Images,	√I:Image cases,	P:Prescription, PA:PVL Ac	D:Diagnosis, DH:Deccepted, PB:problems	clined to history, E:E: s, PP:P V L Performed	xamination, ES:Estima d, PR:PVL Recommen	ites, ded,
B6		Page	18 of 30	Da	te: 4/20/2018 5:	17

Patient History Report

Client: Phone: Address:	36	Patient: B6 Species: Canine Age: B6 Color: Blonde	Breed: Retrieve Sex: Neutere	
Date Type Staf	f History			
		B	6	
	,Sianificant.Phy	sical Exam Findings: Mentation		

Radiographic Findings: CHIEF COMPLAINT/HISTORY: 5/3/2015. Internal Medicine Assessment: B6

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

Patient History Report

Client: Phone: Address:

B6

Patient: B6
Species: Canine
Age: B6

Color: Blonde

Breed: Retriever, Golden Sex: Neutered Male

Date Type

Staff

History

B6

5/7/2015 L

Chemistry results from IDEXX VetLab In-clinic Laboratory Requisition ID: 197 Test Result ALB = ALKP = ALT = AMYL = BUN/UREA = Ca = Chloride = CHOL = CREA = GGT < GLU = LIPA = PHOS = Potassium = Sodium = TBIL = TP =

Posted Final Reference Range 2.3 - 4.0 23 - 21210 - 125 500 - 1500 7 - 27 7.9 - 12.0109 - 122 110 - 320 0.5 - 1.8 0 - 11 74 - 143 200 - 1800 2.5 - 6.83.5 - 5.8144 - 160 0.0 - 0.9 5.2 - 8.2 2.5 - 4.5

GLOB =
ALB/GLOB =
BUN/CREA =
Na/K =
OSM calc =

PCV=49% TS= 6.8g/dl (serum norm)

5/7/2015 V

B6

May 7, 2015 10:20 AM Staff: **B6**Weight: 36.60 kilograms

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

	Patier	nt History Repo	ort	
Client: Phone: Address:	36	Patient: B Species: Canine Age: B Color: Blonde	6 Sex:	Retriever, Golden Neutered Male
Date Type Sta	aff History			
5/7/2015 L	Hematology re		<pre> VetLab In-clini Posted Reference 37.3 - 61. 13.1 - 20. 32.0 - 37. 5.05 - 16. 2.95 - 11. 0.06 - 1.2 148 - 484 10.0 - 110 5.65 - 8.8 61.6 - 73. 21.2 - 25. 13.6 - 21. 8.7 - 13.2 9.1 - 19.4 0.14 - 0.4 1.05 - 5.1 0.16 - 1.1 0.00 - 0.1 </pre>	Final Range 7 5 9 76 64 3 .0 7 5 9 7
5/7/2015 C RADIOGRAPHIC REPOR		PORT - FINAL 05/07/	2015	
CHIEF COMPLAINT/HIST	ΓORY: 5/3/2015.		B6	
		B6		
FINDINGS:	В6			
B:Billing, C:Med note, CB:Call back, I:Departing instr, L:Lab result, M:Imag R:Correspondence, T:Images, TC:Te				
В6	Page 2	1 of 30	Date: 4/20/2018 5:	17 M

Patient History Report Client: Patient: Phone: Species: Canine Address: Age: Color: Blonde Date Type Staff History SUMMARY/CONCLUSIONS: 5/7/2015 CK

No significant abnormalities are present in the extra-thoracic soft tissues, skeletal structures, pleural and mediastinal spaces, pulmonary and cardiovascular structures, as well as in the visible cranial abdomen. **B6** 5/6/2015 C COMMUNICATIONS WITH CLIENT <u>5/6/2015</u> 11:48 **B6 B6** 5/3/2015 C IM TREATMENT NEW 5/3/2015 Internal Medicine Assessment Treatment: no treatment implemented Recommended Follow-up Care: to return Thursday for further evaluation chemistry, CBC thoracic radiographs, oral exam and endoscopy B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates,

B6

В6

Breed: Retriever, Golden

Sex: Neutered Male

I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

B6 Chief Complaint: History: B6 Significant Physical Exam Findings: Mentation B6	Client: Phone: Address:	B	Patient History Report Patient: B6 Species: Canine Breed: Retriever, Golden Age: B6 Color: Blonde
Chief Complaint: History: B6 B6 Significant Physical Exam Findings: Mentation B6	Date Type	Staff	History
B6	5/3/2015 C	В6	
Significant Physical Exam Findings: Mentation B6			History: B6
Significant Physical Exam Findings: Mentation B6			
Significant Physical Exam Findings: Mentation B6			
Significant Physical Exam Findings: Mentation B6			
			БО
DC			Significant Physical Exam Findings: Mentation B6
			B6

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

Patient History Report Patient: Client: Species: Canine Phone: Breed: Retriever, Golden Sex: Neutered Male Address: Age: B6 Color: Blonde Date Type Staff History **B6** Lab Work: none performed today Radiographic Findings: none performed today 5/3/2015 CK Reason for Visit: Recheck Date Patient Checked Out: 05/03/15 Practice TF 11/21/2014 C COMMUNICATIONS WITH CLIENT 11/21/2014 13:54 **B6** 11/14/2014 CK 5/31/2014 C IM TREATMENT NEW 5/31/2014 Internal Medicine Assessment: **B6** B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, l:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs **B6** Page 24 of 30 Date: 4/20/2018 5:17

Patient History Report Patient: Client: Phone: Breed: Retriever, Golden Species: Canine Address: Sex: Neutered Male Age: **B6** Color: Blonde Date Type Staff History Treatment: no treatment implemented at this time **B6** Recommended Follow-up Care: **B6 B6** 5/31/2014 C COMMUNICATIONS WITH CLIENT 5/31/2014 11:29 **B6** 5/31/2014 L **B6** Hematology results from Requisition ID: 315958 Posted rinai Test Result Reference Range HCT 36 - 6012.1 - 20.3HGB MCHC 30 - 38WBC 4.0 - 15.50 - 3Bands RBC 4.8 - 9.358 - 79 19 - 28 MCV MCH 170 - 400 Platelet C Platelet E ADEQUATE -60 - 77 12 - 30 Neutrophil Lymphocyte 3 - 10 Monocytes 2 - 10 Eosinophil 0 - 1 Basophils Absolute N 2060 - 10600 Absolute B 0 - 150Absolute L 690 - 4500Absolute M 0 - 8400 - 1200Absolute E Profile: CBC Ascn: **B6** Platelet count reflects the minimum number due to platelet clumping. **B6** 5/31/2014 L Chemistry results from Requisition B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs Page 25 of 30 Date: 4/20/2018 5:17 **B6**

FDA-CVM-FOIA-2019-1704-005423

Patient History Report Patient: Client: Breed: Retriever, Golden Phone: **Species:** Canine Address: **B6** Sex: Neutered Male Age: Color: Blonde Date Type Staff History ID: 315958 Posted Final Test Reference Range Result ALB 2.7 - 4.4ALKP 5 - 131 12 - 118 ALT 290 - 1125 15 - 66 AMYL AST 6 - 31 BUN/UREA 8.9 - 11.4Ca Chloride 102 - 120 92 - 324 59 - 895 CHOL CK CREA 0.5 - 1.6GGT 70 - 138 77 - 695 GLU LIPA 1.5 - 2.5Mg 2.5 - 6.0PHOS 3.6 - 5.5Potassium 139 - 154 Sodium TBIL 0.1 - 0.3ΤP 5.0 - 7.429 - 291TRIG 1.6 - 3.6 GLOB A/G Ratio 0.8 - 2.04 - 27B/C Ratio 5/31/2014 L Endocrinology results from **B6** Requisition ID: 315 אַכע B6 Posted ---Frinal Test Reference Range Result Т4 В6 0.8 - 3.5**B6** Profile: Total T4 Ascn: 5/31/2014 L Miscellaneous results from B6 B6 Requisition ID: 315958 Posted Final Profile: Superchem

5/30/2014 C

B6

ULTRASOUND REPORT NEW

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

Patient History Report B6 Client: Patient Breed: Retriever, Golden Phone: Species: Canine **B6** Sex: Neutered Male Address: Age: Color: 'Bronde Date Type Staff History Referring Vet: Hospital: **ULTRASONOGRAPHIC FINDING:** # of Films: Written: 5/30/2014 **B6 B6** 5/30/2014 C IM TREATMENT NEW 5/30/2014 **B6** Internal Medicine Assessment: **B6** B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

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B6

FDA-CVM-FOIA-2019-1704-005425

Date: 4/20/2018 5:17

		Patient History Re		
Client: Phone: Address:	B 6	Patient: Species: Can Age: Color: Blor	B6 Breed: B6 Sex:	Retriever, Golden Neutered Male
Date Type	Staff	History		
			B6	
		Treatment: no treatment implement	ed at this time	
		Recommended Follow-up Care: B6	B6	
5/30/2014 C	В6	IM PHYSICAL EXAM NEW 5/30/2014 22:58		
		Presenting Complaint:		
		History:	В6	
			36	
			36	
	M:Image cases,	-in, CM:Communications, D:Diagnosis, DH:Declined t P:Prescription, PA:PVL Accepted, PB:problems, PP:P dl note, V:Vital signs		
В6		Page 28 of 30	Date: 4/20/2018 5	:17

FDA-CVM-FOIA-2019-1704-005426

ΡМ

Patient History Report Client: Patient: Species: Canine Phone: Breed: Retriever, Golden Address: Age: B6 Sex: Neutered Male Color: Blonde Date Type Staff History Lab Work: Radiographic Findings: none performed 5/30/2014 I May 30, 2014 12:26 PM Staff: **B6** 5/30/2014 V Weight : 37.30 kilograms May 30, 2014 12:26 PM 5/30/2014 V 5/30/2014 CK Consult for possible scope **B6** Reason for Visit: Consult Date Patient Checked Out: 05/30/14 Practice TF Chemistry results from IDEXX Laboratory Services Requisition 5/30/2014 L ID: 315958 Posted Final Reference Range Test Result COBALAMIN 284 - 836**B6** FOLATE 4.8 - 19.0Ascn: **B6** SS MN CANINE 5/29/2014 C COMMUNICATIONS WITH CLIENT 5/29/2014 11:08 swo confirmed 5/30 apt at 1130

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

Patient History Report Patient: Client: **B6** Phone: Breed: Retriever, Golden Species: Canine Sex: Neutered Male Address: Age: **B6** Color: Blonde Date Type Staff History 5/27/2014 C RECEPTION ACTIONS NOTE **B6** 5/27/2014 C RECEPTION ACTIONS NOTE ***ADDENDUM 5/27/2014

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

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Date: 4/20/2018 5:17

Report Details - EON-	351031					
ICSR:	2045676					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)			
Reporting Type:	Voluntary					
	2018-04-12 13:26:01 EDT					
Reported Problem:	Problem Description:	Feb 23, 2018 Patien	t presented to the cardiology service at B6			
		B6 for tachypnea. He was diagnosed with dilated cardiomyopathy and left side congestive heart failure. Whole blood taurine level was B6 At the time, patient consuming Zignature Kangaroo Formula and was advised to change.				
	Date Problem Started: Concurrent Medical Problem:	Yes				
	Pre Existing Conditions:					
	Outcome to Date:	te: Stable				
Product Information:	Product Name:	Zignature Kangaroo	Formula			
	Product Type:					
	Lot Number:					
	Package Type:					
	Possess Unopened Product:					
	Possess Opened Product:					
	Product Use	Description:	Owner feeding for 2-3 years prior to diagnosis.			
	Information:	Last Exposure Date:				
		Time Interval between Product Use and Adverse Event:				
		Product Use Stopped After the Onset of the Adverse Event:				
		Relatedness to Adverse Event:				
		Other Foods or Products Given to the Animal During This Time Period:				
	Manufacturer /Distributor Information:	ion:				
	Purchase Location Information:	Name:	Chewy.com			
Animal Information:	Name:	B6				
	Type Of Species:	s: Dog				
	Type Of Breed:	ed: Retriever - Golden				
	Gender:	ler: Male				
	Reproductive Status:	:us: Neutered				
	Weight:	ght: 40 Kilogram				

	Age:	6 Years			
	Assessment of Prior				
	Health:	1			
	Given the Product: Number of Animals	1			
	Reacted: Owner Information:		V		
	Owner imormation.	Owner Information provided:	Yes		
		Contact:	Name: Phone:	B6	
		Address:	B6		
			United States		
	Healthcare Professional	Practice Name:	В6]
	Information:	Contact:		B6	
		Address:	ļ		
			United States		00 00 00 00 00 00 00 00 00 00 00 00 00
		Type of Veterinarian:	Referred veterinari	ian	
		Date First Seen:	02/23/2018		
Sender Information:	Name: Address:	B6			
	Contact:	United States			
		Email:	B6		
	Reporter Wants to Remain Anonymous:				
	Permission To Contact Sender: Preferred Method Of				
	Contact:				
Additional Documents:	Parties:				
Additional Documents.	######################################				