

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: 'Guag, Jake * (Jake.Guag@fda.hhs.gov)'
Sent: 8/3/2017 11:17:34 AM
Subject: 2 boxes in need of shipping labels (800.218)

Jake, Please make 2 shipping labels (no return label needed). There is dog food in the boxes, no hazardous materials. Shipping in small **B4** express boxes.

The first box will go to **B4** F:\6-CASES\800.04-ChickenJerky\3-Jerky-TESTS\1- **B4** Nutr\01-SAMPLES\Samples-2017\07-Taurine-Carnitine-8.3.2017

The second will go to **B4** F:\6-CASES\800.218-EON **B4** 19- **B6** -CA Naturals-DCM\3-samples\ **B4**
For **B4**

B6

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: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: Scalera, Alexander
Sent: 7/21/2017 12:37:40 PM
Subject: 2 Shipping labels-one to a vet office, one back to Vet-LIRN (800.218)

Hi Alex,

Can you make another set of shipping labels for me please? I plan to ship the box to the vet today or Monday, as your schedule allows.

This time, the box will be sent overnight to: Dr. Darcy Adin, 1060 William Moore Dr, Raleigh, North Carolina, 27607, Tel: 919-513-6694

Dimensions: 12.5" x 12.5" x 10.5"

Weight: 1.7 lbs

Contents: packing peanuts, empty (to collect dog food), no hazardous materials

Overnight Shipping-Return Shipping label for the box:

Dimensions: 12.5" x 12.5" x 10.5"

Projected weight: 2.75 lbs.

Contents: Dog food, no hazardous materials

Ship to: Jennifer Jones, Vet-LIRN, 8401 Muirkirk Rd, Laurel, MD 20708

Thank you,
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: Nemser, Sarah </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SARAH.YACHETTI>
To: Jones, Jennifer L
Sent: 7/31/2015 1:00:02 PM
Subject: 800.131 { B6 } case

The dog was euthanized? What does ARF stand for?

Presenting complaint: since switching the food-would eat fast-vomit after occasionally, borborygmous, inappetence x 3 episodes, last 2 inappetence episodes occurred over 1.5 wk span, episodes of lethargy lasting about a day and a half

Diet: primary diet-Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food-fed Oct 2014-April 2015, owner had another dog w/ kidney & liver disease-low P and chose this diet for both of the dogs; 1 cup daily-split into 3 doses; also got carrots & sweet potatoes; treats occasional component of diet: 1.) Fresh Pet Turkey Jerky-started last summer-currently receiving, given 1x per week max from owner's mother in law; 2.) Grandma Lucy's Apple Treats & Honest Kitchen Smooches Treats-both started around 9-10/2014 and last given unknown, total of 2 treats given daily-combo of the 2 brands

Exposures: indoor & outdoor dog; drugs-heartworm (heartgard), only use an herbal spray Earth Animals Flea and Tick; owners with him when go outside; owner has some herbs outside and weeds but no types of poisonous plants in yard; been to a dog park maybe 1-2 times in past month but doesn't go on a regular basis; owners found a tick a few weeks ago, but not attached/only on coat; no psoriasis creams or rat baits w/ Vitamin D; no pesticides or sprays in house or used outside; rural environment; one other dog in house-got the dog food; euthanized of ARF

Sarah Nemser M.S.

**U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Vet-LIRN
8401 Muirkirk Road, G202, HFV 500
Laurel, Maryland 20708
tel: 240-402-0892
fax: 301-210-4685
sarah.nemser@fda.hhs.gov**

P Please consider the environment before printing this email

Vet-LIRN

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Nemser, Sarah </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS /CN=SARAH.YACHETTI>
To: Rotstein, David; Carey, Lauren; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Sent: 5/18/2015 7:21:05 PM
Subject: 800.131 - RE: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: [REDACTED] B6
Attachments: 800.131-EON-208329- [REDACTED] B6 Summary-05-18-2015.doc.html

B5

B5

B5

B5

B5

From: Carey, Lauren
Sent: Thursday, May 14, 2015 2:15 PM
To: CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L; Rotstein, David
Subject: FYI: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: **B6**
B6

Elevated Calcium/Phosphorus with serum elevations of Vitamin D in a 4yo WHWT.
This is a raw diet I believe ("freeze dried")

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Thursday, May 14, 2015 2:00 PM
To: **B6** HQ Pet Food Report Notification; **B6**
B6
Subject: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: **B6**

A PFR Report has been received and PFR Event [EON-208329] has been created in the EON System

A "PDF" report by name "1039540-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 "1039540-attachments.zip" and is attached to this email notification.

Below is the summary of the report

EON Key: EON-208329
EON Title: PFR Event created for Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food; 1039540

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

Product information

Individual Case Safety Report Number: 1039540

Product Group: Pet Food

Product Name: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food

Description: Has been eating Grandma Lucy's Artisan Chicken food for about 8 months. Presented 4/18/15 for intermittent gastrointestinal signs and lethargy. Overall health was good with unremarkable physical exam. Bloodwork showed increased serum calcium and phosphorus levels. Tested negative for Addison's disease, ultrasound showed renal mineralization, negative testing for malignancy (PTHrP) and hyperparathyroidism. Serum Vitamin D levels were elevated, consistent with ingestion of excessive dietary Vitamin D. No history of exposure to cholecalciferol rodenticides, Vitamin D supplements, or Vitamin D-containing ointments.

Submission Type: Initial

Report Type: Both

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

Sender information

B6

Owner information

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.

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.

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'
Sent: 10/16/2017 4:55:14 PM
Subject: 800.218-Final report for review
Attachments: 800.218-FinalReport; **B6**; draft-10.16.2017.doc

F:\6-CASES\1-Working on report\sent to rr for review\800.218-EON-323515-19-**B6**Naturals-DCM\6-REPORT

Jennifer L. A. Jones, DVM

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Vet-LIRN Final Case Report

A. Case Identification:

Case Number: 800.218

Vet-LIRN Director: Renate Reimschuessel, VMD, PhD

Program: Vet-LIRN

Division Code: HFV – 500

Other Investigators:

Jennifer Jones, DVM	Vet-LIRN
Sarah Nemser, MS	Vet-LIRN
Olgica Ceric, DVM, PhD	Vet-LIRN
Jake Guag, MPH	Vet-LIRN
David Rotstein, DVM, MPH	OS&C CERT
Lee Anne Palmer, VMD, MPH	OS&C DVPS
Lauren Carey, DVM	OS&C DVPS

B. Descriptive Title of Case:

Investigation of two dogs with dilated cardiomyopathy after consuming California Natural Venison and Green Lentil food and California Natural Kangaroo and Lentil dog foods.

Address of Vet-LIRN Program Office:

Mod II
Center for Veterinary Medicine
Office of Research
8401 Muirkirk Road
Laurel, MD 20708

C. Initiation and Completion Date:

Initiation Date: 7/13/2017

Completion Date: 8/22/2017

Final Report Submission Date:

Case Summary

Complaint: July 13, 2017, Vet-LIRN received consumer complaint, EON-323515, reporting dilated cardiomyopathy in two dogs after consuming California Natural Venison and Green Lentil food and California Natural Kangaroo and Lentil dog foods.

Signalment:

- **B6** 7 yr MC Miniature Schnauzer
- **B6** 2 yr MC Miniature Schnauzer-deceased

Signs: syncopal episodes, dyspnea, cough, heart failure

Medical Records: Vet-LIRN collected and reviewed medical records.

Name	Clinical Signs	Physical Exam	Lab Work	Significant Medical History
B6	syncopal episodes, hyporexia	P 130 bpm, mild increased breath sounds-all lung fields	suspected DCM, taurine & carnitine normal; negative infectious disease & nutritional disease testing	
B6	dyspnea, cough, inappetance, regurgitation,	P 160 bpm, R 64 rpm, pale pink mm, Gr I-II/VI left apical systolic murmur; hypokinetic, synchronous femoral pulse, jugular venous distention	P 11.7, BG 225, ALT 147, AST 1006, CK 35,930; Toxic NP, Plt 97; hepatomegaly, biventricular heart failure, cardiogenic edema; <u>Necropsy:</u> Suspect primary non-cardiogenic etiology	coffee brown urine with clumps after strenuous activity & hot outside-resolves with 24-36 hours; Crystalluria

Owner Interview: Vet-LIRN did not conduct an owner interview. However, the veterinarian mentioned:

- The owner alternated feedings between the two products
- The owner did not feed anchovies, sardines, or seafood in February or chronically
- The two dogs were from genetically different lineages
- **B6** had clinical signs at the time **B6** was treated but didn't present with CHF for several months

Response: Vet-LIRN collected medical records for review and leftover open product (Kangaroo flavor) for taurine, carnitine, and fumonisin testing.

Results: The food tested negative for fumonisin. The food taurine level (0.26% estimated Dry Matter Basis) was above the minimum level in cats (no AAFCO minimum for dogs). The food carnitine level is 0.0077% estimated on a Dry Matter Basis. There is no AAFCO carnitine minimum for dogs or cats. It is unclear whether or not the food carnitine is low, normal, or high.

Conclusion: Dilated cardiomyopathy (DCM) can be caused by a variety of etiologies including, genetic² (breed related), toxic^{3,4} (fumonisin, acrolein⁵, domoic acid, doxorubicin, lily of valley, digitalis, ionophores, sicklepod, gossypol, white snake root, ethyl alcohol, foxglove, buttercups), infectious (Bartonellosis, *Trypanosoma cruzi*), and nutritional deficiency¹ (e.g. taurine, protein restricted diets with stones, carnitine deficiency). The two genetically unrelated dogs were fed the same foods and began to experience clinical signs approximately the same time. The medical records indicate infectious disease and nutritional deficiency are unlikely etiologies. [B6] records indicated elevated liver enzymes and CK values, which could support a hepatotoxic and myotoxic (cardio +/- muscle) exposure. Because [B6] presented six months after [B6] it is unknown if [B6] also had elevated liver enzymes when [B6] was ill. The history also suggested no exposure to doxorubicin or domoic acid. Vet-LIRN tested the leftover bag of food from [B6] illness time (June 2017), but not from January, when both dogs were initially ill. A test for acrolein was not available.

The cause of the two dogs' DCM is unclear, but is likely an environmental toxin exposure. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that Fumonisin, taurine, or carnitine levels in the food caused the dogs' illness.

References:

1. Sanderson SL. Taurine and Carnitine in Canine Myopathy. *Vet Clin Small Anim* 36 (2006) 1325–1343.
2. Borde D, Calvert CA, Darien BJ, Guerrero J, and Wall M. Acquired Heart and Blood Vessel Disorders in Dogs. *Merck Veterinary Manual*. Found at: <http://www.merckvetmanual.com/dog-owners/heart-and-blood-vessel-disorders-of-dogs/acquired-heart-and-blood-vessel-disorders-in-dogs>
3. Valberg SJ. Toxic Myopathies in Ruminants and Pigs. *Merck Veterinary Manual*. Found at: <http://www.merckvetmanual.com/musculoskeletal-system/myopathies-in-ruminants-and-pigs/toxic-myopathies-in-ruminants-and-pigs>
4. Garland T. Overview of Gossypol Poisoning. *Merck Veterinary Manual*. Found at: <http://www.merckvetmanual.com/toxicology/gossypol-poisoning/overview-of-gossypol-poisoning>
5. Ismahil MA, Hamid T, Haberzettl P, Gu Y, Chandrasekar B, Srivastava S, Bhatnagar A, and Prabhu SD. Chronic oral exposure to the aldehyde pollutant acrolein induces dilated cardiomyopathy. *Am J Physiol Heart Circ Physiol* 301: H2050–H2060, 2011.

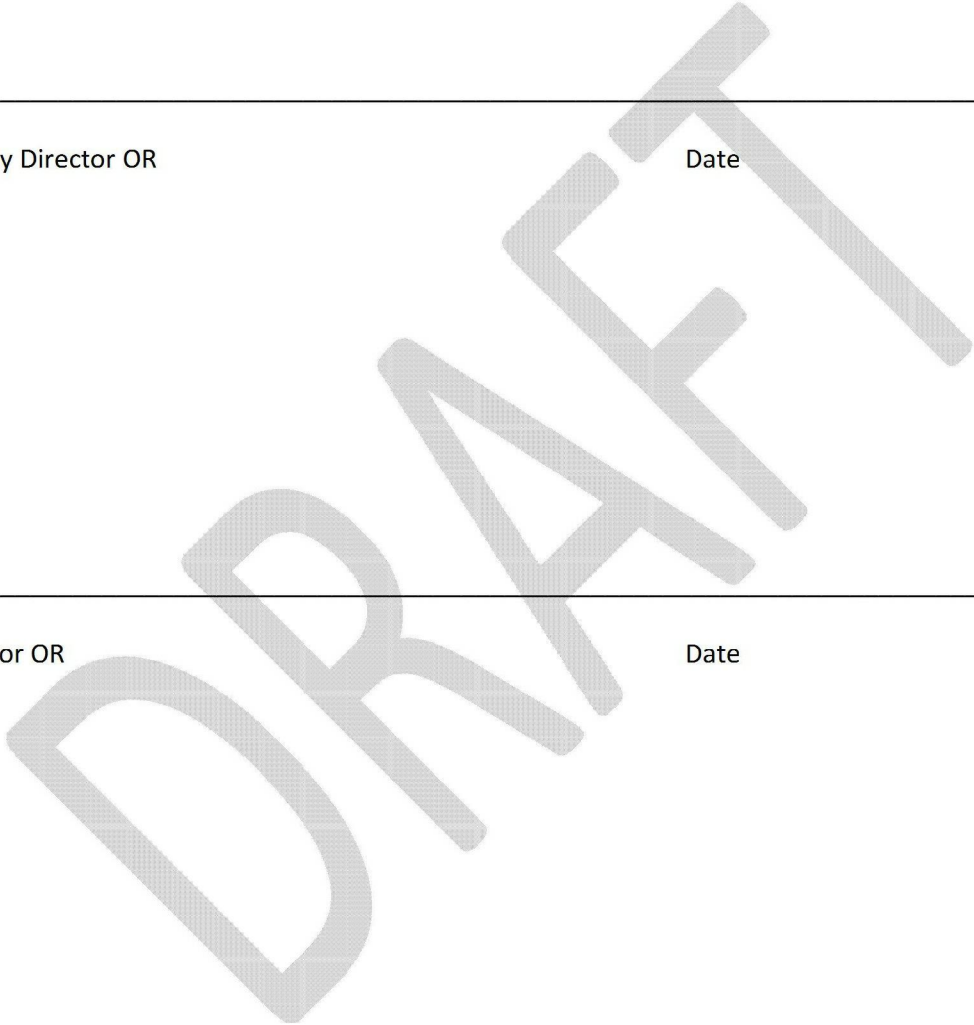
Supplemental Information:

SIGNATURES

Deputy Director OR Date

Director OR Date

Vet-LIRN Director Date



Document properties

Title: OR Final Report
Author: Yachetti, Sarah
Company: FDA
Template: Normal.dotm
Page count: 2
Paragraph count: 70
Line count: 187
Word count: 771
Character count (spaces excluded): 5012
Character count (spaces included): 5773

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: [REDACTED] **B6**
CC: Peloquin, Sarah
Sent: 1/30/2019 6:01:47 PM
Subject: 800.267-cc-210-EON-375111-FDA Case Investigation for [REDACTED] **B6**

Good afternoon [REDACTED] **B6**

I'm sorry to hear that [REDACTED] **B6** passed away. We've been following his case since Dr. Freeman reported it. As a follow-up to our discussion, we'd like to send you a box to collect the fixed formalin heart tissue. To send the box, I need to know the approximate size and weight of the fixed formalin container. Please send me that information.

Then, I'll ship you a box with everything needed to package the sample. You'll reuse the box, package the sample, use the prepaid shipping label we provide, and call UPS for the pick-up. Please return ship the box to us on a Monday through Wednesday.

***If for some reason we are furloughed again mid-February, please do not ship during the government shutdown. ***

We will process the tissue for histopathology and send you the results.

Please email or call with any questions.

Thank you,

Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
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e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6
CC: Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov); Peloquin, Sarah
Sent: [REDACTED] B6 5:40:43 PM
Subject: 800.267-cc-295-RE: Necropsy authorization
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf

Good afternoon [REDACTED] B6

Thank you for contacting us about your case. As we discussed on the phone, for me to send you a box to collect the samples, I'll need an official report. You can mention in the report, that I recommended you submit a complaint. Can you please submit a consumer complaint here?

<https://www.safetyreporting.hhs.gov/>

- Please send me the ICSR number (confirmation code) from the report.

We will send you 2 boxes with the materials to collect the fixed and frozen samples, including jars with formalin. You will reuse the boxes we send and package the samples per the instructions in the box.

- Please send me an estimate for the necropsy. After the necropsy is complete, we will call back with our VISA information to reimburse your hospital.
- After the necropsy is complete, please send me the approximate weight of the following individual groups:
 - Fixed tissues in the jars
 - Frozen tissues

We will use this information to make prepaid shipping labels for you. You'll affix the prepaid shipping label to the box and call UPS for a pick-up on Monday-Wednesday.

I attached a copy of our network procedures. They explain how Vet-LIRN operates and how veterinarians help with our case investigations. An owner friendly version is also attached.

For more information, please also visit our open access article in JAVMA that explains the FDA Animal Food Concern Reporting process. It's free and located here: <https://avmajournals.avma.org/doi/pdf/10.2460/javma.253.5.550>

Thank you again,
Jen

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



From: [REDACTED] B6 <[REDACTED] B6 com>
Sent: Tuesday, [REDACTED] B6 12:33 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Necropsy authorization

Dear Dr. Jones,

I left a message on your number this morning but figured I would also follow up with an email. [REDACTED] B6 gave us your contact information – I reached out to both Renate and Sarah but both appear out of the office today. We have a nutrition mediated DCM case, diagnosed at UC Davis that will be euthanized this afternoon. [REDACTED] B6 is in CHF and isn't responding to treatment. She is a 3.5yroid, FS, Golden Retriever. The owner is willing to submit the body/tissues towards research on this condition. Please give me a call at your earliest convenience

to discuss next steps

B6

Sincerely,

B6

B6



B6

BS, CVPM, PHR

Tel:

B6

Fax:

B6

www:

B6



From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: [REDACTED] DVM
CC: Jones, Jennifer L
Sent: 8/15/2019 1:08:36 PM
Subject: 800.267-cc-297-FDA Case Investigation for [REDACTED] and [REDACTED] (cc-297)

Good morning [REDACTED]

Please send us the invoices for [REDACTED] and [REDACTED] necropsies at your earliest convenience (by email or fax to 301-210-4685). We want to make sure we reimburse your hospital for these costs.

Thank you!
Sarah

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Jones, Jennifer L
Sent: Friday, [REDACTED] 9:10 AM
To: [REDACTED] DVM <[REDACTED].com>
Subject: RE: Re[2]: 800.267-cc-297-FDA Case Investigation for [REDACTED] (cc-297)

Absolutely. We will send a copy of the results as soon as they are read.

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



From: [REDACTED] DVM <[REDACTED].com>
Sent: Friday, [REDACTED] 8:55 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re[2]: 800.267-cc-297-FDA Case Investigation for [REDACTED] (cc-297)

Thank you Jennifer. I did receive an email from Jake.

Also, I believe that I read I should get a copy of the pathology results. Is this correct? I am interested in the results from [REDACTED]

Thank you again.
I appreciate the work you all are doing for this.

[REDACTED]

[REDACTED] DVM

B6

B6

B6

----- Original Message -----

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

To: "[REDACTED] DVM" <[REDACTED].com>

Cc: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>; "Guag, Jake" <Jake.Guag@fda.hhs.gov>

Sent: [REDACTED] 11:01:47 AM

Subject: RE: 800.267-cc-297-FDA Case Investigation for [REDACTED] (cc-297)

Thank you, [REDACTED]

We'll ship the box, and it should arrive before close of business Monday. Jake will send you a copy of the tracking when it ships.

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



From: [REDACTED] DVM <[REDACTED].com>

Sent: Tuesday, [REDACTED] 9:22 AM

To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

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

Subject: Re: 800.267-FDA Case Investigation for [REDACTED] (cc-297)

Good morning,

Weights for the samples from [REDACTED] are as follows:

Frozen tissue is 6 ounces

Refrigerated samples (urine and small intestinal fluid) 2 ounces

Formalin fixed samples 2 pounds 6 ounces

Thank you

B6

[REDACTED] DVM

B6

B6

B6

----- Original Message -----

From: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>

To: "[REDACTED] DVM" <[REDACTED].com>

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

Sent: [REDACTED] 11:59:32 AM

Subject: 800.267-FDA Case Investigation for [REDACTED] (cc-297)

Good morning [REDACTED],

I'm filling in on the DCM case investigation for Dr. Jennifer Jones this week. Dr. Lisa Freeman informed me that [REDACTED] will be euthanized—I'm sorry to hear this. If you are willing, please collect the same samples from [REDACTED] as you did for [REDACTED] (i.e. intact heart in formalin; and if possible, fixed/frozen tissues as described in the rapid necropsy document).

Dr. Jones will return at the end of next week, and we will send you boxes then for shipment.

Please send me the approximate weights of the samples, as you did for [REDACTED]

Let me know if you have any additional questions.

Thank you!
Dr. Sarah Peloquin

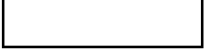
Sarah K. Peloquin, DVM
Veterinary Medical Officer

U.S. Food & Drug Administration
Center for Veterinary Medicine
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
tel: 240-402-1218
fax: 301-210-4685
e-mail: sarah.peloquin@fda.hhs.gov



This email has been checked for viruses by AVG antivirus software.

www.avg.com



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; Burkholder, William
CC: Peloquin, Sarah; Ceric, Olgica
Sent: 7/8/2019 1:52:32 PM
Subject: 800.267-DCM Food Testing

We've gotten some suggestions from the public for food toxicant testing. Looks like some (diquat, cyanamide) do cause cardiomyopathies.

- Dessiccant herbicides-glyphosate, glufosinate, diquat, paraquat, cyanamide, cinidon-ethyl, pyraflufen-ethyl

B5

Any thoughts from the group?

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
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From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: [REDACTED] B6 [REDACTED] DVM
CC: Jones, Jennifer L
Sent: 6/7/2019 3:59:32 PM
Subject: 800.267-FDA Case Investigation for [REDACTED] B6 (cc-297)

Good morning [REDACTED] B6

I'm filling in on the DCM case investigation for Dr. Jennifer Jones this week. Dr. Lisa Freeman informed me that [REDACTED] B6 will be euthanized—I'm sorry to hear this. If you are willing, please collect the same samples from [REDACTED] B6 as you did for [REDACTED] B6 (i.e. intact heart in formalin; and if possible, fixed/frozen tissues as described in the rapid necropsy document).

Dr. Jones will return at the end of next week, and we will send you boxes then for shipment.

Please send me the approximate weights of the samples, as you did for [REDACTED] B6

Let me know if you have any additional questions.

Thank you!
Dr. Sarah Peloquin

Sarah K. Peloquin, DVM
Veterinary Medical Officer

U.S. Food & Drug Administration
Center for Veterinary Medicine
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
tel: 240-402-1218
fax: 301-210-4685
e-mail: sarah.peloquin@fda.hhs.gov



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: cvca[REDACTED]@cvcavets.com
Sent: 4/15/2019 1:31:21 PM
Subject: 800.267-FDA Case Investigation for [REDACTED] (cc-039)

Good morning,

As part of the Dilated Cardiomyopathy Investigation, we are currently requesting a copy of any recent echocardiogram reports for select cases. Are you willing to email or fax (301-210-4685) us a copy?

Here are our recent updates to the public on our testing and investigation.

<https://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm630738.htm>

<https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm630993.htm>

Thank you,

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: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Freeman, Lisa; Joshua A Stern [B6]
Sent: 8/14/2018 11:59:53 PM
Subject: a few NCSU cases
Attachments: [B6].pdf

Hi Jennifer,

I wanted to follow up on the case where NCSU sent you necropsy samples ([B6] 3 yr Fs Great Dane). I've attached her whole blood and plasma taurine concentrations for your records, which were normal.

One of my residents saw a littermate pair of Dobermans back for their 3 month recheck after being diagnosed with DCM while eating Acana. Taurines were normal on these dogs back in April and I honestly didn't have a ton of hope for these dogs (WB 342 and 335) because they were dobermans and their genetic tests were abnormal (the female is homozygous positive for one mutation and negative for a 2nd, the male was heterozygous positive for one mutation and negative for a 2nd). But, 3 months after a diet change to Purina grain-based (and no taurine supplementation), they both have shown significant improvement (the less severely affected female has near normalized and the severely affected male (who was in heart failure) has also significantly improved.

I have asked our resident to report these dogs to the FDA using the portal ([B6] and [B6]) so hopefully you will see these soon. She will also be submitting a taurine deficient Golden eating Acana (WB 5! maybe the lowest I've ever seen).

Thank you!
Darcy

--

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

Sample Submission Form

Amino Acid Laboratory
University of California, Davis
1020 Vet Med 3B
1089 Veterinary Medicine Drive
Davis, CA 95616
Tel: (530)752-5058, Fax: (530)752-4698

UC CUSTOMERS ONLY:
Non-federal funds ID/Account Number
to bill: _____

<http://www.vetmed.ucdavis.edu/vmb/aal/aal.html>

Vet/Tech Contact: Darcy Adin DVM/Allison Klein

Company Name: NC State University, College of Veterinary Medicine

Address: 1060 William Moore Dr
Raleigh, NC 27606

Email: alklein@ncsu.edu

Tel: 919.513.6325 **Fax:** 919.515.9427

Billing Contact: B6 **TAX ID:** B6

Email: B6@ncsu.edu **Te:** B6

Patient Name: B6

Species: canine

Owner's Name: B6

Sample Type: Plasma Whole Blood Urine Food Other: _____

Test Items: Taurine Complete Amino Acid Other: _____

Taurine Results (nmol/ml)

Plasma: 251 Whole Blood: 520 Urine: _____ Food: _____

Reference Ranges (nmol/ml)

	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 5/25/2018 11:32:55 AM
Subject: Action Item: Please Review-800.267-DCM draft testing plan
Attachments: 800.267-draft-Sample Testing Procedures-v1.doc

Please review by COB 6/1.

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>



B4, B5

II. PARTICIPANT INFORMATION

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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: 5/20/2019 6:00:05 PM
Subject: Adin -cardio cases
Attachments: Acana Heritage Poultry dry: Darcy Adin - EON-388255; Blue Buffalo Large Breed Adult: Darcy Adin - EON-388253; Honest Kitchen Turkey dehydrated: Darcy Adin - EON-388245; Natural Balance Venison: Darcy Adin - EON-388246; Origins 6 Fish Grain Free dry: Darcy Adin - EON-388256; Pure Balance Salmon and Potato dry: Darcy Adin - EON-388254; RE: Dr. Adin - U Fla?; Taste of the Wild Pacific Salmon Grain Free: Darcy Adin - EON-388244

Jen and Sarah,

Here are all of the cases. Please note that while there are mostly DCM, there are few with endocardiosis.

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6]; HQ Pet Food Report Notification; [B6]
Sent: 5/20/2019 3:05:29 PM
Subject: Acana Heritage Poultry dry: Darcy Adin - EON-388255
Attachments: 2067176-report.pdf

A PFR Report has been received and PFR Event [EON-388255] has been created in the EON System.

A "PDF" report by name "2067176-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-388255

ICSR #: 2067176

EON Title: PFR Event created for Acana Heritage Poultry dry; 2067176

AE Date	02/14/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Shepherd Dog - German		
Age	4 Years		
District Involved	PFR-Florida DO		

Product information

Individual Case Safety Report Number: 2067176

Product Group: Pet Food

Product Name: Acana Heritage Poultry dry

Description: Dirty presented to the UF Cardiology Service for a 5 month history of progressive exercise intolerance and increased respiratory rate and effort. Patient was diagnosed with Dilated Cardiomyopathy. She has been rechecked once 5/15/19 - clinically stable but no improvement noted on echocardiogram. Her blood taurine results were discordant so she has been on supplementation

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
Acana Heritage Poultry dry		

Sender information

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-388255

ICSR: 2067176
 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
 Report Submission Date: 2019-05-20 10:58:30 EDT

Reported Problem:

Problem Description: Dirty presented to the UF Cardiology Service for a 5 month history of progressive exercise intolerance and increased respiratory rate and effort. Patient was diagnosed with Dilated Cardiomyopathy. She has been rechecked once 5/15/19 - clinically stable but no improvement noted on echocardiogram. Her blood taurine results were discordant so she has been on supplementation

Date Problem Started: 02/14/2019

Concurrent Medical Problem: Yes

Pre Existing Conditions: Patient was bred by artificial insemination over the summer and became pregnant with one pup. The fetus was eventually absorbed. She was returned to the owner in September, at which time the owner noticed exercise intolerance and occasional abdominal distention.

Outcome to Date: Stable

Product Information:

Product Name: Acana Heritage Poultry dry

Product Type: Pet Food

Lot Number:

Product Use Information:

Description: 2 cups dry food fed twice per day Patient also has been receiving deer antlers once per week since Aug 2015 as treats/chews.

First Exposure Date: 08/01/2015

Last Exposure Date: 02/14/2019

Time Interval between Product Use and Adverse Event: 3 Years

Product Use Stopped After the Onset of the Adverse Event: Yes

Adverse Event Abate After Product Stop: Unknown

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Possibly related

Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name: B6

Type Of Species: Dog

	Type Of Breed: Shepherd Dog - German
	Gender: Female
	Reproductive Status: Intact
	Pregnancy Status: Not Pregnant
	Lactation Status: Not lactating
	Weight: 36 Kilogram
	Age: 4 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information: Owner Information provided: No
Healthcare Professional Information:	Practice Name: University of Florida
	Contact: Name: Darcy Adin
	Phone: (614) 582-9798
	Other Phone: 3522948606
	Email: adind@ufl.edu
	Address: 2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
Sender Information:	Name: Darcy Adin
	Address: 2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
	Contact: Phone: 6145829798
	Other Phone: 3522948606
	Email: adind@ufl.edu
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
Reported to Other Parties: None	
Additional Documents:	

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 5/20/2019 3:04:47 PM
Subject: Blue Buffalo Large Breed Adult: Darcy Adin - EON-388253
Attachments: 2067174-report.pdf

A PFR Report has been received and PFR Event [EON-388253] has been created in the EON System.

A "PDF" report by name "2067174-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-388253
ICSR #: 2067174
EON Title: PFR Event created for Blue Buffalo Large Breed Adult, Paul Newman Dog Biscuits various, Spring Hill Fish Oil; 2067174

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Doberman Pinscher		
Age	11 Years		
District Involved	PFR-Florida DO		

Product information

Individual Case Safety Report Number: 2067174

Product Group: Pet Food, Other

Product Name: Blue Buffalo Large Breed Adult, Paul Newman Dog Biscuits, various, Spring Hill Fish Oil

Description: Patient had been stable on Pimobendan for dilated cardiomyopathy for the past two years prior to presentation at UF Cardiology. A few weeks prior to presentation, he was started on Furosemide for coughing episodes. The day of presentation, an EKG performed at the primary care veterinarian showed a ventricular arrhythmia. On presentation to UF Cardiology, patient had collapsed suddenly and was in cardiopulmonary arrest. After CPR and a lidocaine bolus, he converted to sinus tachycardia. Patient was diagnosed with dilated cardiomyopathy. [B6] was euthanized two days later due to gastric dilation volvulus (GDV).

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: Died Euthanized

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 Large Breed Adult		
Paul Newman Dog Biscuits, various		
Spring Hill Fish Oil		

Sender information

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-388253

ICSR:	2067174
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
Report Submission Date:	2019-05-20 10:54:51 EDT

Reported Problem:	Problem Description:	Patient had been stable on Pimobendan for dilated cardiomyopathy for the past two years prior to presentation at UF Cardiology. A few weeks prior to presentation, he was started on Furosemide for coughing episodes. The day of presentation, an EKG performed at the primary care veterinarian showed a ventricular arrhythmia. On presentation to UF Cardiology, patient had collapsed suddenly and was in cardiopulmonary arrest. After CPR and a lidocaine bolus, he converted to sinus tachycardia. Patient was diagnosed with dilated cardiomyopathy. [B6] was euthanized two days later due to gastric dilation volvulus (GDV).
	Date Problem Started:	[B6]
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6] was diagnosed with dilated cardiomyopathy two years prior to presentation at UF Cardiology and had been previously stable on Pimobendan for the past two years. [B6] also underwent TPLO surgery in the past for a torn CCL on the left hind limb. The implant has since been removed due to infection. [B6] was also on carprofen of unknown dose and frequency and Spring Hill Fish Oil 1 pill per day.
	Outcome to Date:	Died Euthanized [B6]

Product Information:	Product Name:	Spring Hill Fish Oil
	Product Type:	Other
	Lot Number:	
	Product Use Information:	Description: 1 pill daily as supplement
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Paul Newman Dog Biscuits, various
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	Description: used as treats patient also received fat free greek yogurt once per day since 2015 and raw carrots as treats
		First Exposure Date: 01/01/2010
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Blue Buffalo Large Breed Adult
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	Description: 2 cups dry fed twice per day
		First Exposure Date: 12/31/2007
	Last Exposure Date: [B6]	
	Time Interval: 9 Years	

		between Product Use and Adverse Event:	
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Doberman Pinscher	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	38 Kilogram	
	Age:	11 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	No
	Healthcare Professional Information:	Practice Name:	University of Florida
		Contact:	Name: Darcy Adin
			Phone: (614) 582-9798
			Other Phone: 3522948606
			Email: adind@ufl.edu
		Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
Sender Information:	Name:	Darcy Adin	
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States	
	Contact:	Phone:	6145829798
		Other Phone:	3522948606
		Email:	adind@ufl.edu

	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None

Additional Documents:

From: PFR Event <pfreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 5/20/2019 2:57:01 PM
Subject: Honest Kitchen Turkey dehydrated: Darcy Adin - EON-388245
Attachments: 2067168-report.pdf

A PFR Report has been received and PFR Event [EON-388245] has been created in the EON System.

A "PDF" report by name "2067168-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-388245

ICSR #: 2067168

EON Title: PFR Event created for Honest Kitchen Turkey dehydrated, N and D Venison and Quinoa dry, Taste of the Wild Prey (Angus Beef and Lentils); 2067168

AE Date	03/13/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		
Age	4.5 Years		
District Involved	PFR-Florida DO		

Product information

Individual Case Safety Report Number: 2067168

Product Group: Pet Food

Product Name: Honest Kitchen Turkey dehydrated, N and D Venison and Quinoa dry, Taste of the Wild Prey (Angus, Beef, and Lentils)

Description: A few days before [B6] was seen by UF Cardiology, he presented to a specialty clinic for a minor orthopedic complaint, at which time an ECG revealed an abnormal rhythm. On 3/10, [B6] became inappetent and vomited twice. On [B6] patient presented to primary care veterinarian, and on [B6] patient presented to an emergency clinic where thoracic radiographs revealed mild to moderate cardiomegaly. He was referred to cardiology on 3/13, where he was diagnosed with Dilated Cardiomyopathy. Anorexia resolved after 2 weeks.

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
N and D Venison and Quinoa dry		
Honest Kitchen Turkey dehydrated		
Taste of the Wild Prey (Angus, Beef, and Lentils)		

Sender information

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-388245

ICSR: 2067168
 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
 Report Submission Date: 2019-05-20 10:45:10 EDT

Reported Problem:

Problem Description: A few days before **B6** was seen by UF Cardiology, he presented to a specialty clinic for a minor orthopedic complaint, at which time an ECG revealed an abnormal rhythm. On 3/10, **B6** became inappetant and vomited twice. On 3/11, patient presented to primary care veterinarian, and on **B6** patient presented to an emergency clinic where thoracic radiographs revealed mild to moderate cardiomegaly. He was referred to cardiology on **B6** where he was diagnosed with Dilated Cardiomyopathy. Anorexia resolved after 2 weeks.

Date Problem Started: 03/13/2019

Concurrent Medical Problem: Yes

Pre Existing Conditions: Patient received flax oil. Patient had a recent history of right hindlimb lameness.

Outcome to Date: Stable

Product Information:

Product Name: Taste of the Wild Prey (Angus, Beef, and Lentils)

Product Type: Pet Food

Lot Number:

Product Use Information:

Description: 3/4 cup fed twice per day

First Exposure Date: 03/13/2018

Last Exposure Date: 03/13/2019

Time Interval between Product Use and Adverse Event: 1 Years

Product Use Stopped After the Onset of the Adverse Event: Yes

Adverse Event Abate After Product Stop: Unknown

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Possibly related

Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: N and D Venison and Quinoa dry

Product Type: Pet Food

Lot Number:

Product Use Description: 1 3/4 cup fed twice per day

Information:	First Exposure Date:	12/13/2018
	Last Exposure Date:	03/13/2019
	Time Interval between Product Use and Adverse Event:	3 Months
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Adverse Event Abate After Product Stop:	Unknown
	Product Use Started Again:	No
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or Products Given to the Animal During This Time Period:	Yes
Manufacturer /Distributor Information:		
Purchase Location Information:		
Product Name:	Honest Kitchen Turkey dehydrated	
Product Type:	Pet Food	
Lot Number:		
Product Use Information:	Description:	1/4 cup fed once per day Patient also receives lung pieces and beef and duck jerky as treats.
	First Exposure Date:	01/01/2015
	Last Exposure Date:	03/13/2019
	Time Interval between Product Use and Adverse Event:	4 Years
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Adverse Event Abate After Product Stop:	Unknown
	Product Use Started Again:	No
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer	

	/Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	86.1 Kilogram	
	Age:	4.5 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	No
	Healthcare Professional Information:	Practice Name:	University of Florida
Contact:		Name:	Darcy Adin
		Phone:	(614) 582-9798
		Other Phone:	3522948606
		Email:	adind@ufl.edu
Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States		
Sender Information:	Name:	Darcy Adin	
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States	
	Contact:	Phone:	6145829798
		Other Phone:	3522948606
		Email:	adind@ufl.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		
Additional Documents:			

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 5/20/2019 2:57:23 PM
Subject: Natural Balance Venison: Darcy Adin - EON-388246
Attachments: 2067170-report.pdf

A PFR Report has been received and PFR Event [EON-388246] has been created in the EON System.

A "PDF" report by name "2067170-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-388246

ICSR #: 2067170

EON Title: PFR Event created for Natural Balance Venison Sweet Potatoes, Pedigree chicken and rice, Dr. Lyon's dental treat (mint), Smart Bones Smart Sticks (peanut butter), Cosequin DS; 2067170

AE Date	04/03/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Sheepdog - Shetland		
Age	10 Years		
District Involved	PFR-Florida DO		

Product information

Individual Case Safety Report Number: 2067170

Product Group: Pet Food, Other

Product Name: Natural Balance Venison, Sweet Potatoes, Pedigree chicken and rice, Dr. Lyon's dental treat (mint), Smart Bones Smart Sticks (peanut butter), Cosequin DS

Description: B6 ws referred to UF Cardiology after her primary care veterinarian noted a Grade 2/6 left systolic murmur. She has been slowing down some over the past year, but still runs and plays regularly. B6 has a sinus arrhythmia. Patient was diagnosed with primary mitral regurgitation with systolic dysfunction.

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
Natural Balance Venison, Sweet Potatoes		
Dr. Lyon's dental treat (mint)		
Pedigree chicken and rice		
Cosequin DS		

Sender information

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-388246

ICSR: 2067170
 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
 Report Submission Date: 2019-05-20 10:48:05 EDT

Reported Problem:
Problem Description: B6 ws referred to UF Cardiology after her primary care veterinarian noted a Grade 2/6 left systolic murmur. She has been slowing down some over the past year, but still runs and plays regularly. B6 has a sinus arrhythmia. Patient was diagnosed with primary mitral regurgitation with systolic dysfunction.
Date Problem Started: 04/03/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6 has a history of "bone spur" in her caudal spine since she was about 4 years old. She is not currently clinical for her vertebral disease. B6 receives 1/2 tablet Cosequin DS daily.
Outcome to Date: Stable

Product Information:
Product Name: Cosequin DS
Product Type: Other
Lot Number:
Product Use Information: **Description:** 1/2 tablet once daily as joint supplement
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Smart Bones Smart Sticks (peanut butter)
Product Type: Pet Food
Lot Number:
Product Use Information: **Description:** 5 inch treat given once per week
First Exposure Date: 01/01/2016
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Dr. Lyon's dental treat (mint)
Product Type: Pet Food
Lot Number:
Product Use Information: **Description:** 3 inch treat fed once per week
First Exposure Date: 01/01/2018
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Pedigree chicken and rice
Product Type: Pet Food
Lot Number:
Product Use Information: **Description:** 1/4 cup fed once per day
First Exposure Date: 01/01/2012

	Time Interval between Product Use and Adverse Event:	7 Years
	Product Use Stopped After the Onset of the Adverse Event:	No
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Natural Balance Venison, Sweet Potatoes
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	
	Description:	1/2 cup dry fed twice per day Patient also receives 2TBSP 100% pure pumpkin once daily and 1/2 hard boiled egg white once per week.
	First Exposure Date:	10/01/2010
	Time Interval between Product Use and Adverse Event:	9 Years
	Product Use Stopped After the Onset of the Adverse Event:	No
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Sheepdog - Shetland
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	11.5 Kilogram
	Age:	10 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1

	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	No
	Healthcare Professional Information:	Practice Name:	University of Florida
		Contact:	Name: Darcy Adin
			Phone: (614) 582-9798
			Other Phone: 3522948606
			Email: adind@ufl.edu
		Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
Sender Information:	Name:	Darcy Adin	
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States	
	Contact:	Phone:	6145829798
		Other Phone:	3522948606
		Email:	adind@ufl.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 5/20/2019 3:05:50 PM
Subject: Origins 6 Fish Grain Free dry: Darcy Adin - EON-388256
Attachments: 2067173-report.pdf

A PFR Report has been received and PFR Event [EON-388256] has been created in the EON System.

A "PDF" report by name "2067173-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-388256

ICSR #: 2067173

EON Title: PFR Event created for Origins 6 Fish Grain Free dry, Dasuquin (Nutramax) Glucosamine MSM Chonroitin ASU; 2067173

AE Date	03/19/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		
Age	7 Years		
District Involved	PFR-Florida DO		

Product information

Individual Case Safety Report Number: 2067173

Product Group: Pet Food, Other

Product Name: Origins 6 Fish Grain Free dry, Dasuquin (Nutramax) Glucosamine, MSM, Chonroitin, ASU

Description: B6 presented to UF Cardiology with a history of persistent cough for the past 2-3 months which acutely became more frequent with episodes of wheezing and hacking. Patient was diagnosed with atrial fibrillation and dilated cardiomyopathy.

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
Dasuquin (Nutramax) Glucosamine, MSM, Chonroitin, ASU		
Origins 6 Fish Grain Free dry		

Sender information

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-388256																			
ICSR:	2067173																		
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																		
Report Submission Date:	2019-05-20 10:51:47 EDT																		
Reported Problem:	Problem Description: B6 presented to UF Cardiology with a history of persistent cough for the past 2-3 months which acutely became more frequent with episodes of wheezing and hacking. Patient was diagnosed with atrial fibrillation and dilated cardiomyopathy.																		
	Date Problem Started: 03/19/2019																		
	Concurrent Medical Problem: Yes																		
	Pre Existing Conditions: Previously diagnosed with Wobblers disease in 2012, but is not currently clinical. Patient receives Glucosamine nutramax 800mg daily, MSM nutramax 700mg daily, Chonroitin nutramax 300mg daily, and ASU nutramax 75mg daily.																		
	Outcome to Date: Stable																		
Product Information:	Product Name: Dasuquin (Nutramax) Glucosamine, MSM, Chonroitin, ASU																		
	Product Type: Other																		
	Lot Number:																		
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>joint supplement daily</td> </tr> </table>	Description:	joint supplement daily																
	Description:	joint supplement daily																	
	Manufacturer /Distributor Information:																		
	Purchase Location Information:																		
	Product Name: Origins 6 Fish Grain Free dry																		
	Product Type: Pet Food																		
	Lot Number:																		
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>2 cups fed twice per day</td> </tr> <tr> <td>First Exposure Date:</td> <td>03/01/2013</td> </tr> <tr> <td>Last Exposure Date:</td> <td>03/19/2019</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>6 Years</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Adverse Event Abate After Product Stop:</td> <td>Unknown</td> </tr> <tr> <td>Product Use Started Again:</td> <td>No</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Possibly related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	2 cups fed twice per day	First Exposure Date:	03/01/2013	Last Exposure Date:	03/19/2019	Time Interval between Product Use and Adverse Event:	6 Years	Product Use Stopped After the Onset of the Adverse Event:	Yes	Adverse Event Abate After Product Stop:	Unknown	Product Use Started Again:	No	Perceived Relatedness to Adverse Event:	Possibly related	Other Foods or Products Given to the Animal During This Time Period:	Yes
	Description:	2 cups fed twice per day																	
	First Exposure Date:	03/01/2013																	
	Last Exposure Date:	03/19/2019																	
	Time Interval between Product Use and Adverse Event:	6 Years																	
Product Use Stopped After the Onset of the Adverse Event:	Yes																		
Adverse Event Abate After Product Stop:	Unknown																		
Product Use Started Again:	No																		
Perceived Relatedness to Adverse Event:	Possibly related																		
Other Foods or Products Given to the Animal During This Time Period:	Yes																		
Manufacturer:																			

	/Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	65 Kilogram	
	Age:	7 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	No
	Healthcare Professional Information:	Practice Name:	University of Florida
Contact:		Name:	Darcy Adin
		Phone:	(614) 582-9798
		Other Phone:	3522948606
		Email:	adind@ufl.edu
Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States		
Sender Information:	Name:	Darcy Adin	
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States	
	Contact:	Phone:	6145829798
		Other Phone:	3522948606
		Email:	adind@ufl.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		
Additional Documents:			

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 5/20/2019 3:05:09 PM
Subject: Pure Balance Salmon and Potato dry: Darcy Adin - EON-388254
Attachments: 2067175-report.pdf

A PFR Report has been received and PFR Event [EON-388254] has been created in the EON System.

A "PDF" report by name "2067175-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-388254

ICSR #: 2067175

EON Title: PFR Event created for Pure Balance Salmon and Potato dry, 4Health Salmon and Potato canned, Milkbone peanut flavor dry mini treats, Spring Valley Fish Flax and Borage Oil, Good Morning Healthy Joints; 2067175

AE Date	02/20/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Cattle Dog - Australian (blue heeler, red heeler, Queensland cattedog)		
Age	10 Years		
District Involved	PFR-Florida DO		

Product information

Individual Case Safety Report Number: 2067175

Product Group: Pet Food, Other

Product Name: Pure Balance Salmon and Potato dry, 4Health Salmon and Potato canned, Milkbone peanut flavor dry mini treats, Spring Valley Fish, Flax, and Borage Oil, Good Morning Healthy Joints

Description: Patient presented to the UF Cardiology Service after roughly two weeks of coughing. When

coughing initially started, patient was seen by primary care veterinarian and was treated with Diphenoxylate Atropine, Hydroxyzine, Amoxicillin, and Vetprofen. On 2/19/19, **B6** presented to his primary care veterinarian again. He had cyanotic mucous membranes, an enlarged heart, and pulmonary edema. Patient was referred to UF and was diagnosed with Dilated Cardiomyopathy.

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
Spring Valley Fish, Flax, and Borage Oil		
Milkbone peanut flavor dry mini treats		
Pure Balance Salmon and Potato dry		
Good Morning Healthy Joints		

Sender information

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-388254		
ICSR:	2067175	
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	
Report Submission Date:	2019-05-20 10:56:29 EDT	
Reported Problem:	Problem Description:	Patient presented to the UF Cardiology Service after roughly two weeks of coughing. When coughing initially started, patient was seen by primary care veterinarian and was treated with Diphenoxylate Atropine, Hydroxyzine, Amoxicillin, and Vetprofen. On 2/19/19, B6 presented to his primary care veterinarian again. He had cyanotic mucous membranes, an enlarged heart, and pulmonary edema. Patient was referred to UF and was diagnosed with Dilated Cardiomyopathy.
	Date Problem Started:	02/20/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Patient was diagnosed with reactive seizures two years ago and was started on Phenobarbitol (60mg q12) at that time. Patient also receives Spring Valley Fish, Flax, and Borage Oil once daily and Good Morning Healthy Joints twice daily.
	Outcome to Date:	Stable
Product Information:	Product Name:	Good Morning Healthy Joints
	Product Type:	Other
	Lot Number:	
	Product Use Information:	Description: supplement given twice daily
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Spring Valley Fish, Flax, and Borage Oil
	Product Type:	Other
	Lot Number:	
	Product Use Information:	Description: supplement given once daily
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Milkbone peanut flavor dry mini treats
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	Description: used as treats
		First Exposure Date: 01/01/2012
		Other Foods or Products Given to the Animal During This Time Period: Yes
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	4Health Salmon and Potato canned

Product Type: Pet Food	
Lot Number:	
Product Use Information:	Description: 1 TPSP fed twice per day
	First Exposure Date: 01/01/2016
	Last Exposure Date: 02/20/2019
	Time Interval between Product Use and Adverse Event: 3 Years
	Product Use Stopped After the Onset of the Adverse Event: Yes
	Adverse Event Abate After Product Stop: Unknown
	Product Use Started Again: No
	Perceived Relatedness to Adverse Event: Possibly related
	Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:	
Purchase Location Information:	
Product Name:	Pure Balance Salmon and Potato dry
Product Type: Pet Food	
Lot Number:	
Product Use Information:	Description: 1 cup dry food fed twice per day
	First Exposure Date: 01/01/2016
	Last Exposure Date: 02/20/2019
	Time Interval between Product Use and Adverse Event: 3 Years
	Product Use Stopped After the Onset of the Adverse Event: Yes
	Adverse Event Abate After Product Stop: Unknown
	Product Use Started Again: No
	Perceived Relatedness to Adverse Event: Possibly related
	Other Foods or Products Given Yes

		to the Animal During This Time Period:
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Cattle Dog - Australian (blue heeler, red heeler, Queensland cattledog)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	24 Kilogram
	Age:	10 Years
	Assessment of Prior Health:	Fair
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	Practice Name: University of Florida
		Contact: Name: Darcy Adin
		Phone: (614) 582-9798
		Other Phone: 3522948606
		Email: adind@ufl.edu
		Address: 2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
Sender Information:	Name:	Darcy Adin
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
	Contact:	Phone: 6145829798
		Other Phone: 3522948606
		Email: adind@ufl.edu
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Jones, Jennifer L; Rotstein, David; Carey, Lauren; Peloquin, Sarah
Sent: 5/20/2019 5:52:14 PM
Subject: RE: Dr. Adin - U Fla?

Interesting... she must have settled in and is now sending cases our way! 😊

From: Jones, Jennifer L
Sent: Monday, May 20, 2019 1:51 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Dr. Adin - U Fla?

Yes-she's been at UFL for about 6 mo?

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



From: Rotstein, David
Sent: Monday, May 20, 2019 1:04 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>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: Re: Dr. Adin - U Fla?

Thanks Lee Anne

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 20, 2019 at 1:02:38 PM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: Dr. Adin - U Fla?

Hi there – I see a “dump” of DCM cases just rolled in. Is Darcy Adin now at Florida? Looks like she's moved from NC State. I'll let Dave do the forwards as he usually does, just an observation!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov



From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 5/20/2019 2:56:40 PM
Subject: Taste of the Wild Pacific Salmon Grain Free: Darcy Adin - EON-388244
Attachments: 2067171-report.pdf

A PFR Report has been received and PFR Event [EON-388244] has been created in the EON System.

A "PDF" report by name "2067171-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-388244

ICSR #: 2067171

EON Title: PFR Event created for Taste of the Wild Pacific Salmon Grain Free, Red Barn Bully sticks and slices, Sam's Club Chicken Jerky, Nubs Chicken Treats, Nudges Chicken Jerkey; 2067171

AE Date	03/19/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	American Pit Bull Terrier		
Age	7.5 Years		
District Involved	PFR-Florida DO		

Product information

Individual Case Safety Report Number: 2067171

Product Group: Pet Food

Product Name: Taste of the Wild Pacific Salmon Grain Free, Red Barn Bully sticks and slices, Sam's Club Chicken Jerky, Nubs Chicken Treats, Nudges Chicken Jerkey

Description: [B6] presented to UF Cardiology for evaluation of a heart murmur and arrhythmia discovered by his primary care veterinarian. [B6] had a recent history of a progressively worsening cough. On ECG, [B6] had intermittent ventricular premature complexes (right bundle branch block). [B6] was diagnosed with mitral regurgitation with systolic dysfunction.

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
Sam's Club Chicken Jerky		
Nudges Chicken Jerkey		
Red Barn Bully sticks and slices		
Nubs Chicken Treats		

Sender information

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-388244

ICSR: 2067171
 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
 Report Submission Date: 2019-05-20 10:49:42 EDT

Reported Problem:

Problem Description: B6 presented to UF Cardiology for evaluation of a heart murmur and arrhythmia discovered by his primary care veterinarian. B6 had a recent history of a progressively worsening cough. On ECG B6 had intermittent ventricular premature complexes (right bundle branch block). B6 was diagnosed with mitral regurgitation with systolic dysfunction.

Date Problem Started: 03/19/2019

Concurrent Medical Problem: Yes

Pre Existing Conditions: History of dermatologic skin issues, but no other relevant medical history. Patient is on Heartgard and Seresto collar as preventatives.

Outcome to Date: Stable

Product Information:

Product Name: Nudges Chicken Jerkey

Product Type: Pet Food

Lot Number:

Product Use Information:

Description: 2-3 slices fed 2-3 times per day as a treat

First Exposure Date: 02/01/2019

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Nubs Chicken Treats

Product Type: Pet Food

Lot Number:

Product Use Information:

Description: one bone once per day as a treat

First Exposure Date: 10/01/2017

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Sam's Club Chicken Jerky

Product Type: Pet Food

Lot Number:

Product Use Information:

Description: fed as treats 2-3 slices, 2-3 times per day

First Exposure Date: 01/01/2018

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Red Barn Bully sticks and slices

Product Type: Pet Food

Lot Number:

Product Use Information:

Description: treats - 1 stick per day

First Exposure Date: 08/01/2018

		Date:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Taste of the Wild Pacific Salmon Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	Description:	2 cups fed once per day
		First Exposure Date:	01/01/2017
		Last Exposure Date:	03/19/2019
		Time Interval between Product Use and Adverse Event:	2 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
		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	
	Weight:	35.9 Kilogram	
	Age:	7.5 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	No
		Healthcare Professional Information:	Practice Name:
		Contact: Name:	Darcy Adin

			Phone: (614) 582-9798
			Other Phone: 3522948606
			Email: adind@ufl.edu
		Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States

Sender Information:	Name:	Darcy Adin	
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States	
	Contact:	Phone:	6145829798
		Other Phone:	3522948606
		Email:	adind@ufl.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		

Additional Documents:	
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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren; Jones, Jennifer L; Nemser, Sarah; Ceric, Olgica; Glover, Mark
CC: Rotstein, David
Sent: 4/12/2018 6:00:27 PM
Subject: another DCM: FW: Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food: **B6** - EON-351034
Attachments: 2045680-report.pdf

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



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From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Thursday, April 12, 2018 1:56 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; **B6**
Subject: Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food: **B6**
EON-351034

A PFR Report has been received and PFR Event [EON-351034] has been created in the EON System.

A "PDF" report by name "2045680-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-351034

ICSR #: 2045680

EON Title: PFR Event created for Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food; 2045680

AE Date	08/04/2016	Number Fed/Exposed	1
Best By Date		Number Reacted	1

Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	11 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2045680

Product Group: Pet Food

Product Name: Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food

Description: **B6** was diagnosed with dilated cardiomyopathy and left sided congestive heart failure by the cardiology service at **B6** 8/4/2016. Her disease has been stable. Due to reports of DCM related to taurine deficiency on grain free diets, a whole blood taurine level was submitted on 3/2/2018 by the cardiology service. Whole blood taurine was 57 (ref range 200-350, critical <150). owner was advised to stop current diet and start taurine supplementation.

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
Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food		

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:

<https://eon.fda.gov/eon/>

B6

B6

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Report Details - EON-351034	
ICSR:	2045680
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
Report Submission Date:	2018-04-12 13:51:10 EDT
Reported Problem:	Problem Description: B6 was diagnosed with dilated cardiomyopathy and left sided congestive heart failure by the cardiology service at B6 8/4/2016. Her disease has been stable. Due to reports of DCM related to taurine deficiency on grain free diets, a whole blood taurine level was submitted on 3/2/2018 by the cardiology service. Whole blood taurine was 57 (ref range 200-350, critical <150). owner was advised to stop current diet and start taurine supplementation.
	Date Problem Started: 08/04/2016
	Concurrent Medical Problem: Yes
	Pre Existing Conditions: Heart murmur first documented 4/3/2016 - 2/6 left basilar systolic
	Outcome to Date: Stable
Product Information:	Product Name: Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food
	Product Type: Pet Food
	Lot Number:
	Product Use Information:
	Description: Owner has been feeding daily for several years. Briefly switched diets for 3 months over 1 year prior but switched back as the Kirkland was better tolerated by the dog's GI tract.
	Last Exposure Date: 03/09/2018
	Product Use Stopped After the Onset of the Adverse Event: Unknown
	Perceived Relatedness to Adverse Event: Possibly related
	Other Foods or Products Given to the Animal During This Time Period: Yes
	Manufacturer /Distributor Information:
Purchase Location Information: Name: Costco Wholesale	
Animal Information:	Name: B6
	Type Of Species: Dog
	Type Of Breed: Retriever - Golden
	Gender: Female
	Reproductive Status: Neutered
	Weight: 31.1 Kilogram
	Age: 11 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
Number of Animals Reacted: 1	

	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6
			Phone: B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6
		Phone: B6	
Address:		B6 United States	
Type of Veterinarian:		Referred veterinarian	
	Date First Seen:	08/04/2016	
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone: B6	
		Email: B6	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		
Additional Documents:			

From: ADIN,DARCY BRITTAIN <adind@ufl.edu>
To: Jones, Jennifer L
Sent: 12/7/2018 12:48:35 PM
Subject: article
Attachments: Published diet manuscript.pdf

Hi Jen,

Just thought I'd share out diet DCM paper from NCSU with you. It is available for sharing but won't be in the journal til 2019.

It was great to talk this week and hear all the progress you've made!

Take care
Darcy

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Echocardiographic phenotype of canine dilated cardiomyopathy differs based on diet type[☆]



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KEYWORDS

Nutritional;
Heart failure;
Dog;
Taurine

Abstract *Introduction:* Canine dilated cardiomyopathy (DCM) can result from numerous etiologies including genetic mutations, infections, toxins, and nutritional imbalances. This study sought to characterize differences in echocardiographic findings between dogs with DCM fed grain-free (GF) diets and grain-based (GB) diets.

Animals: Forty-eight dogs with DCM and known diet history.

Methods: This was a retrospective analysis of dogs with DCM from January 1, 2015 to May 1, 2018 with a known diet history. Dogs were grouped by diet (GF and GB), and the GF group was further divided into dogs eating the most common grain-free diet (GF-1) and other grain-free diets (GF-o). Demographics, diet history, echocardiographic parameters, taurine concentrations, and vertebral heart scale were compared between GB, all GF, GF-1, and GF-o groups at diagnosis and recheck.

Results: Dogs eating GF-1 weighed less than GB and GF-o dogs, but age and sex were not different between groups. Left ventricular size in diastole and systole

Presented in abstract form at the American College of Veterinary Internal Medicine Forum, Seattle, WA, June 2018.

^{*} A unique aspect of the Journal of Veterinary Cardiology is the emphasis of additional web-based materials permitting the detailing of procedures and diagnostics. These materials can be viewed (by those readers with subscription access) by going to <http://www.sciencedirect.com/science/journal/17602734>. The issue to be viewed is clicked and the available PDF and image downloading is available via the Summary Plus link. The supplementary material for a given article appears at the end of the page. To view the material is to go to <http://www.doi.org> and enter the doi number unique to this paper which is indicated at the end of the manuscript.

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was greater, and sphericity index was less for GF-1 compared with GB dogs. Diastolic left ventricular size was greater for all GF compared with that of GB dogs. Fractional shortening, left atrial size, and vertebral heart scale were not different between groups. Taurine deficiency was not identified in GF dogs, and presence of congestive heart failure was not different between groups. Seven dogs that were reevaluated after diet change (6 received taurine supplementation) had clinical and echocardiographic improvement.

Conclusions: Dietary-associated DCM occurs with some GF diets and can improve with nutritional management, including diet change. The role of taurine supplementation, even without deficiency, is uncertain.

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Abbreviations

CHF	congestive heart failure
GF	grain-free
GB	grain-based
GF-1	most common grain-free diet
GF-o	other grain-free diets
IFA	immunofluorescence assay
LVIDdN	normalized left ventricular internal diastolic diameter
LVIDsN	normalized left ventricular internal systolic diameter
PCR	polymerase chain reaction

Introduction

Dilated cardiomyopathy (DCM) is a common cause of congestive heart failure (CHF) in dogs and is historically more common in male, large-breed dogs with certain breed predilections including Doberman Pinschers, Great Danes, and Irish Wolfhounds [1–5]. Ventricular dilation and impaired contractility in the absence of primary valvular or vascular diseases are the hallmark findings of DCM [1]. A number of disease processes can lead to the development of systolic dysfunction, which is the major pathophysiologic driver for clinical signs including dyspnea, tachypnea, syncope, and sudden death. Genetic mutations associated with DCM have been suspected or identified in some predisposed breeds [3–5]. Additionally, systemic disease, toxins, and a variety of infectious agents have been reported to cause myocardial failure resembling DCM and leading to CHF [6–9]. Nutritional causes of DCM, such as taurine and carnitine deficiency, are especially important to identify in clinical patients, as there appears to be a degree of reversibility associated with supplementation of these compounds [10–14]. Although taurine and L-

carnitine deficiencies have been associated with DCM in some dogs, with suspected breed predispositions, little is known about other diet-related etiologies [13–15]. In people, macronutrient or micronutrient deficiencies (e.g. selenium, zinc, thiamine, copper, iron, taurine, and carnitine) as well as nutrient toxicities (e.g. iron and cobalt) have also been associated with DCM [16–19]. Nutrient imbalances may promote inefficient myocardial energy expenditure and could cause or exacerbate DCM.

This study was initiated because of increased recognition of DCM in dogs without a known breed or demographic predilection, and an observation that many of these dogs were eating specialty meat-based grain-free (GF) diets. We hypothesized that among dogs diagnosed with DCM, those eating meat-based GF diets would have more advanced left ventricular systolic dysfunction and remodeling than those eating meat and grain-based (GB) diets. We also hypothesized that dogs eating one particular brand of most common grain-free diet (GF-1) would have more advanced disease than dogs eating other brands of grain-free diet (GF-o).

Animal, materials, and methods

Medical records at the North Carolina State University, College of Veterinary Medicine, were retrospectively evaluated for the diagnosis of canine DCM from January 1, 2015 to May 1, 2018. Dogs were included if the food brand and variety were known and an echocardiographic diagnosis of DCM was made based on fractional shortening $\leq 25\%$, normalized left ventricular internal diastolic diameter (LVIDdN) ≥ 1.8 , and normalized left ventricular internal systolic diameter (LVIDsN) ≥ 1.2 [1,20]. Exclusion criteria were congenital heart disease, primary valve disease,

unknown diet history, or vegan, vegetarian, or home-cooked diets.

Dogs were grouped by diet type into GF and GB based on label ingredients as reported by the manufacturer. Foods were considered GB if wheat, rice, oats, cornmeal, barley, bulgur, millet, rye, or spelt were listed as ingredients and GF if none of these grain products were listed. The GF group was subdivided into dogs fed GF-1 and GF-o. Demographic information (age, breed, weight in kilograms [kg], and sex) was recorded. The recorded diet represented the main calorie source as reported by the owner. Echocardiographic parameters that were independent of or normalized for body weight (fractional shortening, LVIDdN by M-mode, LVIDsN by M-mode, ratio of the left atrial dimension to the aortic annulus dimension by 2-D right parasternal short-axis view [21], and diastolic left ventricular sphericity index [SI] as previously described [22,23]) were recorded from each included case. In addition, records were evaluated for the presence or absence of CHF at the time of diagnosis, and radiographic vertebral heart scale [24] was evaluated and recorded. Echocardiograms were reviewed by one investigator (DA). Results of ancillary testing such as whole blood or plasma taurine concentrations, plasma L-carnitine concentrations, blood selenium concentrations, infectious disease testing (Bartonella immunofluorescence assay [IFA] and polymerase chain reaction [PCR], Rickettsia IFA and PCR, Anaplasma IFA and PCR, Babesia PCR, Ehrlichia IFA and PCR, Mycoplasma PCR, Lyme IFA, Trypanosoma cruzi PCR, and Leishmania IFA), and necropsies were recorded where available. The established reference range for laboratories^{a,b,c} and published studies were utilized for interpretation of tests [14,25,26].

Dogs that were diagnosed with DCM and underwent a diet change had serial echocardiographic information collected at each recheck during the study period.

Statistical analysis was performed using commercially available software^d. Data collected from each group were tested for normality using the Kolmogorov-Smirnov test and presented as median and 95% confidence intervals. Demographic data, echocardiographic parameters, whole blood taurine concentrations, and radiographic vertebral

heart scale at the time of diagnoses were compared between groups using one-way analysis of variance if data were normally distributed or Kruskal-Wallis test if data were not normally distributed. Post hoc testing was performed where indicated (Tukey's or Dunn's respectively). The presence or absence of CHF and sex were compared between groups using Fisher's exact test. Data from dogs with follow-up evaluations after diet change were assessed for echocardiographic changes using a 2-tailed, paired *t*-test.

Results

Dogs

A total of 91 dogs were diagnosed with DCM at the North Carolina State University, College of Veterinary Medicine, from January 1, 2015 to May 1, 2018. Forty-three dogs were excluded from group comparisons because of the lack of a diet history (41) or vegan or vegetarian diet (2). All dogs were treated with standard medications at recommended doses for CHF or for preclinical heart disease using a combination of pimobendan, enalapril, and furosemide if indicated.

Diets

Twelve of the included dogs were eating GB at the time of DCM diagnosis, and 36 were eating GF. Of the GF dogs, 14 were eating GF-1, and 22 were eating GF-o. There were two pairs of unrelated housemates included (both eating GF-1) and one pair of related housemate dogs included in the GF group. Seven brands of GB diets were represented, and 13 brands of GF were represented. The number of dogs eating each GB brand ranged from 1 to 3. The number of dogs eating each GF brand ranged from 1 to 5 for GF-o with 14 dogs eating GF-1.

A diet change from GF to GB manufactured by a major brand pet food company with veterinary nutritionists on staff was consistently recommended for all dogs in the GF group after June 2017 but was not recommended for the GB group and inconsistently recommended for the GF group before this time. Two dogs in the GF group were switched to a major brand food that was GF. All but one dog in the GF group received supplementation with taurine (30 mg/kg twice daily) after diagnosis and diet change, even if whole blood taurine concentrations were within or above the reference range.

^a Metabolic Analysis Labs, Inc. Madison, WI.

^b Amino Acid Laboratory, Davis, CA.

^c Michigan State University, Veterinary Diagnostic Laboratory, Lansing, MI.

^d GraphPad Prism 6, La Jolla, CA, USA.

Table 1 Median and 95% confidence intervals for weight, age, percentage male, percentage of dogs with congestive heart failure (CHF) at diagnosis, and vertebral heart scale.

	GB (n = 12)	All GF (n = 36)	GF-1 (n = 14)	GF-o (n = 22)	P value
Weight (kg)	36.5 (25.3–41.2)	30 (23.3–33.7)	21.0 (13.0–26.5) ^{a,b}	31.7 (27.1–39.9)	0.01
Age (yrs)	7.5 (4.7–9.7)	5.0 (4.9–6.9)	5.0 (4.6–7.6)	5.0 (4.5–8.0)	0.6
Male (%)	75	56	57	55	0.65
CHF (%)	67	78	93	68	0.32
VHS	11.4 (11.1–12.3)	12.4 (12.0–12.8)	12.5 (12.3–13.5)	11.9 (11.5–12.5)	NS

GB, grain-based diets; All GF, all grain-free diets, GF-1, most common grain-free diet, GF-o, other grain-free diets; VHS, vertebral heart scale.

^a Significantly different from GB.

^b significantly different from GF-o. VHS was significantly different between groups ($p=0.04$); however, this significance was lost after multiple comparison testing.

Demographic and radiographic data

Breeds of dogs eating GB diets included Doberman Pinscher (4), Labrador Retriever (2), Chihuahua (1), Weimaraner (1), Australian Shepherd (1), Cavalier King Charles Spaniel (1), Bouvier des Flandres (1), and German shepherd (1). Breeds of dogs eating GF diets included Doberman Pinscher (6), Golden Retriever (5), Great Dane (4), Labrador Retriever (4), mixed breed (4), Miniature Schnauzer (2), Yorkshire Terrier (1), Miniature Poodle (1), Standard Poodle (1), Maltipoo (1), Shetland Sheepdog (1), Old English Sheepdog (1), Chesapeake Bay Retriever (1), German Shorthaired Pointer (1), German Shepherd (1), Miniature Pinscher (1), and Boxer (1).

Table 1 summarizes demographic information (age, sex, and weight) and presence or absence of CHF at the time of diagnosis. There was no difference in age or sex between groups, but GF-1 dogs weighed less than GF-o dogs and less than GB dogs ($p=0.01$). No differences were identified between groups with regard to the presence of CHF at the time of diagnosis ($p=0.3$) or radiographic heart size as assessed by vertebral heart scale ($p=0.04$ between groups but not significant after multiple comparison testing).

Echocardiographic data

Table 2 shows the echocardiographic variables for each diet group. There was no difference in fractional shortening ($p=0.9$) between groups, but GF-1 dogs had higher LVIDdN ($p=0.003$) and LVIDsN ($p=0.01$) than GB dogs. Additionally, all GF dogs, regardless of brand, had higher LVIDdN compared with GB ($p=0.003$). Left ventricular diastolic SI was lower for GF-1 compared with GB diets indicating a more spherical left ventricular shape ($p=0.02$). Left atrial size, as assessed by the ratio of the left atrial dimension to the aortic annulus dimension, was not different between groups ($p=0.5$).

Ancillary testing

Figure 1 shows whole blood taurine and L-carnitine concentrations from dogs that were tested (21 [61%] of GF dogs and 5 [42%] of GB dogs had taurine testing, 4 [11%] of GF dogs had L-carnitine testing). No taurine (as assessed by whole blood or plasma concentrations) or plasma L-carnitine deficiencies were identified among the GF dogs tested (21 taurine, 4 L-carnitine) when utilizing the reference ranges supplied by the testing laboratory, and there was no difference in whole blood taurine

Table 2 Median and 95% confidence intervals for echocardiographic variables at diagnosis.

	GB (n = 12)	All GF (n = 36)	GF-1 (n = 14)	GF-o (n = 22)	P value
FS (%)	13.0 (11.1–17.8)	15.5 (13.8–16.9)	14.5 (11.9–18.2)	16.5 (13.6–17.3)	0.9
LVIDdN	2.13 (2.01–2.20)	2.36 (2.28–2.48) ^a	2.49 (2.36–2.64) ^a	2.22 (2.15–2.42)	0.003
LVIDsN	1.71 (1.57–1.79)	1.85 (1.80–1.99)	1.91 (1.86–2.16) ^a	1.77 (1.68–1.93)	0.01
SI	1.34 (1.30–1.58)	1.27 (1.26–1.37)	1.23 (1.19–1.30) ^a	1.32 (1.30–1.44)	0.02
LA:Ao	1.98 (1.74–2.16)	2.02 (1.88–2.15)	2.11 (1.89–2.39)	1.94 (1.78–2.10)	0.5

FS (%), percent fractional shortening; LVIDdN, normalized left ventricular internal diameter in diastole; LVIDsN, normalized left ventricular diameter in systole; SI, diastolic left ventricular sphericity index; LA:Ao, left atrial to aortic ratio; GB, grain-based diets; All GF, all grain-free diets, GF-1, most common grain-free diet, GF-o, other grain-free diets.

^a Significantly different from GB.

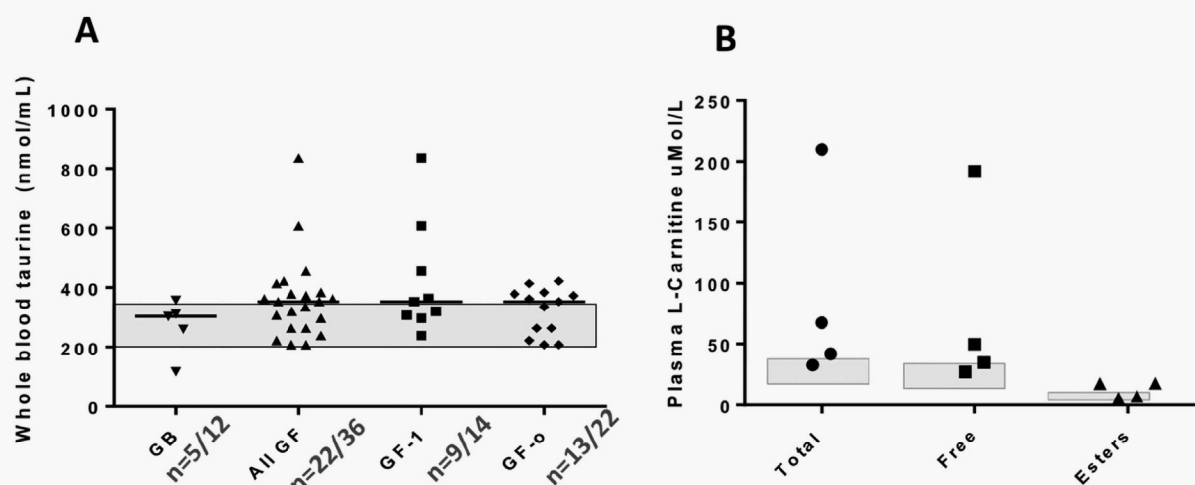


Fig 1 A) Dot plot for whole blood taurine concentrations for each group. The shaded area represents the reference range. The central line is the median. The number of dogs in each group with blood taurine concentrations evaluated is listed on the x-axis next to the group. $P = 0.4$ between groups. (B) Dot plot for plasma L-carnitine concentrations (total, free and esters) for 4 dogs in the GF group (2 GF-1 and 2 GF-o). The shaded area represents the reference range. GB, grain-based diets; All GF, all grain-free diets; GF-1, most common grain-free diet; GF-o, other grain-free diets.

concentrations between groups ($p=0.4$). Three dogs in the GF group had whole blood taurine concentrations that were within the reference range (200–350 nmol/mL) but in the 25th percentile reported for normal dogs (whole blood 208, 208 and 222 nmol/mL) [25]. Twelve GF dogs and one GB dog had whole blood taurine concentrations above the reference range. Taurine deficiency was identified in two dogs being fed GB (whole blood 118 nmol/ml and plasma 38 nmol/ml). One of these GB died in-hospital (German shepherd), and the other dog clinically, radiographically, and echocardiographically improved with a diet change and taurine supplementation (Bouvier des Flandres), similar to previous reports of taurine-responsive DCM [10,12].

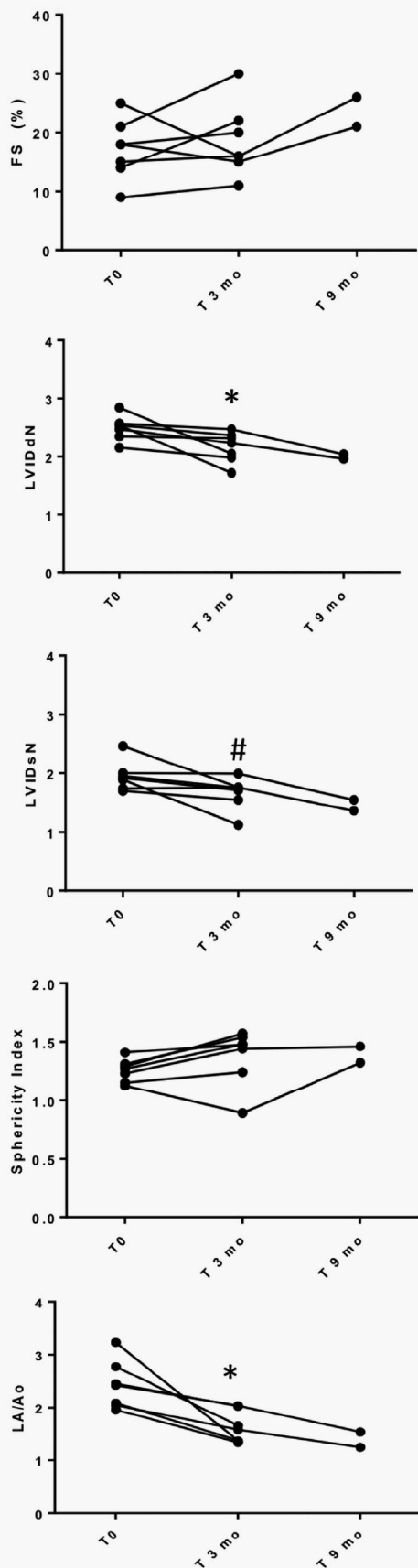
Four dogs in the GB group and eight dogs in the GF group had cardiac troponin I evaluated, and values were not different between groups ($p=0.2$, GB median = 0.37 ng/mL, range <0.20–0.83 ng/mL; GF median = 0.88 ng/mL, range = 0.26–14.30 ng/ml; reference range <0.2 ng/mL). Two dogs in the GF group were negative for selenium deficiency (serum = 331 ng/mL for one dog, reference range = 200–300 ng/mL, and whole blood = 405 ng/ml for another dog, reference range = 200–400 ng/mL). Five GF dogs were tested for infectious diseases with all negative results.

Three dogs in the GF group had myocardial histopathology performed as part of necropsy; findings were unremarkable in one dog, disclosed

mild myocardial fibrosis with myofiber degeneration in a second dog, and myofiber vacuolar degeneration and atrophy with moderate sub-endocardial fibroelastosis and interstitial edema in a third dog. No specific etiology for DCM was evident on necropsy in any case.

Serial echocardiographic evaluations

Seven GF dogs had follow-up echocardiograms 3 months after DCM diagnosis and a diet change, and 2/7 dogs had another follow-up echocardiogram 9 months after diagnosis and a diet change. Six of these seven dogs were eating GF-1 at the time of diagnosis, and one was eating GF-o. The diet was changed from GF to GB in 5/7 dogs and to a major brand GF diet in 2/7 dogs. Taurine was supplemented in 6/7 dogs despite whole blood taurine concentrations that were within or above the reference range (5 dogs), or because taurine was not measured at presentation (1 dog). One of the seven dogs did not receive taurine supplementation because whole blood taurine concentration was above the reference range. Figure 2 shows the change in echocardiographic parameters between diagnosis and 3 months after diagnosis for seven dogs and 9 months after diagnosis for two of these dogs. There was a decrease in LVIDdN ($p=0.02$), LVIDsN ($p=0.05$), and ratio of the left atrial dimension to the aortic annulus dimension ($p=0.02$) at the 3-month recheck. Fractional shortening ($p=0.9$) and SI ($p=0.2$) did not change



at the 3-month recheck. Two dogs were rechecked a second time 9 months after diet change. One of these dogs received taurine supplementation and showed progressive improvement at both 3 and 9 months. The other dog did not receive taurine supplementation because whole blood taurine concentrations were high, and this dog showed improvement at 9 months that was not evident at 3 months. One of the seven dogs had a normal echocardiogram 2 years prior to presentation with CHF due to DCM, and this dog also showed echocardiographic improvement 3 months after DCM diagnosis, diet change, and taurine supplementation.

Serial clinical evaluations

No GF dogs experienced new onset or recurrent CHF after diet change, but one dog died suddenly 4 months after diagnosis (1 month after the 3-month recheck which showed echocardiographic improvement). No GF dogs required an increase in diuretic dosage, and furosemide was discontinued in three dogs 6–9 months after diagnosis and diet change.

Discussion

This retrospective study showed that body weight and some echocardiographic variables differ between dogs with DCM depending on the diet-type being fed. The lower median weight for GF-1 dogs compared with GB dogs supports causes other than genetic because small breed dogs are not considered typically predisposed to the development of DCM [2]. For their size, dogs eating all GF diets had larger left ventricular diastolic diameters than dogs eating GB diets. Additionally, dogs eating the GF-1 in this study not only had larger left

Fig 2 Echocardiographic parameters are shown for seven dogs eating GF diets at the time of diagnosis and at subsequent recheck evaluations after diet change and taurine supplementation in 6/7 dogs. Seven dogs were reevaluated 3 months after they were switched to a GB diet (5 dogs) or major brand GF diet (2 dogs). Two of these dogs were evaluated again 9 months after diagnosis. * $p < 0.05$ compared to baseline. # $p = 0.05$ compared to baseline. FS (%), percent fractional shortening; LVIDdN, normalized left ventricular internal diameter in diastole; LVIDsN, normalized left ventricular diameter in systole; SI, diastolic left ventricular sphericity index; LA:Ao, left atrial to aortic ratio; T 0, time 0 months (baseline); T 3 mo, time 3 months; T 9 mo, time 9 months.

ventricular end diastolic diameters but also had larger left ventricular end systolic diameters and lower sphericity indices compared with dogs eating GB, indicating more advanced myocardial dysfunction and remodeling in these dogs. These findings do not appear to be explained by differences in disease stage because the number of dogs with CHF in each group was not statistically different. Significant differences in echocardiographic variables were not found between GF-o and GB. It is possible that the differences between all GF and GB are mainly due to the dramatic effect of GF-1 values, but small numbers and inadequate statistical power may have also influenced these results.

The clinical and echocardiographic improvement observed in seven dogs that were eating GF diets following a diet change deserves emphasis. The improvement in GF dogs after diet change supports potential causality, and the finding of two affected pairs of unrelated housemates eating GF-1 also causally supports diet as a common environmental factor for the development of DCM in these dogs.

The differences in echocardiographic variables suggest a unique pathologic remodeling process occurring in dogs eating GF diets and especially GF-1, but the cause of this presumed diet-related DCM is not known. The predominant legumes in these diets are peas or lentils, and it is possible that the processing, sourcing, or interactions of these or other ingredients could have resulted in deficiency or toxicity of important nutrients in a manner that did not occur with GB diets. The predominance of one particular GF diet (GF-1) in these dogs with DCM suggests that there are differences within the category of GF diets, and that there may be a separate, unidentified mechanism other than GF composition that is responsible for disease. Additionally, the clinical and echocardiographic improvement seen in two GF-1 dogs that were switched to a major brand GF diet suggests that factors besides GF composition or legume type are important, again raising the possibility that sourcing, processing, or interaction of ingredients may be problematic for some diets. Although most of the group differences in echocardiographic parameters appear attributable to GF-1 diet, one of the dogs that responded to a diet change was eating GF-o, supporting a similar pathophysiological process and reversibility for GF-o diets.

Most dogs eating GF diets in this study received taurine supplementation in addition to undergoing a diet change, even though whole blood taurine concentrations were normal or elevated in the

dogs that were evaluated. The role of taurine supplementation in this condition is, therefore, uncertain. Taurine may have contributed to improvement in these dogs as a result of its antioxidant effects, calcium handling effects, or positive inotropic effects [27–29]. Oxidative damage and negative energy balance in the failing myocardium may be improved with taurine supplementation, and it is possible that whole blood concentrations within the reference range provide insufficient support for the failing heart, essentially rendering it a conditionally required amino acid [27,28]. While it is difficult to draw conclusions from low case numbers, the single dog that did not receive taurine supplementation showed minimal echocardiographic improvement at 3 months but did improve 9 months after diagnosis, potentially suggesting slower improvement compared with dogs that were supplemented with taurine. Variability between dogs may also account for this slower improvement. We noted that several dogs eating GF diets had very high whole blood taurine concentrations. These dogs were not supplemented before the diagnosis of DCM; therefore, these values are unexpected in light of studies of taurine concentrations of normal dogs and dogs with DCM [25,26]. Elevated whole blood taurine has been reported in people after myocardial infarction because taurine is rapidly taken up by platelets after myocardial release into the bloodstream with cardiomyocyte injury and death [30,31]. The high values noted in some GF dogs may have been related to myocardial injury. Although some dogs also had cardiac troponin I evaluated, there were too few dogs with both tests performed to meaningfully explore a correlation. The possibility of masked taurine deficiency could be investigated in the future by assessing paired plasma and whole blood taurine concentrations in affected dogs.

This study had several limitations inherent in its retrospective design. The presence of a detailed diet history was inconsistent in our medical records during this study period, which reduced the number of included dogs and could have introduced bias. Dietary intake beyond the commercial dog food that was reported by the owner as the major source of calories, such as treats and supplements, was not recorded and could play an important role in the development of nutritionally based DCM. Additionally, the length of time that dogs had been eating their commercial food before presentation was not consistently recorded. Ancillary testing was not always performed. Although a relatively large number of GF dogs underwent taurine testing which was normal or

elevated, not all dogs had taurine assessed, and we may have missed some deficient dogs. Although our data are most supportive of a causation with one particular diet (GF-1), other GF diets were fed to dogs in the GF group, some to as many as four or five dogs with DCM and some only to a single dog. Because these numbers are small, it is difficult to interpret a role for causation for some less represented diets. Additionally, the improvement noted in two dogs that were switched from GF-1 to a major brand of dog food that was also GF raises the possibility that GF composition may not be the problem. Thus, our group divisions into GF and GB may be irrelevant and subject to refinement in the future, pending ongoing investigations. Additionally, group divisions could be incorrect if the underlying cause of this nutritional cardiomyopathy is related to unusual protein sources or specific manufacturing practices. Some of the dogs in this study were breeds that have a known predisposition to DCM, and follow-up was not obtained for most of the dogs, so it is possible that diet was independent of their disease process. While we cannot discount this possibility for many dogs, one dog that showed echocardiographic improvement was a Great Dane eating GF-o, indicating a probable role for diet in his disease process.

Grain-free diets are rapidly growing in popularity, and it is impossible to determine the prevalence of DCM in dogs eating GF diets without broadly screening populations of dogs by echocardiography. Although we identified 36 dogs with DCM eating GF diets during a 30-month period, this is no doubt a vanishingly small percentage of dogs eating GF diets. Factors such as age, exercise, genetic predisposition, dietary or microbiota modification of gene expression, or other unknown factors may clearly also influence the manifestation of disease in some dogs. A specific and possibly even variable milieu, to which some GF diets may contribute, may be responsible for the clinical development of DCM. Additionally, the length of time necessary for disease development on a specific diet is unknown.

Despite these limitations, this study reveals morphologic differences between the echocardiograms of dogs eating GF and GB diets that point to a potential association between some GF diets and DCM in dogs. Additionally, the echocardiographic differences between GF-1 and GF-o suggest brand differences that could be related to ingredient bioavailability, processing, sourcing, or interactions. This descriptive study should serve as a springboard for future studies to mechanistically explore this relationship and also to encourage clinicians to incorporate dietary history as part of

every examination. Food analysis is underway to investigate possible nutrient deficiency or toxicity that could promote the development of DCM possibly related to legume sourcing or processing or interactions with absorption of other nutrients. Dietary trials to determine the risk of DCM associated with certain GF diets would also be useful.

Conclusions

This study shows compelling evidence that a nutritionally based, partially reversible cardiomyopathy occurs in some dogs fed non-major brand GF diets and may be associated with factors other than the omission of grains. The echocardiographic changes seen in these dogs indicate more advanced disease or a diet-enhanced pathophysiology compared with dogs eating GB diets. Importantly, clinical and echocardiographic improvement was noted in a subset of dogs that were reevaluated after a diet change. The role of taurine supplementation despite adequate blood concentrations is uncertain, but it may be therapeutically additive. Dietary-induced DCM associated with some GF diets remains unproven but should be considered a potential underlying cause or contributor in dogs with DCM, regardless of signalment.

Conflicts of interest statement

Dr. Adin has received/acknowledges research support from Nestlé Purina PetCare. None of the other authors have a conflict of interest to disclose that relate to this study.

Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jvc.2018.11.002>.

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From: Steven Rosenthal <Steven.Rosenthal@cvcavets.com>
To: Jones, Jennifer L
Sent: 7/30/2019 2:44:45 PM
Subject: AVMA covention and publication names

Dr Jones

Unfortunately I have a full day of appointments booked on Friday. I can see if another Dr from our team can come to AVMA on Friday in support of your presentation.

Let us know how we can help

Going though the list of cases the most active enrollers of cases were myself and [REDACTED] **B6**
In addition to myself and [REDACTED] **B6** was active in promoting and contributing to the study.
[REDACTED] **B6** had 1 case or saw a recheck of the patients.
[REDACTED] **B6** our technician in [REDACTED] **B4** was the most active in helping getting the data points squared away

--

Steven L. Rosenthal DVM Dip ACVIM Cardiology
CVCA: Cardiac Care for Pets
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Phone: 410.339.3461
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Visit our website at: www.cvcavets.com
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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 12/27/2018 3:33:42 PM
Subject: [REDACTED] **B6**

Hi Jen
[REDACTED] **B6** was euthanized on [REDACTED] **B6** for worsening CHF, anorexia,
and poor quality of life.

I have food bag and samples if you'd like

Owner gave us permission to report but may want to wait to contact since she recently lost [REDACTED] **B6**

Thanks

Lisa

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

**NC State University
Veterinary Hospital**
Detailed Order Report - BLR0004

Attending DVM: ACCESSION, NON

Order

Client #	Client Name	Patient Name	Sex	Batch #	Invoice #	Number	Type	St	Opened		Closed		Current Charges
									Date	Time	Date	Time	

B6

Comments:

Item	Prod #	Description	Date	DVM	Adj	Qty	Tax	Item Total
------	--------	-------------	------	-----	-----	-----	-----	------------

1 790-170 IRON AND TOTAL IRON BINDING, SO

B6

NO ESTIMATE

THIS IS NOT A FINALIZED BILL. This report displays an itemized listing of charges to date. Additional charges may be added and/or listed charges may be modified during the course of treatment for this patient.

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 1/14/2019 10:00:15 PM
Subject: **B6** update

Hi Jen

B6 taurine came back 145 plasma, 308 whole blood
Still only 1 dog of all of our cases with low taurine
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
Sent: 6/20/2018 5:44:34 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; [B6]
[B6] Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Canine Dilated Cardiomyopathy
Start: 6/28/2018 2:00:00 PM
End: 6/28/2018 3:00:00 PM
Show Time As: Free

Recurrence: (none)
Required Attendees: Hartogenesis, Martine; [B6] Palmer, Lee Anne; Norris, Anne; Jones, Jennifer L
Optional Attendees: DeLancey, Siobhan

Good Afternoon,

We would like to discuss reports of dilated cardiomyopathy in dogs and current findings.

Topic: Discussion of canine dilated cardiomyopathy reports and current findings

Agenda:

- 1) Roll Call (CVM)
- 2) Dilated Cardiomyopathy-Findings (Jones/Palmer)
- 3) Open Discussion

-- Do not delete or change any of the following text. --

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Palmer, Lee Anne; Jones, Jennifer L; Carey, Lauren; Ceric, Olgica; Nemser, Sarah; Queen, Jackie L; Glover, Mark
Sent: 7/2/2018 8:49:21 PM
Subject: cardiomyopathy-FW: 4Health Grain Free; [REDACTED] EON-358131
Attachments: 2051199-report.pdf; 2051199-attachments.zip

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

[REDACTED]



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From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Monday, July 02, 2018 4:28 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [REDACTED] EON-358131
Subject: 4Health Grain Free; [REDACTED] EON-358131

A PFR Report has been received and PFR Event [EON-358131] has been created in the EON System.

A "PDF" report by name "2051199-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 "2051199-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-358131
ICSR #: 2051199
EON Title: PFR Event created for 4Health Grain Free; 2051199

AE Date	05/30/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1

Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mixed (Dog)		
Age	9 Years		
District Involved	PFR [B6]		

Product information

Individual Case Safety Report Number: 2051199

Product Group: Pet Food

Product Name: 4Health Grain Free

Description: Presented as emergency appointment for evaluation of intermittent, persistent cough, first documented five weeks ago. After cough did not respond to course of doxycycline and "cough tabs," Hycodan was added with no improvement. rDVM thoracic radiographs taken on 6/22/18 showed cardiomegaly. Owner describes cough as dry and harsh, which is worse in the evening and when [B6] is in sternal recumbency. [B6] is very active, without any exercise intolerance or weakness. She tends to graze throughout the day, though has been slower to finish her meals recently. [B6] has lost a noticeable amount of weight in the last four weeks. Diagnosed with DCM and taurine level is pending.

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: Better/Improved/Recovering

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4Health Grain Free		

Sender information

[B6]

USA

Owner information

[B6]

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.

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Report Details - EON-358131

ICSR: 2051199
 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
 Report Submission Date: 2018-07-02 16:17:19 EDT

Reported Problem:

Problem Description: Presented as emergency appointment for evaluation of intermittent, persistent cough, first documented five weeks ago. After cough did not respond to course of doxycycline and "cough tabs," Hycodan was added with no improvement. rDVM thoracic radiographs taken on 6/22/18 showed cardiomegaly. Owner describes cough as dry and harsh, which is worse in the evening and when [B6] is in sternal recumbency. [B6] is very active, without any exercise intolerance or weakness. She tends to graze throughout the day, though has been slower to finish her meals recently. [B6] has lost a noticeable amount of weight in the last four weeks. Diagnosed with DCM and taurine level is pending.

Date Problem Started: 05/30/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: Hx of being Lyme positive.

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: 4Health Grain Free

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: Yes

Product Use Information:

Description: 4Health grain free dry- 4 cups daily since late 2016. Also offered rawhide chews from Walmart for years, Canine Carryout Treats for years, and various ham, chicken, and beef table scraps for years.

Time Interval between Product Use and Adverse Event: 2 Years

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Probably related

Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer /Distributor Information:

Purchase Location Information: **Address:** [B6] United States

Animal Information:

Name: [B6]

Type Of Species: Dog

Type Of Breed: Mixed (Dog)

	Gender: Female
	Reproductive Status: Neutered
	Weight: 29.9 Kilogram
	Age: 9 Years
	Assessment of Prior Health: Good
	Number of Animals Reacted: 1
	Owner Information:
	Owner Information provided: Yes
	Contact:
	Name: B6
	Phone: B6
	Email: B6
	Address: B6
	United States
	Healthcare Professional Information:
	Practice Name: B6
	Contact:
	Name: B6
	Phone: B6
	Other Phone: B6
	Email: B6
	Address: B6
	United States
Sender Information:	Name: B6
	Address: B6
	United States
	Contact:
	Phone: B6
	Other Phone: B6
	Email: B6
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
	Reported to Other Parties: None
Additional Documents:	Attachment: cardio0013.pdf
	Description: echo report, diet history
	Type: Medical Records

B6

B6

Patient Information

Patient: **B6** Age: 11 years Referring Veterinarian: **B6**
Patient Number: 229844 Weight:(kg) 29.90 Cardiologist: **B6** DVM, DACVIM
Breed: Blue Heeler Mix Sex: FS Client Number: 152979
Exam Date: 06/28/2018 08:07 BSA: 0.97

History: **B6** was presented as an emergency appointment for evaluation of an intermittent, persistent cough, first documented five weeks ago. After the cough did not respond to a course of doxycycline and "cough tabs," Hycodan was added with no improvement. Regular veterinarian thoracic radiographs taken on 6/22/18 showed cardiomegaly. The owner describes the cough as "dry and harsh," which is worse in the evening and when **B6** is in sternal recumbency. **B6** is a very active dog, without any exercise intolerance or weakness. She is fed 4Health grain free, and tends to graze throughout the day, though has been slower to finish her meals in the last 2-3 days. The owner reports that **B6** has lost a noticeable amount of weight the last four weeks. **B6** has a history of being Lyme positive and is not currently on any heartworm prevention.

Physical Examination: Temp: 101.8 Heart Rate: 110 bpm. RR: Pant. Quiet/muffled heart sounds with gallop and grade 2-3/6 systolic left apical murmur. Regular rhythm. Poor femoral pulse quality. Normal lung sounds with frequent harsh cough. Normal abdominal palpation. mm pink, normal refill, well hydrated. Normal PLNs.

Diagnostic Tests: Blood pressure: 150 mmHg with 4 cm cuff on right forelimb.
Taurine level pending
Echocardiogram: See below. ECG during echo showed a sinus tachycardia.

Echocardiographic Report

B6

Left Ventricle: Moderate dilation with poor global contractility.
Left Atrium: Moderate to severe dilation.

Right Ventricle: Moderate dilation with poor global contractility.
Right Atrium: Moderate dilation.
Mitral Valve: 2-3+ central jet of regurgitation.
Aortic Valve: Normal.
Tricuspid Valve: 2+ central jet of regurgitation. TR velocity is mildly elevated suggestive of mild pulmonary hypertension.
Pulmonic Valve: Reduced outflow velocity. Normal valve morphology. Mild dilation of pulmonary artery.
Aorta: Normal.
Pericardium: Normal.

Diagnosis

Dilated cardiomyopathy - This is a disease characterized by weakening of the heart muscle and dilation of the heart chambers. As the disease progresses, it can lead to congestive heart failure (fluid in the lungs causing shortness of breath and cough). Abnormal heart rhythms are common and can result in sudden death. Most commonly this is an inherited disease, though it can occur secondary to a deficiency in an amino acid called taurine. We have also become concerned that there may be a link between grain free and/or unusual protein source diets and dilated cardiomyopathy in some animals.

Recommendations

Please give all medications as directed:

Furosemide (Lasix, Salix) 40mg tablets- Give 1 tablet by mouth every 12 hours. DUE: 7pm

This is a diuretic (water pill), that prevents the body from retaining excessive sodium and water. It will cause your pet to drink and urinate more frequently. It is important that fresh water is always available.

Pimobendan (Vetmedin) 10mg tablets- Give 1 tablet (10mg) by mouth in the morning and 1/2 tablet (5mg) by mouth in the evening, at 12 hour intervals. DUE: 7pm

This is a drug that is approved for the treatment of congestive heart failure secondary to dilated cardiomyopathy or chronic valve disease (endocardiosis). However, two studies of dogs with dilated cardiomyopathy, one in Doberman Pinschers (PROTECT) and one in Irish Wolfhounds, have shown a delay in the onset of heart failure in preclinical dogs treated with Vetmedin compared to placebo. Recently, another study (EPIC) has shown significant prolongation of the asymptomatic period in animals with progressive disease and heart enlargement from chronic valve disease, prior to the onset of congestive heart failure, as well. This is off-label use of this medication. In our experience, side effects are uncommon, but it is important that you advise us if you feel your pet is having any potential adverse effects from this medication. The reported potential side effects listed for this medication are increased heart rate, vomiting, diarrhea, inappetence, uneasiness, incoordination, convulsions, increased drinking and increase urinating.

Spirinolactone (Aldactone) 50mg tablets- Give 1 tablet by mouth every 24 hours. DUE: 7pm.

This is a diuretic (water pill) that also blocks a hormone that can injure the heart muscle. It works well in combination with the furosemide and enalapril.

Benazepril 10mg tablet- Give 1 tablet by mouth every 12 hours. DUE: 7 pm.

This medication is a strong drug that dilates blood vessels, permitting the heart to pump blood more efficiently. It can lower blood pressure (hypotension) and cause changes in kidney function and electrolyte values. If your pet develops weakness or depression, decrease the drug dose by 1/2 and call. A kidney panel and blood pressure should be reevaluated 7-10 days after beginning this medication.

Taurine supplementation - Give 1000mg of taurine by mouth every 12 hours. Please refer to the handout titled "Canine Dilated Cardiomyopathy Nutrition Recommendations" for information on recommended brands. L-carnitine supplementation is optional at this time (doses on this handout), but is strongly recommended if we confirm taurine deficiency.

One thing that can be very helpful for home monitoring is checking sleeping or resting respiratory rates. A recent study showed that even pets with severe heart disease rarely have resting respiratory rates greater than 30 breaths per minute unless they are starting to decompensate for that disease. Elevated respiratory rates at home may be even more sensitive than chest radiographs at picking up early decompensation. Count your pet's respiratory rate when he/she is at rest or sleeping (not within 20 minutes of being active). If his/her respiratory rate is greater than 30 breaths per minute, recheck again in a couple of hours. If persistently elevated above this level, call.

With advanced heart disease, our biggest dietary concerns are adequate calorie content and low sodium content. We aim for less than 80mg sodium per 100 kilocalories (kcal) in patients that have developed congestive heart failure, and less than 100mg/100kcal in animals that have advanced heart disease without heart failure. We do not advise protein restriction unless there is concurrent kidney disease (i.e. kidney diets are not advised unless there is concurrent kidney disease). Please refer to the recommended diet handout for our recommendations.

Exercise is also a concern in advanced heart disease. While cage rest is ideal with active heart failure, some exercise is permissible in asymptomatic disease. However, vigorous or extended exercise should be avoided.

We would like re-evaluate **B6** in 10-14 days. At that time we will recheck a blood pressure, kidney panel with electrolytes and a thorough physical exam +/- chest radiographs. Please call if you do not see a significant improvement in her cough within 72 hours or if at any time she seems like she is getting worse.

B6

DVM, DACVIM (Cardiology)

(Electronically Signed)

Final Date: 28 June 2018 21:17

B6

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www.facebook.com

B6

Notes to our clients

-Please bring all medications to your pet's scheduled appointments.

-We require a 48 hour notice for all refills. When you call to request a refill, please leave the pharmacy phone number or clearly indicate if you plan on picking up the medication at our facility. **PRESCRIPTION REFILLS ARE NOT AVAILABLE AFTER **B6** REGULAR BUSINESS HOURS (Evenings, Fridays, holidays and weekends).**

-Check out WWW.GOODRX.COM and enter your local zip code to search for the best prices on your medications at your local pharmacies.

-If an emergency arises with your pet, **B6** is a 24 hour facility.

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 6-28-18

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: Poor _____ | _____ Excellent
Poor _____ | _____ Excellent

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

Eats about the same amount as usual Eats less than usual Eats more than usual
 Seems to prefer different foods than usual Other _____

3. Over the last few weeks, has your pet (check one)

Lost weight Gained weight Stayed about the same weight Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

Food (include specific product and flavor) Form Amount How often? Fed since
Examples are shown in the table – please provide enough detail that we could go do the store and buy the exact same food.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
Pupperoni original beef flavor	treat	1/2	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
<u>4 HEALTH GRAIN FREE</u>	<u>DRY</u>	<u>4 CUPS</u>	<u>DAILY</u>	<u>LATE 2016</u>
<u>RAWHIDE CHEWS (WALMART)</u>	<u>BOUTIE</u>	<u>1</u>	<u>2-3 times</u>	<u>YEARS</u>
<u>VARIOUS Ham, Chicken, Beef</u>	<u>COOKED</u>	<u>TABLE SCRAPS</u>	<u>2-3 times</u>	<u>YEARS</u>
<u>CANINE CARRYOUT TREATS</u>	<u>DRY</u>	<u>3-4 PCS</u>	<u>3+ times</u>	<u>YEARS</u>

*Any additional diet information can be listed on the back of this sheet

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? Yes No

If yes, please list which ones and give brands and amounts:

	Brand/Concentration	Amount per day
Taurine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Carnitine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Antioxidants <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Multivitamin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Fish oil <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Coenzyme Q10 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Other (please list): Example: Vitamin C	<u>Nature's Bounty</u>	<u>500 mg tablets – 1 per day</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

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): _____

Information below to be completed by the veterinarian: DUPS! SORRY!

Current body weight: 65 LB. kg Current body condition score (1-9): 8 /9

Muscle Condition Score: normal muscle mild muscle loss moderate muscle loss severe muscle loss

wt - 29.9kg
+ 10.8
P 110
R - Pant
BP

Name: B6 ID: 229844 Client: B6

Age: 9 Yrs. 0 Mos. DOB: B6

Breed: Blue Heeler, Australian Mix Sex: Spayed Female Lyme + 5/22/18.

Current History: good health until coughing about 5 wks ago.
weight loss -> initially concern for kennel cough, but
Concurrent Condition: x-rays b/22 -> Cardomegly. Cough is dry & harsh. LTR

Respiratory symptoms (cough, difficulty breathing, voice changes):
- Panting w/ cold weather -> not new. Started Doxy & cough tabs on 5/22 -> no change in cough. Added in Hycodan on 6/8. Still no A

Exercise tolerance (activity level, lameness, weakness/lethargy):
- nothing, very active.

Heartworm prevention (seasonal vs. year round, brand, last heartworm test):
- Hwt 5/22/18 -> no prevention. Cough intermittent. Cough worsened at night. And while laying sternally.

Ownership period (rescue/breeder):
- Since 6 wks of age from friend

Diet (brand, canned vs. dry, appetite):
- 4 Health grain-free about a year now. EID fine. tends to graze 2-3 days ago, ↓ Appetite.

Indoor and/or Outdoor (feline patients):
-

Travel History:
- nothing.

Abnormal weight loss/gain:
 Yes No Explain: lost 6# in 4 wks, per O

Current Medications:

Refills needed? (30 vs. 90 day supply): off cough tabs & Hycodan ≈ 2 wks ago. Finished Doxy ≈ 3 wks ago.

Diagnostic Plan:

- | | | | |
|---|---|--|---------------------------------------|
| <input type="checkbox"/> Blood pressure | <input type="checkbox"/> Holter/Event | <input type="checkbox"/> CBC | <input type="checkbox"/> Digoxin |
| <input type="checkbox"/> Thoracic Radiographs | <input type="checkbox"/> Echocardiogram | <input type="checkbox"/> Profile | <input type="checkbox"/> T4 |
| <input type="checkbox"/> ECG | <input type="checkbox"/> PCV/TP | <input type="checkbox"/> Renal | <input type="checkbox"/> TSH |
| <input type="checkbox"/> Sedation | <input type="checkbox"/> U/A | <input type="checkbox"/> Urine culture | <input type="checkbox"/> Abdominal US |

Other diagnostics: _____

Technician:
Veterinarian:

Small lump on thorax 2 years, no change.

B6

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Nemser, Sarah; Ceric, Olgica; 'Guag, Jake * (Jake.Guag@fda.hhs.gov)'; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 11/28/2017 12:34:03 PM
Subject: Case Final reports-For resume

Jones J, Nemser S, Ceric O, Guag J, Rotstein D, Palmer LA, Carey L, Reimschuessel R. Investigation into the death of one cat and illness of another after consuming Kit and Caboodle cat food-Case Study 800.208. Final Report. 2017.

Jones J, Nemser S, Ceric O, Guag J, Rotstein D, Palmer LA, Carey L, Reimschuessel R. Investigation into the illness of two dogs after consuming Farmer's Market Grain Free Roast Meat dog food and Vegetables and Farmer's Market Meatballs with chicken, sweet potato, and pea dog food-Case Study 800.209. Final Report. 2017.

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
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fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Nemser, Sarah </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS /CN=SARAH.YACHETTI>
To: Reimschuessel, Renate; Ceric, Olgica; Jones, Jennifer L
Sent: 11/21/2016 9:21:15 PM
Subject: Case Review document - follow up via email
Attachments: follow up review-11-21-2016.doc

11-21-2016

PENDING

CC-147575- [B6] BlueRidgeBeef-kitten deaths – currently no Vet-LIRN action
CC-147708- [B6] Purina-FrostyPaws – No diagnostic sample available – NFA?
EON pending- [B6] Dog DCM-vegan – Tufts is working on the case and will submit
EON-288439- [B6] -dead-MRx-hold food – NFA?
EON-291123- [B6] CesarClassic-dog – waiting for response from owner
No CC-3 dead-dog food-outdoors- [B6] – waiting for complaint

CASE FOLLOW UP

Signed and need to file

800.175 – Final Report - Ceric
800.180 – Final Report – Jones
800.184 – Final Report- Jones

Submitted for Signature

800.169 – Final Report
800.173 – Final Report - Ceric
800.185 – Final Report - Nemser

Sent to RR for review

Working on Final Report

800.179 – Final Report - Nemser
800.183 – Final Report - Nemser
800.186 – Final Report - Jones
800.187 – Final Report - Jones
800.193- Final Report - Jones

Pending cases

800.06 – [B6] – paper submitted
800.188-EON-283065- [B6] Diamond – NFA?
800.189-EON-282600- [B6] Fresh Pet – WGS pending
800.190-CC-147100- [B6] Iams-Salm – ORA is testing dog food
800.191-cc-147287- [B6] Zignature Zssentials- results of purchased food pending
800.192-EON-287255- [B6] Big Heart-sal-sweet pot – testing open product
800.194-EON-285575- [B6] PurinaProPlan-cat – received formalin fixed tissue – plan to collect food
800.195-EON-289034- [B6] Blue Ridge Beef-Salm – fecal testing pending
800.196 – Bone Stomacher project – samples received

Sarah Nemser M.S.

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Vet-LIRN Network Coordinator

8401 Muirkirk Road, G202, HFV 500

Laurel, Maryland 20708

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

P Please consider the environment before printing this email

Vet-LIRN

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

11-21-2016

PENDING

CC-147575- [B6] -BlueRidgeBeef-kitten deaths – currently no Vet-LIRN action
CC-147708- [B6] Purina-FrostyPaws – No diagnostic sample available – NFA?
EON pending [B6] -Dog DCM-vegan – Tufts is working on the case and will submit
EON-288439- [B6] -dead-MRx-hold food – NFA?
EON-291123- [B6] -CesarClassic-dog – waiting for response from owner
No CC-3 dead-dog food-outdoors- [B6] – waiting for complaint

CASE FOLLOW UP

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800.175 – Final Report - Ceric
800.180 – Final Report – Jones
800.184 – Final Report- Jones

Submitted for Signature

800.169 – Final Report
800.173 – Final Report - Ceric
800.185 – Final Report - Nemser

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Working on Final Report

800.179 – Final Report - Nemser
800.183 – Final Report - Nemser
800.186 – Final Report - Jones
800.187 – Final Report - Jones
800.193- Final Report - Jones

Pending cases

B4, B5, B6

Document properties

Author: Nemser, Sarah
Company: US FDA
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Character count (spaces included): 1416

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Nemser, Sarah; Jones, Jennifer L; Ceric, Olgica
Sent: 11/4/2016 7:04:50 PM
Subject: Cases for YOU!
Attachments: 800.179-EON-246811.docx; 800.183-CC146411.docx; 800.183-CC146411-Photomicrographs.pdf; CC-503-800.04-EON-276400.docx; CC-503-800.04-EON-276400-Photomicrographs.pdf

Here's all of the cases:

Note
800.179 No photos

800.04 CC-503 A couple of additional findings of note including vasculitis and fibrin exudation in the intestine (which goes along with findings in other organs) plus a mild lymphangiectasia.

B5, B6

dave

Accession #	800.179	Species	CN		
Date 11/4/2016	EON-246811	Study #	800	Initial dsr	

**Diagnostic Report:
Dr. Rotstein**

Organ	Diagnosis	Slide #	Photo
Nervous/Sensory			
Brain			<input type="checkbox"/>
Peripheral Nerve			
Eye			<input type="checkbox"/>
Cardiopulmonary			
Nares			<input type="checkbox"/>
Heart	NSF	3,4	<input type="checkbox"/>
Trachea			<input type="checkbox"/>
Lung	NSF	5,6	<input type="checkbox"/>
Digestive/Hepato biliary			
Liver	NSF	3,4	<input type="checkbox"/>
Gall Bladder			<input type="checkbox"/>
Tongue			<input type="checkbox"/>
Esophagus			<input type="checkbox"/>
Stomach	NSF	2	<input type="checkbox"/>
Intestine	A. Enteritis, lymphoplasmacytic, chronic-active, diffuse, mild to moderate with multifocal lamina propria and submucosal hemorrhages.	1,2	<input type="checkbox"/>
Peritoneum			<input type="checkbox"/>
Salivary Gland			<input type="checkbox"/>
Pancreas	NSF	3,4	<input type="checkbox"/>
Mesentery			<input type="checkbox"/>
Hematopoietic/Lymphoreticular			
Spleen	NSF	5,6	<input type="checkbox"/>
Thymus			<input type="checkbox"/>
Lymph Node, NOS			<input type="checkbox"/>
Mesenteric Lymph Node			<input type="checkbox"/>
Tonsil			<input type="checkbox"/>
Bone Marrow			<input type="checkbox"/>
Urogenital			
Kidney	NSF	5,6	<input type="checkbox"/>

x = examined

lg = liver glycogen

Severity codes:

- 1 - minimal
- 2 - mild
- 3 - moderate
- 4 - marked
- 5 - severe

Extent codes

- F - focal
- M - multifocal
- D - diffuse

Gonad codes

- Organ
- t - testis
- o - ovary

Stage

- i - immature
- d - developing
- s - spent

Accession #	800.179	Species	CN		
Date 11/4/2016	EON-246811	Study #	800	Initial dsr	

Organ	Diagnosis	Slide #	Photo
Urinary Bladder			<input type="checkbox"/>
Repro			<input type="checkbox"/>
Musculoskeletal			
Diaphragm			<input type="checkbox"/>
Skeletal Muscle, NOS			<input type="checkbox"/>
Integumentary			
Skin			<input type="checkbox"/>
Endocrine			
Thyroid Gland			<input type="checkbox"/>
Adrenal Gland	NSF	3,4	<input type="checkbox"/>
Parathyroid Gland			<input type="checkbox"/>
Pituitary Gland			<input type="checkbox"/>
			<input type="checkbox"/>
Misc			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

Ancillary Diagnostics:

Test	Sample	Result	Comment

Summary Diagnoses

Enteritis

Primary Diagnostic Category: Inflammatory (Organ Specific)

Linked to Food Exposure: Likely Not Related

Comments:

The cause of the enteritis was not evident. There were bacilli on the mucosal surface which may be cadaver/overgrowth bacteria. Culture/PCR for Clostridia may aid in determining if these may actually be a bacteria of concern such as C. difficile or C. perfringens. The inciting cause was not evident. A non-specific response to the food can't be excluded, but this could have been an idiosyncratic reaction as opposed to a food-specific issue.

David S. Rotstein, DVM, MPVM, Dipl. ACVP

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Document properties

Title: 24-96-F1-5 (S3.90)
Author: J R Myers
Company: US FDA
Template: Normal.dotm
Page count: 2
Paragraph count: 115
Line count: 240
Word count: 238
Character count (spaces excluded): 1269
Character count (spaces included): 1399

Accession #	800.183	Species	FE		
Date	CC146411	Study #	800	Initial dsr	
B6					

Diagnostic Report: Dr. Rotstein

Summary:

Pyothorax

Isolates:

- Anaerobic Culture of Thorax fluid- isolates identified using MALDI-TOF:
 - *Filifactor villosus* (formerly *Clostridium villosum*)-many
 - *Actinomyces sp*-many
 - *Fusobacterium sp*-many
 - *Porphyromonas sp*-few
- Aerobic Culture of Thorax fluid-isolates identified MALDI-TOF:
 - *E. coli*-few
- Gram Stain of thorax fluid:
 - very many gram positive rods & many fungal elements consistent with yeast
- Mycoplasma culture of thorax fluid:
 - Negative

Organ	Diagnosis	Slide #	Photo
Nervous/Sensory			
Brain	NSF	8,9,10	<input type="checkbox"/>
Peripheral Nerve			
Eye			<input type="checkbox"/>
Cardiopulmonary			
Nares			<input type="checkbox"/>
Heart			<input type="checkbox"/>
Trachea	NSF	3	<input type="checkbox"/>
Lung	A. Lung: <ul style="list-style-type: none"> a. Pleuritis, fibrinosuppurative, subacute, diffuse, marked with intralesional bacterial coccobacilli. b. Atelectasis, marginal, multifocal, moderate. c. Alveolar histiocytosis, multifocal, mild. 	1,2	<input checked="" type="checkbox"/>
Digestive/Hepato biliary			
Liver	NSF	3	<input type="checkbox"/>
Gall Bladder			<input type="checkbox"/>
Tongue	NSF	4	<input type="checkbox"/>
Esophagus	NSF	5	<input type="checkbox"/>

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Accession #	800.183	Species	FE		
Date	CC146411	Study #	800	Initial dsr	
B6					

Organ	Diagnosis	Slide #	Photo
Stomach			<input type="checkbox"/>
Intestine	NSF	5,6,7	<input type="checkbox"/>
Peritoneum			<input type="checkbox"/>
Salivary Gland			<input type="checkbox"/>
Pancreas			<input type="checkbox"/>
Mesentery			<input type="checkbox"/>
Hematopoietic/ Lymphoreticular			
Spleen	NSF	1	<input type="checkbox"/>
Thymus			<input type="checkbox"/>
Lymph Node, NOS	NSF	3,4	<input type="checkbox"/>
Mesenteric Lymph Node			<input type="checkbox"/>
Tonsil			<input type="checkbox"/>
Bone Marrow			<input type="checkbox"/>
Urogenital			
Kidney	NSF	4	<input type="checkbox"/>
Urinary Bladder	NSF	7	<input type="checkbox"/>
Repro			<input type="checkbox"/>
Musculoskeletal			
Diaphragm	A. Diaphragmitis, fibrinosuppurative, subacute, diffuse, moderate with intralesional bacterial cocci. B. Myofiber degeneration, multifocal, mild.	2,5	<input type="checkbox"/>
Skeletal Muscle, NOS			<input type="checkbox"/>
Integumentary			
Skin			<input type="checkbox"/>
Endocrine			
Thyroid Gland			<input type="checkbox"/>
Adrenal Gland	NSF	7	<input type="checkbox"/>
Parathyroid Gland			<input type="checkbox"/>
Pituitary Gland		10	<input type="checkbox"/>
			<input type="checkbox"/>
Misc			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

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Accession #	800.183	Species	FE		
Date	CC146411	Study #	800	Initial	dsr
B6					

Ancillary Diagnostics:

Test	Sample	Result	Comment

Summary Diagnoses

Pyothorax

Primary Diagnostic Category: Infectious

Linked to Food Exposure: Likely not related

Comments:

The cause of death of this feline is from pyothorax. Mixed bacterial populations were isolated and may represent post-mortem overgrowth with a sole initiating bacteria.

David S. Rotstein, DVM, MPVM, Dipl. ACVP

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Document properties

Title: 24-96-F1-5 (S3.90)
Author: J R Myers
Company: US FDA
Template: Normal.dotm
Page count: 2
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Line count: 268
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800.183-CC146411

by Vet-LIRN

B6

800.183-CC146411-Lung 4X

B6

800.183-CC146411-Lung 10X

Accession #	800.04-CC-503	Species	CN		
Date 11/4/2016	EON-276400	Study #	800	Initial dsr	

Diagnostic Report: Dr. Rotstein

Summary:

- Renal disease
- Icterus
- Lymes 4D: Positive

Organ	Diagnosis	Slide #	Photo
Nervous/Sensory			
Brain			<input type="checkbox"/>
Peripheral Nerve			
Eye			<input type="checkbox"/>
Cardiopulmonary			
Nares			<input type="checkbox"/>
Heart	A. Myocardial necrosis and hemorrhage, acute, multifocal to coalescing, moderate to marked with suppurative myocarditis. B. Vascular fibrinoid necrosis, multifocal, mild to moderate.	2	<input checked="" type="checkbox"/>
Trachea			<input type="checkbox"/>
Lung	A. Pulmonary edema, diffuse, moderate.	1	<input type="checkbox"/>
Digestive/Hepato biliary			
Liver	A. Bile duct and canalicular cholestasis, multifocal, mild to moderate. B. Fibrinoid vasculitis, multifocal.	3	<input checked="" type="checkbox"/>
Gall Bladder			<input type="checkbox"/>
Tongue			<input type="checkbox"/>
Esophagus			<input type="checkbox"/>
Stomach			<input type="checkbox"/>
Intestine	A. Venular fibrin thromboses, multifocal, moderate B. Lymphangiectasia, multifocal, mild.	4	<input checked="" type="checkbox"/>
Peritoneum			<input type="checkbox"/>
Salivary Gland			<input type="checkbox"/>
Pancreas	A. Peripancreatic fat necrosis, acute. B. Lobular, fibrinous pancreatitis (4 only)	3,4	<input type="checkbox"/>
Mesentery			<input type="checkbox"/>
Hematopoietic/Lymphoreticular			

x = examined

lg = liver glycogen

Severity codes:

- 1 - minimal
- 2 - mild
- 3 - moderate
- 4 - marked
- 5 - severe

Extent codes

- F - focal
- M - multifocal
- D - diffuse

Gonad codes

- Organ
- t - testis
- o - ovary

Stage

- i - immature
- d - developing
- s - spent

Accession #	800.04-CC-503	Species	CN		
Date 11/4/2016	EON-276400	Study #	800	Initial dsr	

Organ	Diagnosis	Slide #	Photo
Spleen	A. Vascular fibrinoid necrosis, multifocal, mild to moderate with associated lymphoid necrosis.	5	<input type="checkbox"/>
Thymus			<input type="checkbox"/>
Lymph Node, NOS	Pancreatic Lymph Node: A. Congestion and hemorrhage, multifocal, moderate with sinus histiocytosis and mild hemosiderosis. B. Fibrinous lymphadenitis, multifocal, mild. C. Lymphoid depletion, diffuse, mild.	4	<input type="checkbox"/>
Mesenteric Lymph Node			<input type="checkbox"/>
Tonsil			<input type="checkbox"/>
Bone Marrow			<input type="checkbox"/>
Urogenital			
Kidney	A. Membranoproliferative glomerulonephritis, global, diffuse, moderate to marked with synechia formation and periglomerular fibrosis. B. Interstitial nephritis, lymphoplasmacytic, multifocal, mild to moderate. C. Tubular necrosis, acute, multifocal, mild to occasionally moderate. D. Fibrinoid vasculitis, multifocal, moderate with multifocal hemorrhage.	6,7	<input checked="" type="checkbox"/>
Urinary Bladder			<input type="checkbox"/>
Repro			<input type="checkbox"/>
Musculoskeletal			
Diaphragm			<input type="checkbox"/>
Skeletal Muscle, NOS			<input type="checkbox"/>
Integumentary			
Skin			<input type="checkbox"/>
Endocrine			
Thyroid Gland			<input type="checkbox"/>
Adrenal Gland			<input type="checkbox"/>
Parathyroid Gland			<input type="checkbox"/>
Pituitary Gland			<input type="checkbox"/>
			<input type="checkbox"/>
Misc			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

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lg = liver glycogen

Severity codes:

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- 4 - marked
- 5 - severe

Extent codes

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Gonad codes

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- d - developing
- s - spent

Accession #	800.04-CC-503	Species	CN		
Date 11/4/2016	EON-276400	Study #	800	Initial dsr	

Ancillary Diagnostics:

Test	Sample	Result	Comment

Summary Diagnoses

Lyme's Associated Glomerulonephritis, Myocarditis, and Vasculitis
Acute Pancreatitis
Bile Stasis
Myocarditis

Primary Diagnostic Category: Infectious (Borreliosis/Lyme's Disease)

Linked to Food Exposure: Not Related

Comments:

Findings of vasculitis, myocarditis, and membranoproliferative glomerulonephritis coupled with the Lyme's positive status are most consistent with Lyme's disease. Given the chronicity of renal changes, this was a prior exposure with acute systemic exacerbation. Bartonellosis was also considered given the cardiovascular lesions and screening for Bartonella and other tickborne etiologies should be considered if additional diagnostics (immunohistochemistry and PCR) fail to detect Borellia burgdorferi. Bile duct stasis is likely associated with the acute fibrinous pancreatitis.

There was mild lymphangiectasia in the intestine. This could be associated with the vasculitis/fibrin exudation, but an underlying enteropathy was also considered.

David S. Rotstein, DVM, MPVM, Dipl. ACVP

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Document properties

Title: 24-96-F1-5 (S3.90)
Author: J R Myers
Company: US FDA
Template: Normal.dotm
Page count: 2
Paragraph count: 132
Line count: 277
Word count: 398
Character count (spaces excluded): 2551
Character count (spaces included): 2831

CC-503-800.04-EON-276400

by Vet-LIRN

B6

CC-503-800.04-EON-276400-Heart 4X

B6

CC-503-800.04-EON-276400-Heart 10X

B6

CC-503-800.04-EON-276400-Heart 20X

B6

CC-503-800.04-EON-276400-Heart 20X-2

B6

CC-503-800.04-EON-276400-Intestine 4XX

B6

CC-503-800.04-EON-276400-Intestine 20X

B6

CC-503-800.04-EON-276400-kidney 2X

B6

CC-503-800.04-EON-276400-kidney 4X

B6

CC-503-800.04-EON-276400-kidney 4X-2

B6

CC-503-800.04-EON-276400-kidney 20X

B6

CC-503-800.04-EON-276400-kidney 20X-2

B6

CC-503-800.04-EON-276400-kidney 20X-3

B6

CC-503-800.04-EON-276400-Liver 4X

B6

CC-503-800.04-EON-276400-Liver 40X

B6

CC-503-800.04-EON-276400-Pancreas 10X

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Jones, Jennifer L
Sent: 12/11/2015 6:51:02 PM
Subject: CC-466-800.04-CC-143384
Attachments: CC-466-800.04-CC-143384.docx; CC-466-800.04-CC-143384-Photomicrographs.pdf

Here you go!

thanks

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison (http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm#Network_Laboratories_)
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)

B6

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B6	800.04	Species	CN		
Date 12/11/2015	NA	Study #	800	Initial dsr	

**Diagnostic Report:
Dr. Rotstein**

Organ	Diagnosis	Slide #	Photo
Nervous/Sensory/ Sensory			
Brain	NSF	A-1-2, A-2-2	<input type="checkbox"/>
Peripheral Nerve			
Eye	NSF	A-3-2	<input type="checkbox"/>
Cardiopulmonary			
Nares			<input type="checkbox"/>
Heart	A. Ventricular cardiomyocyte hypertrophy, multifocal to coalescing, moderate with occasional cardiomyocyte disarray and mild interstitial fibrosis. B. Epicardial vascular degeneration with subintimal hemorrhage. C. Valvular myxomatous degeneration.	A-8-2, A-9-2, A-10-2, A-11-2	<input checked="" type="checkbox"/>
Trachea			<input type="checkbox"/>
Lung	A. Increased circulating neutrophils. B. Pulmonary edema and congestion, diffuse, moderate.	A-4-2	<input type="checkbox"/>
Digestive/Hepato biliary			
Liver	A. Mild periportal fibrosis, multifocal.	A-5-2	<input type="checkbox"/>
Tongue	A. Glossitis, ulcerative, neutrophilic, acute, regionally extensive, moderate with congestion, hemorrhage, and rare, individual myofiber degeneration.	A- 4-2	<input type="checkbox"/>
Esophagus			<input type="checkbox"/>
Stomach	A. Mucosal mineralization, multifocal to coalescing, mild.	A-7-2	<input checked="" type="checkbox"/>
Intestine	NSF	A-7-2	<input type="checkbox"/>
Peritoneum/Abdo minal Adipose			<input type="checkbox"/>
Salivary Gland			<input type="checkbox"/>
Pancreas			<input type="checkbox"/>
Hematopoietic/ Lymphoreticular			
Spleen	NSF	A-5-2	<input type="checkbox"/>

x = examined

lg = liver glycogen

Severity codes:

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Accession # B6	800.04	Species	CN		
Date 12/11/2015	NA	Study #	800	Initial dsr	

Organ	Diagnosis	Slide #	Photo
Thymus			<input type="checkbox"/>
Lymph Node, NOS			<input type="checkbox"/>
Adrenal Gland			<input type="checkbox"/>
Lymph Node			<input type="checkbox"/>
Tonsil			<input type="checkbox"/>
Bone Marrow			<input type="checkbox"/>
Urogenital			
Kidney	A. Tubulointerstitial nephritis, lymphoplasmacytic, multifocal to coalescing, subacute to chronic, marked with Warthin-Starry positive spirochaetes and Leptospira-positive immunohistochemistry.	A-6-2 (HE, WS, & IHC)	<input checked="" type="checkbox"/>
Urinary Bladder			<input type="checkbox"/>
Repro			<input type="checkbox"/>
Musculoskeletal			
Diaphragm			<input type="checkbox"/>
Skeletal Muscle, NOS			<input type="checkbox"/>
Integumentary			
Skin			<input type="checkbox"/>
Endocrine			
Thyroid Gland			<input type="checkbox"/>
Adrenal Gland			<input type="checkbox"/>
Parathyroid Gland			<input type="checkbox"/>
Pituitary Gland			<input type="checkbox"/>
			<input type="checkbox"/>
Misc			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

Ancillary Diagnostics:

Test	Sample	Result	Comment

Primary Diagnostic Category: Infectious-Bacterial (Etiology: Leptospira spp.)

x = examined

lg = liver glycogen

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- 4 - marked
- 5 - severe

Extent codes

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- M - multifocal
- D - diffuse

Gonad codes

- Organ
- t - testis
- o - ovary

Stage

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- d - developing
- s - spent

Accession #	800.04	Species	CN		
B6					
Date	NA	Study #	800	Initial dsr	
12/11/2015					

Linked to Food Exposure: No

Comments:

The cause of renal disease including changes in glucose are associated with the pronounced tubulointerstitial nephritis. The cause of the nephritis was Leptospirosis spp. which was evident with silver stains and immunohistochemistry. This dog had an underlying cardiomyopathy which in this debilitated animal may have led to cardiovascular collapse and death.

David S. Rotstein, DVM, MPVM, Dipl. ACVP

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lg = liver glycogen

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Document properties

Title: 24-96-F1-5 (S3.90)

B6

Company: US FDA

Template: Normal.dotm

Page count: 2

Paragraph count: 117

Line count: 258

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CC-466-800.04-CC-143384

by Vet-LIRN

B6

CC-466-800.04-CC-143384-Heart-10X

B6

CC-466-800.04-CC-143384-Heart-20X

B6

CC-466-800.04-CC-143384-Heart-20X-2

B6

CC-466-800.04-CC-143384-Heart-20X-3

B6

CC-466-800.04-CC-143384-Heart-40X

B6

CC-466-800.04-CC-143384-Kidney-4X

B6

CC-466-800.04-CC-143384-Kidney-10X

B6

CC-466-800.04-CC-143384-Kidney-20X

B6

CC-466-800.04-CC-143384-Kidney-40X

B6

CC-466-800.04-CC-143384-Kidney-Lepto IHC-20X

B6

CC-466-800.04-CC-143384-Kidney-Lepto IHC-40X

B6

CC-466-800.04-CC-143384-Kidney-Warthin-Starry 20X

B6

CC-466-800.04-CC-143384-Kidney-Warthin-Starry 100X

B6

CC-466-800.04-CC-143384-Kidney-Warthin-Starry 100X-2

B6

CC-466-800.04-CC-143384Stomach 10X

B6

CC-466-800.04-CC-143384Stomach 40X

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
Sent: 12/18/2014 10:10:49 PM
Subject: CC-139390-Medical Records
Attachments: cc139390 - Purina Cat Chow Indoor Formula Dry.pdf.html; CC-139390-MRx.pdf.html

Everyone,

Medical Records are attached.

B6

B6

Rads-possible congenital cardiac or cardiomyopathy

Interp: acute renal failure; acute on chronic renal failure

B6

12/12 mild proteinuria; cbc and chem-unremarkable

B6

12/13 mild increase Amylase, mild hematuria

Fed 11/10 to 11/20; diarrhea around 11/18 for several cats; cat with renal signs seen on 11/28.

My feeling is NFA on this one.

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)

B6

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From: [B6]@dcpah.msu.edu>
To: Jones, Jennifer L
CC: [B6]
Sent: 11/11/2015 2:08:18 PM
Subject: [B6]

Dr. Jennifer Jones,

I have completed the histologic evaluation from [B6] possible food toxicity case. The heart has advanced hypertrophic cardiomyopathy, the kidneys have moderate to severe interstitial nephritis, and there are additional lesions consistent with uremia in the tongue and the stomach. You will get the final report in the next 2-3 days. Between the cardiomyopathy and advanced inflammatory renal disease, I have sufficient lesions to account for this dog's renal failure with no evidence of a toxicity. I am still waiting for a couple microbiologic tests (kidney bacterial culture, PCR for leptospirosis). However, I am aware that a formal complaint has been submitted to the FDA, and that you are willing to fund toxicologic screening tests if indicated. Below are listed the additional toxicologic tests we could run in our laboratory, and the associated fees:

GCMS screen for organic toxicants on liver: \$140
Tissue mineral screen on liver (heavy metals): \$40
Ethylene Glycol assay on liver: \$53
Melamine and related compounds assay on kidney: \$205

With no calcium oxalate or melamine crystals present in kidney sections, I doubt if there is any need for either the Ethylene Glycol or Melamine tests.

The organic compounds and heavy metal screens can be run if you wish, these toxicants may not result in any specific histologic lesions.

We had no stomach contents to run mycotoxin screens on. Nor are we set-up to test the jerky treats submitted – if you wish to run contaminant assays on these we can forward those samples to your laboratory.

You can send me an email ([B6]@dcpah.msu.edu), call me [B6], or wait for the final report and then decide if you want to approve toxicologic screening tests. Thanks for your assistance on this case.

Dr. [B6]

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren
CC: Ceric, Olgica; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Nemser, Sarah
Sent: 6/3/2016 11:56:28 AM
Subject: CC-145856- [B6] Acana Grain Free Heritage Meats
Attachments: CC-145856- [B6] Acana GF Heritage Meats.pdf.html; CC-145856- [B6] case summary-6.3.2016.doc.html

Vet-LIRN Case Summary Document

Vet-LIRN Case Number:	
EON/CC #:	CC-145856
Vet-LIRN Initiation Date:	6.3.2016
MedRec: Requested:	6.3.2016
MedRec: Received:	
MedRec: Significant finding:	
Vet-LIRN Tests (planned):	MRx review & owner interview-then decide
Vet-LIRN Test Results:	
Result Interpretation:	
IF NFA, justification:	

COMPLAINT: On 6/2/16, a complainant reported illness in her three dogs after she introduced Acana Grain Free Heritage Meats Formula with Angus Beef, Yorkshire Pork & Suffolk Lamb Dry Dog Food (Champion Pet Foods). The complainant explained that she has three pugs; [B6] a 3-year-old, 17-pound female; [B6] a 4-year-old, 19-pound male; and [B6] a 9-year-old, 18-pound female. The dogs have no pre-existing health conditions, except for [B6] environmental allergies. They are primarily indoor dogs. [B6] and [B6] received a quarter cup of the food twice daily, while [B6] gets a little bit less than a quarter cup twice daily. The food they were provided prior to this introduction was a Fromm Family Pet Food dry recipe, which they received for 3-months with no problems. The new food was gradually introduced to the dogs over a week's time, beginning on 5/17/16. On 5/19/16 (2-days) [B6] began exhibiting a lack of appetite, lethargy and vomiting. She was taken to the vet and underwent testing of blood, urine and X-rays and was diagnosed with pancreatitis. She received Clavomox and was started on a low fat/ protein diet. She then recovered after 5-days. [B6] who is older, was taken off the food at the same time as [B6] as a precaution. She also appeared lethargic at the time. On 5/21/16 (5-days), [B6] began suffering the same symptoms and the complainant called and conferred with the vet and started him on the same low fat/ protein diet as [B6]. He recovered after several days.

The complainant, who is employed at the pet food store where the Acana was purchased, was speaking to the receptionist at the vet clinic about the illness and the new food. The receptionist told her she had visited the same store and purchased the Acana Heritage Free-Run Poultry Formula Grain-Free Dry Dog Food in the same 2-week period as the complainant and her five English bulldogs became ill with the same symptoms. She had three of the dogs tested and they also were diagnosed with pancreatitis. It was at this point that the complainant decided to inform the FDA of the issue.

Signalment: 3 pugs: unknown reproductive status a [B6] 3yo F, [B6] 4yo M, [B6] 9yo F

Signs: lethargy, vomiting, inappetance

Food: Acana Grain Free Heritage Meats Formula with Angus Beef, Yorkshire Pork & Suffolk Lamb Dry Dog food

[B6]

B6

Narrative from the complaint: see above

Vet-LIRN PLAN OF ACTION: MRx review and owner interview, then decide

FINAL CONCLUSION: pending

Follow-up:

JJ-Emailed District officer for last digit of owner's phone number. Will call this afternoon to arrange interview & request MRx (PST).

B5, B6

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: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 2/24/2019 11:19:19 PM
Subject: B6
Attachments: rpt_medical_record_preview.pdf

Hi Jen

Sorry – only attached the dog's previous visit, not the current one. Here's the full record.

This is a housemate of a previously reported dog.

Thanks

Lisa

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

B6

B6

B6

All Medical Records

B6

Breed: Labrador Retriever

B6

Species: Canine
Sex: Female
(Spayed)

B6

Referring Information

B6

Initial Complaint:

Emergency

SOAP Text Jul 1 2017 1:23PM **B6**

7/1/2017 12:13 PM NEW VISIT (ER)

B6

Presenting complaint: Right hind lameness

Diagnostics completed prior to visit: Recent blood work at rDVM per owner, normal results before dental cleaning

HISTORY:

Signalment: 3 yo FS Labrador retriever

Current history: Limping while playing fetch today, non-weight bearing on the right hind limb. Otherwise healthy.

Prior medical history: Left CCL rupture, surgically repaired in **B6**

Current medications: None

Diet: Acana, whole earth

Vaccination status/flea & tick preventative use: Ivermectin, Advantix II

EXAM:

B6

B6

B6

ASSESSMENT:

A1: Suspect R CCL rupture

PLAN:

- 1) Strict rest
- 2) Carprofen 2.2 mg/kg PO q12 x 5 days
- 3) Ideally check kidney and liver values - declined by owner
- 4) Recommend orthopedics appointment

Client communication: Briefly discussed cranial cruciate rupture with owner and that 50% of labs with one CCL rupture will rupture contralateral very soon, owner is familiar with disease process and treatment. Recommended scheduling appointment with orthopedic surgery. Owner expressed frustration that surgery cannot be done today. I explained that we can diagnose **B6** and prescribe medications to keep her comfortable on an emergency basis. Owner declined blood work to check kidney and liver values.

SOAP approved (DVM to sign): **B6**

7/1/2017 1:25:46 PM

Prescribed - carprofen 100mg RIMADYL - FHSA (5)

Instructions - Give 1/2 tablet orally every 12 hours. Give with food. - Expires: 7/1/2018 No Refills

Initial Complaint:

Cardiology DCM study

SOAP Text Jan 16 2019 3:09PM **B6**

Subjective

Objective

Assessment

Plan

Disposition/Recommendations

B6

B6

B6

B6

B6

Veterinarian:
Patient ID: 395550
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Labrador Retriever
Sex:	Female (Spayed)
Age:	5.2 Years Old

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units
------	---------	-----------------	-------

B6

4/20

B6

Printed Sunday, February 24, 2019

Vitals Results

7/1/2017 12:21:40 PM	Heart Rate (/min)
7/1/2017 12:21:41 PM	Respiratory Rate
7/1/2017 12:21:42 PM	Temperature (F)
7/1/2017 12:21:43 PM	Weight (kg)

B6

Patient History

07/01/2017 12:14 PM	UserForm
07/01/2017 12:15 PM	UserForm
07/01/2017 12:21 PM	Vitals
07/01/2017 12:21 PM	Vitals
07/01/2017 12:21 PM	Vitals
07/01/2017 12:21 PM	Vitals
07/01/2017 12:21 PM	Vitals
07/01/2017 01:37 PM	Prescription
07/01/2017 01:44 PM	UserForm
07/01/2017 01:48 PM	Purchase

B6

B6

Patient History

07/02/2017 02:06 AM	Vitals
07/02/2017 02:06 AM	Vitals
07/02/2017 02:06 AM	Vitals
07/02/2017 02:06 AM	Vitals
07/02/2017 02:06 AM	Vitals
07/05/2017 11:40 AM	Email
01/16/2019 01:27 PM	Appointment
01/16/2019 01:30 PM	UserForm
01/16/2019 02:03 PM	Treatment
01/16/2019 03:14 PM	UserForm

B6

B6

B6

STANDARD CONSENT FORM

B6

B6

B6

Date: 7/1/2017

B6

Owner's Name Signature

Date

**If the individual admitting the animal is someone other than the legal owner,
please complete the portion below:**

B6

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City

State

Zip

B6

B6

STANDARD CONSENT FORM

B6

B6

B6

7/11/17

Owner's Name Signature

Date

**If the individual admitting the animal is someone other than the legal owner,
please complete the portion below:**

B6

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City

State

Zip

B6

B6

Patient

Name:

B6

Signalment:

3.55 Years Old Yellow Female
(Spayed) Labrador Retriever

Owner

Name:

Address:

B6

Patient ID:

395550

B6

ER Supervisor:

B6

Discharge Instructions

Admit Date: B6 12:12:46 PM

Check Out Date: B6

Case Summary

Diagnosis:

1. Right cranial cruciate rupture

General Summary:

B6 was presented to Tufts Emergency Service to evaluate right hind limb lameness. B6 began limping while playing fetch today. She has a history of a left cranial cruciate rupture, which was surgically repaired in B6. She is otherwise doing well.

On physical examination, B6 right knee has effusion (joint swelling). She was painful on full extension of the knee joint. Cranial drawer was present. It is highly suspected that B6 has torn the cruciate ligament in her right knee.

B6 physical examination was otherwise unremarkable. We recommend that B6 is evaluated by an orthopedic surgeon. In the meantime, we can give her medications to keep her comfortable. Today you have declined blood work before starting medications, as B6 has had recent blood work checked by your primary care veterinarian. We recommend close monitoring of B6 kidney and liver values while she is receiving carprofen (Rimadyl), as Labrador retrievers may be predisposed to unexpected reactions from this medication.

Patient Care Instructions:

1. Strict activity restriction: Please restrict B6 daily activity. She should not be allowed to run, jump, or rough house. She should be taken on short controlled (5 min) leash walks only to eliminate.

2. Please monitor for vomiting, diarrhea, decreased appetite, lethargy, and changes in urination. If you have any concerns, please contact a veterinarian.

Medications:

1. Rimadyl (carprofen) 100 mg - Give 1/2 tablet by mouth every 12 hours (twice daily). Give with food. This is a non-steroidal anti-inflammatory medication. It should NOT be given with other NSAIDs or steroids. If you notice dark, tarry stools, please stop this medication and call a veterinarian.

Recheck Visits: Please schedule an appointment with our Orthopedic Surgery Service by B6 You may call Monday-Friday 8am-6pm.

Prescription Refill Disclaimer:

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 B6 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: B6

B6

Discharge Instructions

B6

B6

Discharge Instructions

B6

Species: Canine
Yellow Female (Spayed) Labrador
Retriever

B6

Patient ID: 395550

B6

Attending Cardiologist:

B6

B6

Admit Date: B6 1:29:08 PM

Discharge Date: B6

Thank you for bringing B6 to screen her for heart disease related to being on a "BEG" (Boutique, Exotic Ingredient, or Grain-Free) diet. On physical exam, she had no heart murmur. She had strong pulses and no arrhythmias were heard.

B6 echocardiogram showed that her heart was not contracting with normal vigor, and she had a few premature heart beats (arrhythmia - ventricular premature depolarizations). Her left atrium was also slightly enlarged, and her right heart was also slightly enlarged. These changes could perhaps be a variation of normal in athletic dogs, but we think it is more likely that she has mild heart disease, because of the premature heartbeats (arrhythmia).

We may be able to enroll B6 in our DCM study looking at heart disease associated with BEG diets today. We submitted blood tests and will contact you with the results when available. The taurine levels will take up to 2-3 weeks to come back and we would like to start taurine supplementation in the interim. If the taurine level comes back low, we'll give taurine supplementation. Either way, it's very important to change her diet, and we would have you continue with the Purina diet you are currently feeding. B6 does not require any other heart medications at this time, however if she does qualify for the study (based on an elevated NT-proBNP or an elevated troponin), we will want to follow up with another echo in 3 months, now that her diet has been changed.

If her NT-proBNP and troponin are normal then she does not qualify for the study, but we would recommend a repeat echo in 8 to 10 months, because of the changes we saw today with the heart and the premature heart beats.

Medications and supplements:

None at this time.

Monitoring at Home:

[B6] does not appear to have any significant heart disease at this time. However, please monitor for any weakness or collapse, exercise intolerance, cough or distension of the belly. If you notice any abnormalities we would like to see her for a recheck exam.

Diet Suggestions:

Please continue the Purina diet that [B6] is now eating.

Recheck Visits and Follow Up: The taurine levels will take 2-3 weeks so we'll let you know when we get these back. If she does qualify for the study (based on an elevated NT-proBNP or an elevated troponin), we will want to follow up with another echo in 3 months and in 6 months. If she does not qualify then a recheck cardiac exam is recommended in 8 to 10 months.

Thank you for entrusting us with [B6] care – she is a sweet, beautiful girl and we loved meeting her today!

Please contact our Cardiology liaison at [B6] or email us at [B6] for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

[B6]

Prescription Refill Disclaimer:

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 [B6] 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: [B6]

[B6]

Discharge Instructions

B6

B6

B6 Canine
5.1 Years Old Female (Spayed) Labrador Retriever
Yellow

**Cardiology Appointment Report
ENROLLED IN DCM STUDY**

Date: 1/16/2019

B6

Presenting Complaint:

Possible exercise intolerance, eats grain free food

Exercise intolerance start at about one year - breathes loudly, more hard, will sometimes lay down; same all year, been at a stable state since noticing at one year old

Concurrent Diseases: bilat TPLO

General Medical History:

Overall good at home, good appetite, no coughing

Diet and Supplements:

Taste of the wild, has had Acana in the past

On purina pro plan switched about 1 week ago

Cardiovascular History:

Prior CHF diagnosis? no

Prior heart murmur? no

Prior ATE? no

Prior arrhythmia? no

Monitoring respiratory rate and effort at home? no

Cough? no

Shortness of breath or difficulty breathing? yes but since a puppy

Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? yes but since dog is a puppy

Current Medications Pertinent to CV System:

None

Cardiac Physical Examination:

General PE: WNL, bow legged
MM Color and CRT: pink, < 2
BCS (1-9): 6
BW (kg): 28.5

Heart rate: 100
Respiratory rate: panting
Temp (if possible):

Muscle condition:

- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

Murmur location/description:

None heard

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:

- Weak
- Fair
- 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

Problems: Exercise intolerance

Differential Diagnoses:

DCM vs pain related (hx TPLO x2) vs congenital

Diagnostic plan:

- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests:

Echocardiogram Findings:

General/2-D findings:

The LA is mildly dilated. The LV walls are normal in thickness with mildly reduced contractile function. The RH is mildly dilated.

Doppler findings:

Trace MR. 1+ PI

Mitral inflow:

- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

ECG findings:

HR - 75; sinus arrhythmia during echocardiogram

Assessment and recommendations:

Overall the LV cavity has slightly reduced contractile function and the LA looks to be mildly enlarged.

Final Diagnosis:

Mildly reduced LV contractile function R/O diet related vs variation of normal.

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM Classification:

- A vs
- B1
- B2
- C
- D

M-Mode

IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
EDV(Teich)	ml
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
Ao Diam	cm
LA Diam	cm
LA/Ao	
Max LA	cm
EPSS	cm

M-Mode Normalized

IVSdN	{0.290 - 0.520}
LVIDdN	{1.350 - 1.730}
LVPWdN	{0.330 - 0.530}
IVSsN	{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

SA LA	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(Teich)	%
%FS	%
SV(Teich)	ml
LV Major	cm
LV Minor	cm
Sphericity Index	
LVLd LAX	cm
LVAAd LAX	cm
LVEDV A-L LAX	ml

B6

LVEDV MOD LAX
LVIs LAX
LVAs LAX
LVESV A-L LAX
LVESV MOD LAX
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX
R-R
HR
CO A-L LAX
CO MOD LAX

Doppler

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

B6

ml
cm
cm
ml
ml
BPM
%
%
ml
ml
l/min
l/min
ms
BPM
l/min
l/min

m/s
ms
m/s
m/s

m/s

m/s
m/s
m/s
mmHg
m/s
mmHg

B6

B6

B6

B6

B6 Female (Spayed)
Canine Labrador Retriever Yellow
395550

1/21/2019

Dear **B6**

Thank you for referring **B6** with their pet **B6**

If you have any questions, or concerns, please contact us at **B6**

Thank you,

B6

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Reimschuessel, Renate; Nemser, Sarah; Carey, Lauren; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Sent: 11/13/2014 7:43:50 PM
Subject: [B6] RE: Possible Necropsy? EON-186243-ICSR-1036619 [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

[B6]

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)

[B6]

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From: Reimschuessel, Renate
Sent: Thursday, November 13, 2014 2:43 PM
To: Nemser, Sarah; Rotstein, David; Carey, Lauren; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619 [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Which state!?

Renate Reimschuessel
Phone and fax- 301-210-4024
Alternate FAX 301-210-4685
renate.reimschuessel@fda.hhs.gov
Vet-LIRN
<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Nemser, Sarah
Sent: Thursday, November 13, 2014 2:31 PM
To: Reimschuessel, Renate; Rotstein, David; Carey, Lauren; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619 [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

The vet emailed yesterday that they will do the necropsy when the body is returned from the crematorium. So I am not sure at this point if it has been returned yet, but is on the way to the vet.

S

From: Reimschuessel, Renate
Sent: Thursday, November 13, 2014 2:28 PM
To: Rotstein, David; Carey, Lauren; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619 [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Where is the animal?

Renate Reimschuessel
Phone and fax- 301-210-4024
Alternate FAX 301-210-4685
renate_reimschuessel@fda.hhs.gov
Vet-LIRN
<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Rotstein, David
Sent: Thursday, November 13, 2014 2:08 PM
To: Carey, Lauren; Reimschuessel, Renate; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

J bonesaw I can handle, it's the bandsaw that still freaks me out!!!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)

[B6]

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From: Carey, Lauren
Sent: Thursday, November 13, 2014 2:05 PM
To: Rotstein, David; Reimschuessel, Renate; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Ah! I see. Just thinking to my days in the back room with just a blade and some formalin jars + 1 tech staring on. No bone saw for me!

From: Rotstein, David
Sent: Thursday, November 13, 2014 2:03 PM
To: Carey, Lauren; Reimschuessel, Renate; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Lauren,

Yes-it would be the whole CNS. I figured that the

[B5]

[B5]

There maybe a few things going on here and it may be better if we could get the
Vet-LIRN lab...or to any interested pathologists .."hint" J

[B5]

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)

[B6]

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sender immediately at david.rotstein@fda.hhs.gov.

From: Carey, Lauren
Sent: Thursday, November 13, 2014 2:00 PM
To: Reimschuessel, Renate; Rotstein, David; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Sorry, just finally read the MRx. The seizures do not fit Wobbler's

[B5]

[B5]

From: Reimschuessel, Renate
Sent: Thursday, November 13, 2014 5:42 AM
To: Rotstein, David; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Olga – either you or Dave should discuss with vet the need and potential options.

I'm at White Oak today – in meetings – you guys work out between yourselves who should call.

Renate Reimschuessel
Phone and fax- 301-210-4024
Alternate FAX 301-210-4685
renate.reimschuessel@fda.hhs.gov
Vet-LIRN
<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Rotstein, David
Sent: Wednesday, November 12, 2014 10:51 PM
To: Reimschuessel, Renate; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

My thought is:

[B5]

[B5]

I'm glad to talk to the vet. I think if the vet could

[B5]

[B5]

[B5]

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)

[B6]

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From: Reimschuessel, Renate

Sent: Wednesday, November 12, 2014 9:44 PM

To: Rotstein, David; Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619 [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

B5

Renate Reimschuessel

Phone and fax- 301-210-4024

Alternate FAX 301-210-4685

renate.reimschuessel@fda.hhs.gov

Vet-LIRN

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Rotstein, David

Sent: Wednesday, November 12, 2014 9:42 PM

To: Ceric, Olgica; Reimschuessel, Renate; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: Re: Possible Necropsy? EON-186243-ICSR-1036619 [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

B5

Sent from BlackBerry

From: Ceric, Olgica

Sent: Wednesday, November 12, 2014 07:30 PM Eastern Standard Time

To: Reimschuessel, Renate; Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619 [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Attached are the medical records from [B5, B6] They will be performing necropsy.

Dog was a new patient-two pages only. **Veterinarian suspected Wobblers syndrome (cervical spondylopathy).**

I will contact primary veterinarian tomorrow, they have additional medical records.

[B5, B6]

will also send bloodwork and x-rays (done at primary vet, sending by fax tomorrow).

Olgica Ceric, DVM, PhD

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

tel: 301-210-4262

fax: 301-210-4685

e-mail: olgica.ceric@fda.hhs.gov

Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Ceric, Olgica

Sent: Tuesday, November 11, 2014 12:18 PM

To: Reimschuessel, Renate; Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: Re: Possible Necropsy? EON-186243-ICSR-1036619; **B6** Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

One more save at the last moment :)

Olgica Ceric

From: Reimschuessel, Renate

Sent: Tuesday, November 11, 2014 12:10 PM

To: Ceric, Olgica; Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: Re: Possible Necropsy? EON-186243-ICSR-1036619; **B6** Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Excellent ! Thanks

RR-----

Sent using BlackBerry

From: Ceric, Olgica

Sent: Tuesday, November 11, 2014 11:18 AM Eastern Standard Time

To: Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619; **B6** Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Update: I arranged necropsy.

Body was sent to crematorium but clinic contacted them and put the hold on cremation. Crematorium is returning the body to clinic (body is frozen) **B6**

Olgica Ceric, DVM, PhD

Veterinary Medical Officer

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

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fax: 301-210-4685

e-mail: olgica.ceric@fda.hhs.gov

Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Rotstein, David

Sent: Tuesday, November 11, 2014 10:29 AM

To: Ceric, Olgica; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619; **B6** Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Thanks Olga!!

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM OSC/DC/ICERT

7519 Standish Place, RM 120

240-276-9213 (Office and Fax)

B6

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From: Ceric, Olgica

Sent: Tuesday, November 11, 2014 10:14 AM

To: Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Subject: RE: Possible Necropsy? EON-186243-ICSR-1036619; **B6** Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

Vet-LIRN Case Summary Document

Vet-LIRN Case Number:	
EON/CC #:	EON-186243
Vet-LIRN Initiation Date:	11.11.2014
MedRec: Requested:	yes
MedRec: Received:	
MedRec: Significant finding:	
Vet-LIRN Tests (planned):	MRx, necropsy
Vet-LIRN Test Results:	
Result Interpretation:	
IF NFA, justification:	

11.11.2014

Dog: 21 months **B6** male, neutered

Received new bag of dog food (same variety/flavor as always) **B6** Fed normal feeding that evening. Next couple days dog did not show interest in eating, then finally a small amount mid week, then nothing for few more days. Noticed lethargic behavior. Some drooling. Reported concerns to the distributor **B6** who assured me it would be reported to manufacturer immediately. Provided all information from bag. Purchased **B6** a new bag, different flavor and from a different supplier as well as some wet food of the same. At time of purchase, a representative of manufacturer was in the store and also took a report who assured me I would be contacted. This did not happen. Dog ate wet food well. Little of the new dry. But continued to be lethargic and increasingly ill. Visit to veterinarian, including a sample of food for testing on **B6** Dog showing signs of paralysis. Again to different veterinarian for further treatment **B6** Passed away on **B6**

Plan: necropsy if possible, MRx

Follow up: OC-called the owner and discussed the case with her. Dog passed away **B6** and was taken to veterinarian on Monday. Owner will call veterinarian and find out if they still have the body or if it was cremated already. If body is available she will ask them to hold it.

Additional information from owner: no vomiting or diarrhea noted. Dog was urinating normally (kept in the kennel during the day while family is at work). Dog was taken to regular veterinarian and new veterinarian (owner will provide email and contact information for other veterinarian). Blood work was done. Owner still has the food with original package, no other pets. No raisins, grapes, chocolate. No vitamins and supplements. Dog was previously healthy. No table scraps. Dog was given one treat each day (Doggy Delirious Peanut butter):

<http://www.amazon.com/Doggy-Delirious-Peanut-Butter-1-Pound/dp/B006SU4RMI>

Olgica Ceric, DVM, PhD

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
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Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Ceric, Olga
Sent: Monday, November 10, 2014 10:09 PM
To: Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Subject: Re: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

I will contact owner and vet tomorrow and see about necropsy, will request med.records.
Olgica Ceric

From: Rotstein, David
Sent: Monday, November 10, 2014 10:01 PM
To: CVM Vet-LRN-OR; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Subject: Possible Necropsy? EON-186243-ICSR-1036619- [B6] Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition:

21 MO MN [B6]

DOD - [B6]

Recc: necropsy if possible, med records, talk to vet about what testing was done.

Signs are a bit vague—lethargy to paralysis—differential list is wide unless there is bloodwork. Can't think that the neurologic form of Listeria would be that fast & in a monogastric. But would have to be on the list.

Raw diet--<http://www.naturesvariety.com/Instinct/dog/kibble/rawboost/all>

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)

[B6]

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From: PFR Event [<mailto:pfreventcreation@fda.hhs.gov>]
Sent: Monday, November 10, 2014 9:52 PM
To: [B6] HQ Pet Food Report Notification;

[B6]

Subject: Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition: Ivy Fischer

A PFR Report has been received and PFR Event [EON-186243] has been created in the EON System

A "PDF" report by name "1036619-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report

EON Key: EON-186243

EON Title: PFR Event created for Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition; 1036619

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

Product information

Individual Case Safety Report Number: 1036619

Product Group: Pet Food

Product Name: Nature's Variety Instinct Raw boost; Duck meal & Turkey meal formula. Grain free edition

Description: Received new bag of dog food (same variety/flavor as always) B6 Fed normal feeding that evening. Next couple days dog did not show interest in eating, then finally a small amount mid week, then nothing for few more days. Noticed lethargic behavior. Some drooling. Reported concerns to the distributor B6 who assured me it would be reported to manufacturer immediately. Provided all information from bag. Purchased B6 a new bag, different flavor and from a different supplier as well as some wet food of the same. At time of purchase, a representative of manufacturer was in the store and also took a report who assured me I would be contacted. This did not happen. Dog ate wet food well. Little of the new dry. But continued to be lethargic and increasingly ill. Visit to veterinarian, including a sample of food for testing on B6 Dog showing signs of paralysis. Again to different veterinarian for further treatment B6 Passed away on B6

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Died Euthanized

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

B6

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From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Jones, Jennifer L
Sent: 6/6/2018 4:04:44 PM
Subject: Copy of products/ingredient lists from cases
Attachments: photos and ingred product info.docx

Hi – I listed all the reported products with ingredients for all the cases from Tufts, NC State, FDA and CVCA.

My spreadsheet is a big mess and probably won't be helpful, but hope this is of some use.

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



Grain-free as defined by absence of corn, wheat, soy.

B4 **Blue Buffalo Basics** Salmon **B4, B5**

Pea and Pumpkin, no corn, wheat, soy, dairy or eggs (LID GF says same info as other Salmon Basics)



Blue Basics LID Salmon & Potato: (no lentil)

Deboned Salmon, Oatmeal, Brown Rice, Peas, Salmon Meal (source of Omega 3 Fatty Acids and Glucosamine), Potatoes, Pea Fiber, Canola Oil (source of Omega 6 Fatty Acids), Natural Flavor, Pea Protein, Calcium Carbonate, Dicalcium Phosphate, Fish Oil (source of Omega 3 Fatty Acids), Dehydrated Alfalfa Meal, Pumpkin, Dried Chicory Root, Flaxseed (source of Omega 3 and 6 Fatty Acids), Potato Starch, Choline Chloride, Natural Flavor, Caramel Color, Salt, Potassium Chloride, Vitamin E Supplement, L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Mixed Tocopherols (a natural preservative), DL-Methionine, Ferrous Sulfate, Parsley, Dried Kelp, Blueberries, Cranberries, Barley Grass, Yucca Schidigera Extract, Iron Amino Acid Chelate, Turmeric, Zinc Amino Acid Chelate, Zinc Sulfate, Oil of Rosemary, L-Carnitine, L-Lysine, Copper Sulfate, Copper Amino Acid Chelate, Nicotinic Acid (Vitamin B3), Calcium Pantothenate (Vitamin B5), Taurine, Biotin (Vitamin B7), Manganese Sulfate, Vitamin A Supplement, Manganese Amino Acid Chelate, Dried Yeast, Dried Enterococcus faecium fermentation product, Dried Lactobacillus acidophilus fermentation product, Dried Aspergillus niger fermentation extract, Dried Trichoderma longibrachiatum fermentation extract, Dried Bacillus subtilis fermentation extract, Thiamine Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Vitamin D3 Supplement, Vitamin B12 Supplement, Pyridoxine Hydrochloride (Vitamin B6), Folic Acid (Vitamin B9), Calcium Iodate, Sodium Selenite.

Blue Basics LID Salmon & Potato – Grain-free formula: (no lentil)

Deboned Salmon, Potatoes, Peas, Pea Starch, Salmon Meal (source of Omega 3 Fatty Acids and Glucosamine), Tapioca Starch, Pea Fiber, Canola Oil (source of Omega 6 Fatty Acids), Pea Protein, Natural Flavor, Dicalcium Phosphate, Calcium Carbonate, Fish Oil (source of Omega 3 Fatty

Acids), Dehydrated Alfalfa Meal, Pumpkin, Dried Chicory Root, Choline Chloride, Flaxseed (source of Omega 3 and 6 Fatty Acids), Potato Starch, Caramel Color, Salt, Vitamin E Supplement, DL-Methionine, Mixed Tocopherols (a natural preservative), L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Ferrous Sulfate, Parsley, Dried Kelp, Blueberries, Cranberries, Barley Grass, Yucca Schidigera Extract, Iron Amino Acid Chelate, Turmeric, Zinc Amino Acid Chelate, Zinc Sulfate, Oil of Rosemary, L-Carnitine, L-Lysine, Copper Sulfate, Copper Amino Acid Chelate, Nicotinic Acid (Vitamin B3), Calcium Pantothenate (Vitamin B5), Taurine, Biotin (Vitamin B7), Manganese Sulfate, Vitamin A Supplement, Manganese Amino Acid Chelate, Dried Yeast, Dried Enterococcus faecium fermentation product, Dried Lactobacillus acidophilus fermentation product, Dried Aspergillus niger fermentation extract, Dried Trichoderma longibrachiatum fermentation extract, Dried Bacillus subtilis fermentation extract, Thiamine Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Vitamin D3 Supplement, Vitamin B12 Supplement, Pyridoxine Hydrochloride (Vitamin B6), Folic Acid (Vitamin B9), Calcium Iodate, Sodium Selenite.

B4

California Naturals Kangaroo and Lentil, Venison and Lentil – Grain free, Kangaroo, red and green lentils, Peas & pea fiber, sunflower oil, flaxseed (vit/min, rosemary extract). No Grains, white potatoes, corn, soy, dairy or eggs.

Ingredients: Kangaroo/Red Lentil:

Kangaroo, Red Lentils, Green Lentils, Peas, Sunflower Oil (Preserved with Mixed Tocopherols), Flaxseed, Pea Fiber, Dicalcium Phosphate, Natural Flavors, Calcium Carbonate, Salt, DL-Methionine, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Calcium Iodate, Vitamins (Betaine Hydrochloride, Vitamin A Supplement, Niacin Supplement, Calcium Pantothenate, Beta Carotene, Vitamin B12 Supplement, Vitamin D3 Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Thiamine Mononitrate, Biotin, Folic Acid), Vitamin E Supplement, Rosemary Extract

Ingredients: Venison/Green Lentil:

Venison, Green Lentils, Red Lentils, Peas, Sunflower Oil (Preserved with Mixed Tocopherols), Flaxseed, Pea Fiber, Calcium Carbonate, Dicalcium Phosphate, Natural Flavors, Salt, Potassium Chloride, DL-Methionine, Taurine, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Calcium Iodate), Vitamin E Supplement, Vitamins (Betaine Hydrochloride, Vitamin A Supplement, Niacin Supplement, Calcium Pantothenate, Beta Carotene, Vitamin B12 Supplement, Vitamin D3 Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Thiamine Mononitrate, Biotin, Folic Acid), Rosemary Extract



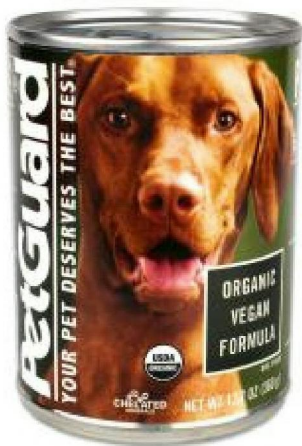
California Naturals Grain-free LID Kangaroo & Red Lentils nutritional analysis:

Crude Protein	B4	
Crude Fat		
Crude Fiber		
Ash		

California Naturals GR LID Venison and Green Lentils:

Crude Protein	B4	
Crude Fat		
Crude Fiber		
Ash		

B4 PetGuard Organic Vegan (only "Organic Vegan" is a canned food)



Organic Vegan Formula

INGREDIENTS:

Sufficient Water For Processing, **Organic Pea Protein**, Organic Oats, Organic Sunflower Oil, Organic Quinoa, Organic Barley, Organic Brown Rice, Deflourinated Tricalcium Phosphate, Organic Guar Gum, Organic Carrots, **Organic Peas**, Organic Potatoes, Organic Spinach, Potassium Chloride, Choline Chloride, **Organic Flaxseed**, Organic Apples, Organic Tomato Powder, Organic Dried Kelp, Zinc Amino Acid Chelate, Iron Amino Acid Chelate, Salt, Vitamin E Supplement, Copper Amino Acid Chelate, Manganese Amino Acid Chelate, Niacin, d-Calcium Pantothenate, Sodium Selenite, Vitamin A Supplement, Riboflavin Supplement (Vitamin B2), Biotin, Thiamine Mononitrate (Vitamin B1), Calcium Iodate, Pyridoxine Hydrochloride (Vitamin B6), Ergocalciferol (Source of Vitamin D2), Vitamin B12 Supplement, Cobalt Amino Acid Chelate, Folic Acid, Inositol.

Zignature Essentials:

Lamb (1), Salmon (3), Kangaroo (6)



Lamb: WHAT'S INSIDE (no lentils)

Lamb, Lamb Meal, **Peas, Chickpeas, Pea Flour**, Sunflower Oil (Preserved with Citric Acid), **Pea Protein, Flaxseed**, Natural Flavors, Dehydrated Alfalfa Meal, Dried Beet Pulp, Potassium Chloride, Salt, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Cobalt Proteinate, Selenium Yeast), Choline Chloride, Vitamins (Vitamin A Acetate, Vitamin D3 Supplement, Vitamin E Supplement, Niacin, d-Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid, Biotin, Vitamin B12 Supplement), Blueberries, Carrots, Cranberries, Lactic Acid, DL Methionine, Calcium Iodate, Preserved with Mixed Tocopherols. [Click here to explore what's inside our food.](#)

Kangaroo WHAT'S INSIDE (lentils)

Kangaroo, Kangaroo Meal, **Peas, Chickpeas, Pea Flour**, Sunflower Oil (preserved with Citric Acid), **Flaxseed, Red Lentils, Green Lentils**, Dehydrated Alfalfa Meal, **Pea Protein**, Natural Flavors, Salt, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Cobalt Proteinate, Selenium Yeast), Choline Chloride, Potassium Chloride, Calcium Carbonate, Vitamins (Vitamin A, Acetate, Vitamin D3 Supplement, Vitamin E Supplement, Niacin, d-Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid, Biotin, Vitamin B12 Supplement), Lactic Acid, Calcium Iodate, Preserved With Mixed Tocopherols. [Click here to explore what's inside our food.](#)

Zignature Essentials Kangaroo Guaranteed Analysis

Crude Protein	26
Crude Fat (min)	14
Crude Fiber (Max)	4.5
Moisture (Max)	10

Salmon WHAT'S INSIDE (no lentils)

Salmon, Salmon Meal, Pea Flour, Chickpeas, Peas, Sunflower Oil (Preserved With Mixed Tocopherols And Citric Acid), Flaxseed, Natural Flavors, Suncured Alfalfa Meal, Calcium Carbonate, Salt, Choline Chloride, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Cobalt Proteinate), Potassium Chloride, Vitamins (Vitamin A Acetate, Vitamin D3 Supplement, Vitamin E Supplement, Niacin, D-Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid, Biotin, Vitamin B12 Lactic Supplement), Lactic Acid, Calcium Iodate, Sodium Selenite. [Click here to explore what's inside our food.](#)

Physiologically Tuned™, limited ingredient premium food for dogs. Hypoallergenic meat first recipe, with no Corn, Wheat, Soy, Dairy, or Chicken, Chicken Eggs, or Chicken By-Products.

Nature's Recipe Salmon & Sweet Potato (2 separate cases): no lentils.



Ingredients

Salmon, garbanzo beans, peas, pea protein, salmon meal, poultry fat (preserved with mixed tocopherols), sweet potatoes, apples, pumpkin, natural flavor, dried tomato pomace, salt, potassium chloride, calcium carbonate, choline chloride, taurine, vitamins (vitamin E supplement, L-ascorbyl-2-polyphosphate (source of vitamin C), Inositol, niacin, d-calcium pantothenate, vitamin A supplement,

riboflavin supplement, thiamine mononitrate, beta-carotene, pyridoxine hydrochloride, vitamin B12 supplement, menadione sodium bisulfite complex, vitamin D3 supplement, folic acid, biotin), minerals (ferrous sulfate, iron proteinate, zinc proteinate, zinc oxide, copper sulfate, manganese proteinate, copper proteinate, manganous oxide, calcium iodate, sodium selenite), lactic acid, citric acid (used as a preservative), yucca schidigera extract, rosemary extract.

Kirkland Nature's Domain Turkey and Sweet Potato: (no lentils) 1 case, had a low blood taurine



Ingredients:

Turkey meal, sweet potatoes, peas, potatoes, canola oil, tomato pomace, flaxseed, natural flavor, salmon oil (a source of DHA), salt, choline chloride, dried chicory root, tomatoes, blueberries, raspberries, yucca schidigera extract, dried Lactobacillus acidophilus fermentation product, dried Bifidobacterium animalis fermentation product, dried Lactobacillus reuteri fermentation product, vitamin E supplement, iron proteinate, zinc proteinate, copper proteinate, ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, thiamine mononitrate (vitamin B1), manganese proteinate, manganous oxide, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, manganese sulfate, sodium selenite, pyridoxine hydrochloride (vitamin B6), vitamin B12 supplement, riboflavin (vitamin B2), vitamin D supplement, folic acid.

B4, B5

B4, B5



INGREDIENTS:

Hasen Duckenpfeffer, Gamebird and Lamb/Lentil:

Rabbit, Duck, Pork Meat Meal, Peas, Potatoes, Lentils, Chickpeas, Pea Flour, Dried Tomato Pomace, Dried Whole Egg, Pork Fat, Rabbit Meal, Pork Liver, Pea Protein, Salmon Oil, Cheese, Flaxseed, Alfalfa Meal, Carrots, Celery, Lettuce, Watercress, Spinach, Potassium Chloride, Salt, Chicory Root Extract, Yucca Schidigera Extract, Sodium Selenite, Folic Acid, Taurine, Parsley, Sorbic Acid (Preservative), Vitamins, Minerals, Probiotics.

Lamb, Lamb Meal, Lentils, chickpeas, Dried Whole Egg, Peas, Dried Tomato Pomace, Pork Fat, Pea Flour, Pork Liver, Salmon oil, cheese, olive oil, yellow squash, zucchini, apples, flaxseed, pea fiber, tomatoes, carrots, broccoli, KCl, salt, chicory root extract, yucca schidigera extract, sodium selenite, folic acid, taurine, sorbic acid, vitamins, minerals, probiotics.

Duck, Duck meal, peas, turkey, potatoes, pea protein, dried tomato pomace, pea flour, dried whole egg, quail, chicken meal, chicken fat, salmon oil, sweet potatoes, chicken, pheasant, cheese, flaxseed, carrots, broccoli, cauliflower, apples, celery, parsley, lettuce, spinach, chicken cartilage, KCl, blueberries, cranberries, salt, chicory root extract, yucca schidigera extract, alfalfa sprouts, sodium selenite, folic acid, taurine, sorbic acid, vitamins, minerals, probiotics.

Earthborn Holistic Meadow Feast/Primitive Natural:



Meadow Feast:

Lamb Meal, Peas, Tapioca, Canola Oil (preserved with Mixed Tocopherols), Pea Protein, Pea Fiber, Flaxseed, Natural Flavors, Blueberries, Cranberries, Apples, Carrots, Spinach, Salt, Potassium Chloride, Choline Chloride, DL-Methionine, L-Lysine, Taurine, L-Carnitine, Beta-Carotene, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Zinc Sulfate, L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Ferrous Sulfate, Niacin, Calcium Pantothenate, Riboflavin Supplement, Copper Sulfate, Pyridoxine Hydrochloride, Thiamine Mononitrate, Beta-Carotene, Manganese Sulfate, Zinc Proteinate, Manganese Proteinate, Copper Proteinate, Calcium Iodate, Cobalt Carbonate, Folic Acid, Sodium Selenite, Biotin, Vitamin B12 Supplement, Yucca Schidigera Extract, Rosemary Extract, Dried Enterococcus Faecium Fermentation Product, Dried Lactobacillus Casei Fermentation Product, Dried Lactobacillus Acidophilus Fermentation Product.

Primitive Natural:

Turkey Meal, Chicken Meal, Peas, Dried Egg, Pea Starch, Chicken Fat (preserved with Mixed Tocopherols), Whitefish Meal, Flaxseed, Natural Flavors, Pea Fiber, Blueberries, Cranberries, Apples, Carrots, Spinach, Salt, Potassium Chloride, Choline Chloride, DL-Methionine, L-Lysine, Taurine, L-Carnitine, Beta-Carotene, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Niacin, Folic Aid, Biotin, Manganese Sulfate, Copper Sulfate, Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Zinc Proteinate, Manganese Proteinate, Copper Proteinate, Calcium Iodate, Sodium Selenite, Cobalt Carbonate, Vitamin B12 Supplement, Yucca Schidigera Extract, Rosemary Extract, Dried Enterococcus Faecium Fermentation Product, Dried Lactobacillus Casei Fermentation Product, Dried Lactobacillus Acidophilus Fermentation Product.

4Health Grain-free:

Free of grain, wheat, soy and corn; added omega fatty acids.

Flavor unknown, but a check of the 4Health Grain-Free Chicken & Vegetable dry shows:

Ingredients:

Chicken, Chicken Meal, Garbanzo Beans, Lentils, Peas, Potatoes, Chicken Fat (Preserved with Mixed Tocopherols), Tapioca, Egg Product, Tomato Pomace, Natural Flavor, Flaxseed, Ocean Fish Meal, Salt, Choline Chloride, Dried Chicory Root, Tomatoes, Blueberries, Raspberries, Glucosamine Hydrochloride, Yucca Schidigera Extract, Chondroitin Sulfate, Dried Lactobacillus Acidophilus Fermentation Product, Dried Bifidobacterium Animalis Fermentation Product, Dried Lactobacillus Reuteri Fermentation Product, Vitamin E Supplement, Beta Carotene, Iron Proteinate, Zinc Proteinate, Copper Proteinate, Ferrous Sulfate, Zinc Sulfate, Copper Sulfate, Potassium Iodide, Thiamine Mononitrate (Vitamin B1), Manganese Proteinate, Manganous Oxide, Ascorbic Acid, Vitamin A Supplement, Biotin, Niacin, Calcium Pantothenate, Manganese Sulfate, Sodium Selenite, Pyridoxine Hydrochloride (Vitamin B6), Vitamin B12 Supplement, Riboflavin (Vitamin B2), Vitamin D Supplement, Folic Acid.

4Health Grain-Free Large Breed:

Ingredients:

Turkey, Turkey Meal, Garbanzo Beans, Lentils, Peas, Potatoes, Tapioca, Chicken Fat (Preserved with Mixed Tocopherols), Egg Product, Tomato Pomace, Natural Flavor, Flaxseed, Ocean Fish Meal, Salt, Choline Chloride, Glucosamine Hydrochloride, Dried Chicory Root, Tomatoes, Blueberries, Raspberries, Chondroitin Sulfate, Yucca Schidigera Extract, Dried Lactobacillus Acidophilus Fermentation Product, Dried Bifidobacterium Animalis Fermentation Product, Dried Lactobacillus Reuteri Fermentation Product, Vitamin E Supplement, Beta Carotene, Iron Proteinate, Zinc Proteinate, Copper Proteinate, Ferrous Sulfate, Zinc Sulfate, Copper Sulfate, Potassium Iodide, Thiamine Mononitrate (Vitamin B1), Manganese Proteinate, Manganous Oxide, Ascorbic Acid, Vitamin A Supplement, Biotin, Niacin, Calcium Pantothenate, Manganese Sulfate, Sodium Selenite, Pyridoxine Hydrochloride (Vitamin B6), Vitamin B12 Supplement, Riboflavin (Vitamin B2), Vitamin D Supplement, Folic Acid.

Petcurean Now Fresh; LID unknown; Raw patties:

Example only: Petcurean Now Fresh Grain Free Adult dog food recipe

De-boned turkey, potato flour, peas, apples, whole dried egg, pea fibre, tomato, potatoes, flaxseed, canola oil (preserved with mixed tocopherols), natural flavour, salmon, de-boned duck, sundried alfalfa, coconut oil (preserved with mixed tocopherols), carrots, pumpkin, bananas, blueberries, cranberries, raspberries, blackberries, papayas, pineapple, grapefruit, lentil beans, broccoli, spinach, cottage cheese, alfalfa sprouts, calcium carbonate, dicalcium phosphate, lecithin, sodium chloride, potassium chloride, vitamins (vitamin E supplement, L-ascorbyl-2-polyposphate (a source of vitamin C), niacin, inositol, vitamin A supplement, thiamine mononitrate, d-calcium pantothenate, pyridoxine hydrochloride, riboflavin, beta-carotene, vitamin D3 supplement, folic acid, biotin, vitamin B12 supplement), minerals (zinc proteinate, ferrous sulphate, zinc oxide, iron proteinate, copper sulphate, copper proteinate, manganese proteinate, manganous oxide, calcium iodate, selenium yeast), taurine, DL-methionine, L-lysine, dried chicory root, dried Lactobacillus acidophilus fermentation product, dried Enterococcus faecium fermentation product, yucca schidigera extract, dried rosemary.

Example 2: Petcurean Now Fresh Fish Recipe for Adult Dogs

De-boned trout, whole dried egg, potatoes, potato flour, peas, pea flour, apples, flaxseed, canola oil (preserved with mixed tocopherols), natural flavour, de-boned salmon, de-boned herring, calcium carbonate, dicalcium phosphate, coconut oil (preserved with mixed tocopherols), tomato, alfalfa, carrots, pumpkin, sweet potatoes, squash, bananas, blueberries, cranberries, blackberries, pomegranate, papayas, lentils, broccoli, dried chicory root, sodium chloride, potassium chloride, choline chloride, vitamins (vitamin A supplement, vitamin D3 supplement, vitamin E supplement, inositol, niacin, L-ascorbyl-2-polyphosphate (a source of vitamin C), d-calcium pantothenate, thiamine mononitrate, beta-carotene, riboflavin, pyridoxine hydrochloride, folic acid, biotin, vitamin B12 supplement), minerals (zinc proteinate, iron proteinate, copper proteinate, zinc oxide, manganese proteinate, copper sulphate, ferrous sulphate, calcium iodate, manganous oxide, selenium yeast), taurine, DL-methionine, L-lysine, dried Lactobacillus acidophilus fermentation product, dried Enterococcus faecium fermentation product, dried rosemary.

Example 3: LID version with venison:

De-boned venison, venison meal, tapioca, peas, pea flour, lentils, chickpeas, canola oil (preserved with mixed tocopherols), dried chicory root, sodium chloride, algae extract, potassium chloride, choline chloride, vitamins (vitamin A supplement, vitamin D3 supplement, vitamin E supplement, inositol, niacin, L-ascorbyl-2-polyphosphate (a source of vitamin C), d-calcium pantothenate, thiamine mononitrate, beta-carotene, riboflavin, pyridoxine hydrochloride, folic acid, biotin, vitamin B12 supplement), minerals (zinc proteinate, iron proteinate, copper proteinate, zinc oxide, manganese proteinate, copper sulphate, ferrous sulphate, calcium iodate, manganous oxide, selenium yeast), DL-methionine, L-lysine, dried rosemary.

Ingredient definitions:

Pea Fiber: An insoluble fibre source that helps to regulate glucose levels, and promotes digestive health

Pea Flour: A source of complex carbohydrates, soluble and insoluble fiber

Peas: A good source of beta-carotene, niacin, Vitamin B6, folate, phosphorus and copper, and a very good source of dietary fibre, Vitamin C, Vitamin K, thiamin and manganese

Lentils: A low glycemic carbohydrate that is also a good source of protein, iron, phosphorus and copper, and a very good source of dietary fibre, folate and manganese

Flaxseed: A source of Omega 3 and 6, naturally preserved, as well as fibre

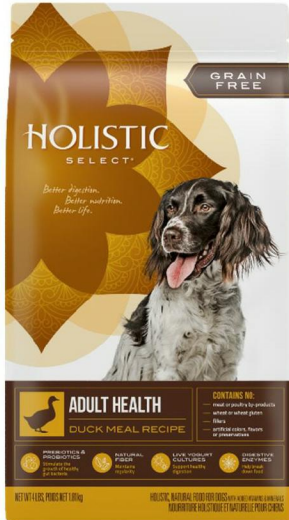


Supreme Source Salmon Meal and Sweet Potato:



Salmon Meal, Peas, Lentils, Faba Beans, Sweet Potatoes, Poultry Fat (Preserved with Mixed Tocopherols), Chickpeas, Tomato Pomace, Dicalcium Phosphate, Natural Flavor, Salmon Oil (Preserved with Mixed Tocopherols), Salt, Dried Seaweed Meal (*Ascophyllum nodosum*), Calcium Carbonate, Betaine, Choline Chloride, Carrots, Blueberries, Cranberries, Spinach, Parsley, Pomegranates, Vitamin E Supplement, Zinc Oxide, Zinc Proteinate, Ferrous Sulfate, Vitamin A Supplement, d-Calcium Pantothenate, Manganous Oxide, Niacin Supplement, Riboflavin Supplement, Thiamine Mononitrate, Copper Sulfate, Pyridoxine Hydrochloride, Manganese Proteinate, Vitamin D3 Supplement, Calcium Iodate, Copper Proteinate, Folic Acid, Biotin, Sodium Selenite, Vitamin B12 Supplement, Cobalt Carbonate, Rosemary Extract.

Holistic Select GF Adult Health Duck Meal Recipe:



Duck Meal, Chickpeas, Peas, Lentils, Chicken Fat (preserved with Mixed Tocopherols), Dried Plain Beet Pulp, Flaxseed, Pumpkin, Cranberries, Apples, Brewers Dried Yeast, Papayas, Choline Chloride, Blueberries, Pomegranates, Vitamin E Supplement, Inulin, Dried Kelp, Zinc Protein, Mixed Tocopherols added to preserve freshness, Zinc Sulfate, Niacin, Ferrous Sulfate, Iron Protein, Vitamin A Supplement, Yucca Schidigera Extract, Glucosamine Hydrochloride, Ascorbic Acid (Vitamin C), Ground Cinnamon, Ground Fennel, Ground Peppermint, Copper Sulfate, Thiamine Mononitrate, Copper Protein, Manganese Protein, Manganese Sulfate, d-Calcium Pantothenate, Sodium Selenite, Dried Enterococcus faecium Fermentation Product, Pyridoxine Hydrochloride, Riboflavin, Vitamin D3 Supplement, Biotin, Dried Lactobacillus bulgaricus Fermentation Product, Dried Enterococcus thermophilus Fermentation Product, Calcium Iodate, Vitamin B12 Supplement, Folic Acid, Dried Bacillus licheniformis Fermentation Product, Dried Bacillus subtilis Fermentation Product, Dried Aspergillus oryzae Fermentation Product, Dried Trichoderma reesei Fermentation Product, Dried Rhizopus oryzae Fermentation Product, Dried Lactobacillus acidophilus Fermentation Product, Dried Lactobacillus casei Fermentation Product, Rosemary Extract, Green Tea Extract, Spearmint Extract.

Canidae LID Duck, Bison, Boar flavors:



Duck, duck meal, turkey meal, sweet potatoes, peas, chicken fat (preserved with mixed tocopherols), potatoes, sun-dried alfalfa, natural flavor, minerals (iron protein, zinc protein, copper protein),

ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, manganese proteinate, manganous oxide, manganese sulfate, sodium selenite), vitamins (vitamin E supplement, thiamine mononitrate, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, pyridoxine hydrochloride, vitamin B12 supplement, riboflavin, vitamin D3 supplement, folic acid), choline chloride, mixed tocopherols (a preservative), dried enterococcus faecium fermentation product, dried lactobacillus acidophilus fermentation product, dried lactobacillus casei fermentation product, dried lactobacillus plantarum fermentation product, dried trichoderma longibrachiatum fermentation extract

Bison, lamb meal, sweet potatoes, **peas**, chickpeas, canola oil, suncured alfalfa, natural flavor, minerals (iron proteinate, zinc proteinate, copper proteinate, ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, manganese proteinate, manganous oxide, manganese sulfate, sodium selenite), vitamins (vitamin E supplement, thiamine mononitrate, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, pyridoxine hydrochloride, vitamin B12 supplement, riboflavin, vitamin D3 supplement, folic acid), choline chloride, mixed tocopherols (a preservative), dried enterococcus faecium fermentation product, dried lactobacillus acidophilus fermentation product, dried lactobacillus casei fermentation product, dried lactobacillus plantarum fermentation product, dried trichoderma longibrachiatum fermentation extract

Wild boar, pork meal, sweet potatoes, **peas**, chickpeas, canola oil, suncured alfalfa, natural flavor, minerals (iron proteinate, zinc proteinate, copper proteinate, ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, manganese proteinate, manganous oxide, manganese sulfate, sodium selenite), vitamins (vitamin E supplement, thiamine mononitrate, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, pyridoxine hydrochloride, vitamin B12 supplement, riboflavin, vitamin D3 supplement, folic acid), choline chloride, mixed tocopherols (a preservative), dried enterococcus faecium fermentation product, dried lactobacillus acidophilus fermentation product, dried lactobacillus casei fermentation product, dried lactobacillus plantarum fermentation product, dried trichoderma longibrachiatum fermentation extract

Merrick GF Buffalo Sw P (same case as above):



Deboned Buffalo, Chicken Meal, Sweet Potatoes, Turkey Meal, Salmon Meal, Potatoes, **Peas**, Chicken Fat (preserved with mixed tocopherols), Natural Pork Flavor, Lamb Meal, **Pea Protein**, Deboned Beef, Natural Chicken Flavor, Deboned Salmon, Deboned Turkey, Deboned Chicken, **Flaxseed Oil**, Apples,

Blueberries, Organic Alfalfa, Salmon Oil, Salt, Minerals (Zinc Amino Acid Complex, Zinc Sulfate, Iron Amino Acid Complex, Manganese Amino Acid Complex, Copper Amino Acid Complex, Potassium Iodide, Cobalt Amino Acid Complex, Sodium Selenite), Vitamins (Vitamin E Supplement, Vitamin A Supplement, Vitamin B12 Supplement, d-Calcium Pantothenate, Vitamin D3 Supplement, Niacin, Riboflavin Supplement, Biotin, Pyridoxine Hydrochloride, Folic Acid, Thiamine Mononitrate), Choline Chloride, Yucca Schidigera Extract, Dried Lactobacillus plantarum Fermentation Product, Dried Lactobacillus casei Fermentation Product, Dried Enterococcus faecium Fermentation Product, Dried Lactobacillus acidophilus Fermentation Product, Rosemary Extract.

Purina ONE Lamb and Rice: 1 case, has corn, soy and wheat, NOT GF. No peas, but Lamb/Rice known in past as issue.



Lamb (source of glucosamine), brewer's rice, whole grain corn, whole grain wheat, poultry by-product meal (source of glucosamine), corn gluten meal, soybean meal, animal fat preserved with mixed-tocopherols, calcium phosphate, glycerin, animal digest, calcium carbonate, potassium chloride, salt, caramel color, Vitamin E supplement, choline chloride, zinc sulfate, L-Lysine monohydrochloride, ferrous sulfate, sulfur, manganese sulfate, niacin, Vitamin A supplement, calcium pantothenate, thiamine mononitrate, copper sulfate, riboflavin supplement, Vitamin B-12 supplement, pyridoxine hydrochloride, garlic oil, folic acid, Vitamin D-3 supplement, calcium iodate, biotin, menadione sodium bisulfite complex (source of Vitamin K activity), sodium selenite.

Taste of the Wild Pacific Stream Canine Formula:



Salmon, ocean fish meal, sweet potatoes, potatoes, peas, canola oil, lentils, salmon meal, smoked salmon, potato fiber, natural flavor, salt, choline chloride, dried chicory root, tomatoes, blueberries, raspberries, 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 (vitamin B1), manganese proteinate, manganous oxide, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, manganese sulfate, sodium selenite, pyridoxine hydrochloride (vitamin B6), vitamin B12 supplement, riboflavin (vitamin B2), vitamin D supplement, folic acid.

Acana Lamb & Apple Limited Ingredient:



Deboned lamb*, lamb meal, whole green peas, red lentils, lamb liver*, lamb fat, pinto beans, chickpeas, herring oil, green lentils, whole yellow peas, lentil fiber, apples*, natural lamb flavor, lamb tripe*, lamb kidney*, lamb cartilage*, dried kelp, whole pumpkin*, whole butternut squash*, kale*, spinach*, mustard greens*, collard greens*, turnip greens*, carrots*, pears*, freeze-dried lamb liver, freeze-dried lamb tripe, pumpkin seeds, sunflower seeds, zinc proteinate, mixed tocopherols (preservative), chicory root, turmeric, sarsaparilla root, althea root, rosehips, juniper berries, dried lactobacillus acidophilus fermentation product, dried bifidobacterium animalis fermentation product, dried lactobacillus casei fermentation product.

Nature's Variety Instinct Limited Ingredient Diet Lamb Meal and Peas:

Only Lamb LID now sold is Instinct LID GF Lamb.

Lamb Meal, Peas, Tapioca, Pea Protein, Canola Oil (preserved with Mixed Tocopherols and Citric Acid), Lamb, Natural Flavor, Montmorillonite Clay, Coconut Oil, Salt, Vitamins (Vitamin E Supplement, L-Ascorbyl-2-Polyphosphate, Niacin Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Vitamin A Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Biotin), Potassium Chloride, Choline Chloride, DL-Methionine, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Sodium Selenite, Ethylenediamine Dihydriodide), Freeze Dried Lamb, Pumpkinseeds, Freeze Dried Lamb Liver, Freeze Dried Lamb Spleen, Freeze Dried Lamb Heart, Freeze Dried Lamb Kidney, Rosemary Extract.



Roll over image to zoom in

Hill's U/D Urinary Care:



Ingredients - Dry

Brewers Rice, Corn Starch, Pork Fat, Egg Product, Powdered Cellulose, Chicken Liver Flavor, Flaxseed,

Lactic Acid, Potassium Citrate, Soybean Oil, Calcium Carbonate, L-Lysine, Iodized Salt, Choline Chloride, vitamins (Vitamin E Supplement, Niacin Supplement, Thiamine Mononitrate, Vitamin A Supplement, Calcium Pantothenate, Biotin, Vitamin B12 Supplement, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid, Vitamin D3 Supplement), Dried Beet Pulp, L-Threonine, Taurine, minerals (Ferrous Sulfate, Zinc Oxide, Manganous Oxide, Copper Sulfate, Calcium Iodate, Sodium Selenite), L-Carnitine, L-Tryptophan, Mixed Tocopherols for freshness, Natural Flavors, Beta-Carotene

Ingredients – Canned

Water, Corn Starch, Egg Product, Chicken Fat, Pork Liver, Sugar, Rice, Powdered Cellulose, Flaxseed, Potassium Citrate, Calcium Carbonate, Choline Chloride, Monosodium Phosphate, vitamins (Vitamin E Supplement, Thiamine Mononitrate, Niacin Supplement, Calcium Pantothenate, Vitamin B12 Supplement, Pyridoxine Hydrochloride, Biotin, Riboflavin Supplement, Vitamin D3 Supplement, Folic Acid), L-Lysine, Iodized Salt, Magnesium Oxide, minerals (Manganese Sulfate, Zinc Oxide, Ferrous Sulfate, Copper Sulfate, Calcium Iodate), Taurine, L-Carnitine, Beta-Carotene.

EVO Grain-Free Turkey and Chicken Formula Cat food:

Turkey, Chicken, Chicken Meal, Tapioca Starch, Chicken Fat (Preserved with Mixed Tocopherols, a Source of Vitamin E), Herring, Pea Fiber, Salmon Meal, Natural Flavors, Potassium Chloride, Apples, Eggs, Carrots, Menhaden Oil, Peas, Cranberries, Alfalfa Sprouts, Pumpkin, Tomatoes, Cottage Cheese, Dried Chicory Root Extract, Minerals (Zinc Proteininate, Iron Proteininate, Copper Proteininate, Manganese Proteininate, Calcium Iodate), DL-Methionine, Vitamins (Betaine Hydrochloride, Niacin Supplement, Vitamin A Supplement, Thiamine Mononitrate, Calcium Pantothenate, Riboflavin Supplement, Beta Carotene, Vitamin B12 Supplement, Vitamin D3 Supplement, Biotin, Pyridoxine Hydrochloride, Folic Acid), Taurine, Ascorbic Acid, Vitamin E Supplement Direct Fed Microbials (Dried Enterococcus faecium, Dried Lactobacillus acidophilus, Dried Lactobacillus casei) Rosemary Extract

Merrick Purrfect Bistro Grain-free Real Chicken Recipe:



Deboned Chicken, Chicken Meal, Turkey Meal, Dried Potatoes, Peas, Natural Pork Flavor, Potato Protein, Powdered Cellulose, Chicken Fat (preserved with mixed tocopherols), Natural Chicken Flavor, Sweet Potatoes, Ground Flaxseed, Dried Egg Product, Chicken Liver, Dried Whey Protein Concentrate, Organic Alfalfa, Cranberries, Phosphoric Acid, Flaxseed Oil (source of Omega 3 fatty acids), Salt, Minerals (Zinc

Sulfate, Iron Amino Acid Complex, Zinc Amino Acid Complex, Manganese Amino Acid Complex, Copper Amino Acid Complex, Potassium Iodide, Cobalt Amino Acid Complex, Sodium Selenite), Vitamins (Vitamin E Supplement, Vitamin A Acetate, Vitamin B12 Supplement, d-Calcium Pantothenate, Vitamin D3 Supplement, Niacin, Riboflavin Supplement, Biotin, Pyridoxine Hydrochloride, Folic Acid, Thiamine Mononitrate), Choline Chloride, **Taurine**, Yucca Schidigera Extract, Dried Bacillus coagulans Fermentation Product, Rosemary Extract, Dried Lactobacillus plantarum Fermentation Product, Dried Lactobacillus casei Fermentation Product, Dried Enterococcus faecium Fermentation Product, Dried Lactobacillus acidophilus Fermentation Product.

Rachael Ray Nutrish: no flavor variety given, so try several. All qualify as GF – in that no corn, wheat or soy.



Ingredients – chicken and brown rice (Salmon & Brown Rice; Chicken w/ Lentils & Salmon; Chicken w/ chickpeas & Salmon; Turkey w Chickpeas & Salmon)

Nutrish Chicken & Brown Rice

Chicken, Chicken Meal, Corn Gluten Meal, Ground **Rice**, Brown **Rice**, Poultry Fat (Preserved with Mixed Tocopherols), Brewer's Dried Yeast, Natural Flavor, Dried Plain Beet Pulp, Potassium Chloride, Choline Chloride, Iron Oxide (color), **Dried Ground Peas**, Dried Carrots, Olive Oil, **Taurine**, Vitamin E Supplement, Zinc Sulfate, Salt, Ferrous Sulfate, Calcium Carbonate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Salmon & Brown Rice:

Salmon, Ground Rice, Corn Gluten Meal, Fish Meal, Brown Rice, Poultry Fat (Preserved with Mixed Tocopherols), Brewer's Dried Yeast, Dried Ground Peas, Pea Protein, Natural Flavor, Salmon Meal, Dried Plain Beet Pulp, Calcium Carbonate, Choline Chloride, Iron Oxide (color), Dried Carrots, Olive Oil,

Taurine, Salt, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Chicken w/ Chickpeas & Salmon

Chicken, Chicken Meal, **Dried Peas**, Brewer's Rice, Corn Protein Concentrate, Dried Chickpeas, Chicken Fat (Preserved with Mixed Tocopherols), Salmon, Dried Plain Beet Pulp, Natural Flavor, Dicalcium Phosphate, Menhaden Fish Meal, Dried Cranberries, Salt, Menhaden Fish Oil (Preserved with Mixed Tocopherols), Potassium Chloride, Choline Chloride, Taurine, Iron Oxide (Color), Dried Blueberry, Dried Pumpkin, Vitamin E Supplement, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Zinc Sulfate, Ferrous Sulfate, Calcium Carbonate, Niacin, Dried Dandelion, Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Biotin, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Potassium Iodide.

Nutrish Lentils and Salmon:

Chicken, Chicken Meal, Corn Gluten Meal, **Dried Ground Peas, Lentils, Pea Protein**, Poultry Fat (Preserved with Mixed Tocopherols), Dried Plain Beet Pulp, Powdered Cellulose, Salmon, Ground Rice, Natural Flavor, Salt, Choline Chloride, Iron Oxide (color), Taurine, Dried Cranberry, Dried Blueberry, Dried Pumpkin, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Calcium Carbonate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Dandelion, Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Zero Grain Chicken:

Chicken, Chicken Meal, **Dried Ground Peas**, Whole Dried Potato, **Pea Protein**, Chicken Fat (Preserved with Mixed Tocopherols), Tapioca, Natural Flavor, Dried Egg Product, Cranberries, **Whole Flaxseed**, Dried Plain Beet Pulp, Salt, Choline Chloride, Taurine, DL-Methionine, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Calcium Carbonate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Zero Grain Whitefish:

Whitefish, Salmon Meal, Fish Meal, Turkey Meal, **Dried Peas**, Tapioca, Poultry Fat (Preserved with Mixed Tocopherols), Whole Dried Potatoes, Dried Egg Product, **Pea Protein**, Turkey, Natural Fish Flavor, Salt, Dried Plain Beet Pulp, **Whole Flaxseed**, Dried Carrots, Choline Chloride, Potassium Chloride, Dried Cranberry, Taurine, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Niacin, L-Ascorbyl-2-

Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Woodland Recipe:

Chicken, Chicken Meal, Menhaden Fish Meal, **Dried Peas, Pea Protein**, Salmon Meal, Chicken Fat (Preserved with Mixed Tocopherols), Tapioca, Turkey Meal, Dried Egg Product, Dried Sweet Potato, Salmon, Trout, Natural Flavor, Salt, Dried Plain Beet Pulp, Choline Chloride, Vitamin E Supplement, Zinc Sulfate, Taurine, Calcium Carbonate, Ferrous Sulfate, Niacin, Dried Dandelion, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Biotin, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Menadione Sodium Bisulfate Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Potassium Iodide, Vitamin D3 Supplement.

FOR COMPARISON ONLY:

IAMS Proactive Health dry dog food:

Chicken, Chicken By-Product Meal, Ground Whole Grain Corn, Ground Whole Grain Sorghum, Chicken Fat (preserved with mixed Tocopherols), Dried Beet Pulp, Natural Flavor, Dried Egg Product, Potassium Chloride, Flaxseed, Caramel Color, L-Lysine Monohydrochloride, Salt, Sodium Hexametaphosphate, Choline Chloride, Carrots, Tomatoes, Fructooligosaccharides, Spinach, **Green Peas**, Minerals (Ferrous Sulfate, Zinc Oxide, Sodium Selenite, Manganese Sulfate, Copper Sulfate, Manganous Oxide, Potassium Iodide), Calcium Carbonate, Vitamins (Vitamin E Supplement, Ascorbic Acid, Calcium Pantothenate, Vitamin A Supplement, Biotin, Thiamine Mononitrate (source of Vitamin B1), Vitamin B12 supplement, Niacin, Riboflavin Supplement (source of Vitamin B2), Inositol, Pyridoxine Hydrochloride (source of Vitamin B6), Vitamin D3 Supplement, Folic Acid), Dried Brewers Yeast, DL-Methionine, Dried Apple Pomace, L-Carnitine , Dried Blueberry Pomace, Mixed Tocopherols, Rosemary Extract.

Crude Protein (min)	25
Crude Fat (Min)	14
Crude Fiber (Max)	4
Moisture (Max)	10

Purina Dog Chow Little Bites w/ Chicken and Beef:

Whole grain corn, corn gluten meal, meat and bone meal, soybean meal, beef fat naturally preserved with mixed-tocopherols, poultry by-product meal, whole grain wheat, chicken, beef, poultry and pork digest, ground rice, salt, calcium carbonate, potassium chloride, L-Lysine monohydrochloride, choline chloride, mono and dicalcium phosphate, **MINERALS** [zinc sulfate, ferrous sulfate, manganese sulfate, copper sulfate, calcium iodate, sodium selenite], **VITAMINS** [Vitamin E supplement, niacin (Vitamin B-3),

Vitamin A supplement, calcium pantothenate (Vitamin B-5), pyridoxine hydrochloride (Vitamin B-6), Vitamin B-12 supplement, thiamine mononitrate (Vitamin B-1), Vitamin D-3 supplement, riboflavin supplement (Vitamin B-2), menadione sodium bisulfite complex (Vitamin K), folic acid (Vitamin B-9), biotin (Vitamin B-7)], Yellow 6, Yellow 5, Red 40, Blue 2, garlic oil. K-4120

Crude Protein (min)	25
Crude Fat (Min)	12
Crude Fiber (Max)	4.5
Moisture (Max)	12

Pedigree Adult Roasted Chicken, Rice and Vegetable Flavor:

Ground Whole Grain Corn, Meat And Bone Meal (Source Of Calcium), Corn Gluten Meal, Animal Fat (Source Of Omega 6 [Preserved With Bha & Citric Acid]), Soybean Meal, Natural Flavor, Chicken By-Product Meal, Dried Plain Beet Pulp, Ground Whole Grain Wheat, Salt, Potassium Chloride, Brewers Rice, Choline Chloride, **Dried Peas**, Calcium Carbonate, Zinc Sulfate, DL-Methionine, Vitamin E Supplement, Niacin [Vitamin B3], Biotin, Dried Carrots, L-Tryptophan, Bha & Citric Acid (A Preservative), Blue 2, Yellow 5, Yellow 6, D-Calcium Pantothenate [Source Of Vitamin B5], Riboflavin Supplement [Vitamin B2], Red 40, Pyridoxine Hydrochloride [Vitamin B6], Copper Sulfate, Sodium Selenite, Potassium Iodide, Vitamin A Supplement, Thiamine Mononitrate [Vitamin B1], Vitamin B12 Supplement, Vitamin D3 Supplement, Folic Acid

Crude Protein (min)	21
Crude Fat (min)	10
Crude Fiber (Max)	4
Moisture (Max)	12

Fascetti paper, 2003: For the 5 diets fed to dogs with DCM and low blood and/or plasma taurine

Crude Protein	24	23	17	22	28
Crude Fat	14	13	7	11	13
NFE*	48	57	63	62	46
Crude Fiber	2	1	7	5	4
Ash	10	6	6	-	9
ME	3.8	3.9	3.4	3.5	3.8

*NFE = calculated or reported nitrogen-free extract; ME = metabolizable energy

Document properties

Author: Palmer, Lee Anne
Template: Normal.dotm
Page count: 8
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Line count: 624
Word count: 5267
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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Nemser, Sarah; Ceric, Olgica; Palmer, Lee Anne; Carey, Lauren; Glover, Mark; Queen, Jackie L
Sent: 6/4/2018 8:57:58 PM
Subject: DCM -should be a PFR-FW: EON-355590 RFR Event: **B6** (owner)

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



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Sent: Monday, June 04, 2018 4:56 PM
To: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; orahqreportablefoodnotificationtriagegroup@fda.hhs.gov; Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Johnston, Ying F <Ying.Johnston@fda.hhs.gov>; Edwards, Elizabeth <Elizabeth.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Yowell, Ruth <Ruth.Yowell@fda.hhs.gov>; ORA HAF EAST1 Reportable Food Notification <orahafeast1reportablefoodnotification@fda.hhs.gov>; Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>; CFSAN Reportable Food Registry <CFSANReportableFoodRegistry@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; Weems, Shellie * <Shellie.Weems@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; ORA OEIO RECALLS Branch <oraoiorecallsbranch@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; **B6**
Subject: EON-355590 RFR Event: **B6**

A RFR Report has been received and RFR Event [EON-355590] has been created in the EON System under ICSR # 2048966.

Reason this food is reportable: Other
Please describe Other: possible diet-associated DCM
Product Name: 4health Grain-Free Large Breed Formula Adult Dog Food

Type of Site:	Sender	Food Facility Site
---------------	--------	--------------------

FDA Districts Impacted:	NWE	NWE
Organization Name:	B6	(owner)
Address:		B6
	United States	

Discovery Date: 2018-05-29

Product Group: Pet Food

Description: 4health Grain-Free Large Breed Formula Adult Dog Food. Owner was asked to save food. Plasma taurine 57 (ref range 60-120), WB taurine 262 (ref range 200-350)

Product Recall: No

Human Symptoms Present: No

Animal Symptoms Present: Yes

Animal Symptoms Description: Dog has dilated cardiomyopathy and congestive heart failure. Can provide additional details

Product Distribution Type: Retail

Discovery Code: Other

Submission Type: Initial

Reporting Type: Voluntary

EON Key: EON-355590

EON Title: RFR Event created for 4health Grain-Free Large Breed Formula Adult Dog Food; 2048966

To view this RFR Event, please click the link below:

B6

To view the RFR Report, please click the link below:

B6

B6

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26346

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

Veterinarian Contact: **B6**

Clinic/Company Name: **B6**

B6

B6

Tax ID: _____

Species: canine

B6

Breed: Chihuahua

Current Diet: solid Gold Weebites

Sample type: Plasma Whole Blood Urine Food Other _____

Test: Taurine Complete Amino Acids Other: _____

Taurine Results (lab use only)

Plasma: _____ Whole Blood: 335 Urine: _____ Food: _____

	Plasma (nMol/ml)		Whole Blood (nMol/ml)	
	Normal Range	No known risk for deficiency	Normal Range	No known risk 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.

Report Details - EON-384905

ICSR:	2065743
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-04-12 14:38:15 EDT
Initial Report Date:	02/24/2019
Parent ICSR:	2063119
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Has been regularly rechecked after PDA occlusion. Progressive reduction in left ventricular contractile function noted on most recent echo. Eating BEG diet. Owner changed to Royal Canin Early Cardiac diet and we will recheck in April April cardiology recheck - echo measurements improved overall - eating Royal Canin Cardiac diet, no additional medications prescribed. PDA remains occluded. Patient has purposefully lost weight.
	Date Problem Started:	01/02/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	PDA - occluded 2016; overweight
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	Description:	1/4 cup kibble (divided into 2 meals) 1 tbsp cooked chicken BID Owner switched to Weight Control version of same diet (salmon, lentil, green bean) just a few days before visit	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			

Animal Information:	Name:	B6			
	Type Of Species:	Dog			
	Type Of Breed:	Chihuahua			
	Gender:	Female			
	Reproductive Status:	Neutered			
	Weight:	3.72 Kilogram			
	Age:	9 Years			
	Assessment of Prior Health:	Good			
	Number of Animals Given the Product:	1			
	Number of Animals Reacted:	1			
	Owner Information:	Owner Information provided:	Yes		
		Contact:	Name:	B6	
		Phone:			
		Email:			

		Address:	<div style="border: 1px dashed black; padding: 5px; display: inline-block;"> B6 </div> United States	
Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine		
	Contact:	Name:	Lisa Freeman	
		Phone:	(508) 887-4523	
	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		
Reported to Other Parties:	None			
Additional Documents:	Attachment:	NT-proBNP & Diet Hx 4-5-19.pdf		
	Description:	Medical records		
	Type:	Medical Records		
	Attachment:	Medical record 1 as of 4-12-19.pdf		
	Description:	Medical record to date		
	Type:	Medical Records		

Client:
Patient:

B6

Diet Hx 4/5/19

338315

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 4/5/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: Poor _____ | _____ Excellent
Poor _____ | _____ Excellent

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

Eats about the same amount as usual Eats less than usual Eats more than usual
 Seems to prefer different foods than usual Other _____

3. Over the last few weeks, has your pet (check one)

Lost weight Gained weight Stayed about the same weight Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 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
rice cake - salt free (1/4 case)	treat		1x day	
Solid Gold Mighty Mini - Sweet Potato + Apple recipe	dry	1/4 cup	split 2x 1x daily	prior to 1-2-19
Royal Canin - Early Cardio	dry	1/4 cup	split 2x daily	Jan 19 - present

*Any additional diet information can be listed on the back of this sheet

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? Yes No If yes, please list which ones and give brands and amounts:

	Brand/Concentration	Amount per day
Taurine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Carnitine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Antioxidants <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Multivitamin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Fish oil <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Coenzyme Q10 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	_____	_____
Other (please list): Example: Vitamin C	Nature's Bounty	500 mg 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 (liquid)
- 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): _____

Client:
Patient:

B6

NT-proBNP 4/5/19

B4, B6

Client: **B6**

Client: **B6**
Patient: **B6**
Species: CANINE
Breed: CHIHUAHUA
Gender:
Age: 9Y

Date: 04/05/2019
Requisition #: 338315
Accession #: **B6**
Ordered by: **B6**

B4, B6
TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395
Account: **B6**

CARDIOPET proBNP- CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP -CANINE	B6	0 - 900 pmol/L	HIGH		

Comments

1. Cardiopet, proBNP: **B6**
Abnormal. **B6**
B6

Please note: Complete interpretive comments for all concentrations of **B6** are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

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 10:48:25 AM
Subject: DCM cases 10/9/18 0630
Attachments: Acana Heritage formula dog food (mostly freshwater fish: Lisa Freeman - EON-367839; Acana Singles Limited Ingredient Lamb and Apple 25 pound bag: B6 - EON-367777; Blue Buffalo Wilderness- High Protein Grain Free -Natures Evolutionary Diet- with Chicken Life Source bits- Senior: B6 - EON-367745; Core Wellness Ocean Formula: B6 B6 - EON-367873; Fromm Four Star Salmon a la Vega dog food: B6 - EON-367810; Pro Plan Savory dry - chicken: B6 - EON-367850; Rawz meal free dry food limited recipe wild salmon dry: B6 - EON-367845; Taste of the Wild High Forest dry: B6 - EON-367841; Taste of the Wild Pacific Stream (dry): B6 - EON-367849

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



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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 10/8/2018 5:44:37 PM
Subject: Acana Heritage formula dog food (mostly freshwater fish: Lisa Freeman - EON-367839
Attachments: 2055788-report.pdf; 2055788-attachments.zip

A PFR Report has been received and PFR Event [EON-367839] has been created in the EON System.

A "PDF" report by name "2055788-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 "2055788-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367839

ICSR #: 2055788

EON Title: PFR Event created for Acana Heritage formula dog food (mostly freshwater fish free run poultry and meats (beef pork and lamb) formulas. Also Meadowlands; 2055788

AE Date	10/04/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		
Age	3.6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055788

Product Group: Pet Food

Product Name: Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands

Description: Murmur identified by RDVM 7/17/18. Asymptomatic. DCM diagnosed 10/4/18. Has been eating Acana diet. Owner is happy to talk to FDA and to provide more info. Taurine levels pending. Details on diet and treats below: I can tell you, for starters, that [B6] was put on a Fromm diet from July of 2015 thru about March

of 2016. Since that period, she has been eating only Acana Heritage formula dog food. This contains "0% grain, potato, gluten, meat by-products, and plant protein concentrates" as listed on their label. She has had a variety of flavors from this brand. Primarily, it has been "freshwater fish", "free run poultry", and "meats formula" (beef, pork, and lamb). **B6** has also had multiple bags of Acana "meadowland" which is advertised as poultry, fish, and eggs. I have also discovered that all of her treats have been produced by Acana. One is labeled as macarel and greens, another is poultry and monkfish, and the last is lamb, liver, and tripe. I should be able to get some records from our local pet store as they have a rewards program we are part of and all of our purchases from the last three years are on our account.

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
Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

To view this PFR Event, please click the link below:

B6

To view the 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-367839

ICSR:	2055788
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
Report Submission Date:	2018-10-08 13:38:04 EDT

Reported Problem:	Problem Description:	Murmur identified by RDVM 7/17/18. Asymptomatic. DCM diagnosed 10/4/18. Has been eating Acana diet. Owner is happy to talk to FDA and to provide more info. Taurine levels pending. Details on diet and treats below: I can tell you, for starters, that B6 was put on a Fromm diet from July of 2015 thru about March of 2016. Since that period, she has been eating only Acana Heritage formula dog food. This contains "0% grain, potato, gluten, meat by-products, and plant protein concentrates" as listed on their label. She has had a variety of flavors from this brand. Primarily, it has been "freshwater fish", "free run poultry", and "meats formula" (beef, pork, and lamb). B6 has also had multiple bags of Acana "meadowland" which is advertised as poultry, fish, and eggs. I have also discovered that all of her treats have been produced by Acana. One is labeled as macarel and greens, another is poultry and monkfish, and the last is lamb, liver, and tripe. I should be able to get some records from our local pet store as they have a rewards program we are part of and all of our purchases from the last three years are on our account.
	Date Problem Started:	10/04/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: Owner can provide more details.
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Great Dane
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	42.2 Kilogram
	Age:	3.6 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: B6
		Phone: B6
		Email: B6

		Address:	B6 United States	
Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine		
	Contact:	Name:	Lisa Freeman	
		Phone:	(508) 887-4523	
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:	B6	compiled records.pdf	
	Description:	B6	compiled medical records	
	Type:	Medical Records		

B6

B4, B6

All Medical Records

Client: **B6**

Address: **B6**

Patient: **B6**

Breed: Great Dane

DOB: **B6**

Species: Canine
Sex: Female
(Spayed)

Home Phone: **B6**

Work Phone: **B6**

Cell Phone: **B6**

Referring Information

B6
B6

B6
B6

B6
B6

B6
B6

Client: **B6**

Patient: **B6**

Initial Complaint:

Scanned Record

Initial Complaint:

New **B6** murmur

SOAP Text **B6** 2:50PM - Rush, John

Disposition/Recommendations

Client: B6
Patient: B6

Client: B6
Patient: B6

B6

B4, B6

Client: B6
Veterinarian:
Patient ID: B6
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Great Dane
Sex:	Female (Spayed)
Age:	3.6 Years Old

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units
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3/21

B6

B6

Printed Monday, October 08, 2018

Client: B6

Patient: B6

rDVM: B6 hx 5/21/15-7/17/18

07/17/2018 05:44

B6

B6 ANIMAL HOSPIT

PAGE 02/05

B6

MEDICAL RECORD

OWNER	B6				
PET'S NAME		SPECIES	Y9	AGE	B6
				SEX	F
DATE	WEIGHT	PHYSICAL EXAMINATION			

B6

Client: B6

Patient: B6

rDVM: B6 hx 5/21/15-7/17/18

07/17/2018 05:44

B6

B6

PAGE 03/06

B6

MEDICAL RECORD

B6

Client: B6

Patient: B6

rDVM: B6 hx 5/21/15-7/17/18

07/17/2018 05:44 B6

B6

PAGE 05/06

Client: B6

Patient Name: B6

Species: Canine

Breed: Great Dane

Gender: Female/Spayed

Weight:

Age: 3 Years

Doctor: B6

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
SNAP Pro (July 17, 2018 3:02 PM)					
AP_spp	B6				
EC-EE					
HW					
Lyme					

B6

Printed: July 17, 2018 3:02 PM

Page 1 of 1

B4, B6

Client: B6

Patient: B6

rDVM: B6 hx 5/21/15-7/17/18

07/17/2018 05:44 B6

B6

PAGE 05/05

Client: B6

Patient Name: B6

Species: Canine

Breed: Great Dane

Gender: Female Spayed

Weight:

Age: 2 Years

Doctor: B6

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
------	---------	--------------------	-----	--------	------

SNAP Pro (June 21, 2017 3:31 PM)

AP_spp
EC-EE
HW
Lyme

B6

5/31/18
9:53 AM

B6

Printed: June 21, 2017 3:31 PM

Page 1 of 1

B4, B6

Client: B6
Patient: B6

B4, B6 10/4/18

B4, B6

Client: B6 Patient: B6

Client: B6
Patient: B6
Species: CANINE
Breed: GREAT_DANE
Gender: FEMALE SPAYED
Age: 3Y

Date: 10/04/2018
Requisition #: B6
Accession #: B6
Ordered by: RUSH, JOHN

B4, B6
B6
Account: B6

B4, B6 CANINE

Test	Result	Reference Range	Low	Normal	High
B4, B6 -CANINE	B6	0 - 900 pmol/L	HIGH		

Comments:

1. B4, B6 1,180 pmol/L
Abnormal B6

B6

Please note: Complete interpretive comments for all concentrations of B4, B6 B4, B6 are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Client: B6
Patient: B6

Vitals Results

B6	:50:15 PM	Weight (kg)	42.2000
	:33:56 PM	Sedation	5.6mg midazolam and 8.6mg butorphanol IV in cardio - k. antoon

Patient History

B6	03:46 PM	Appointment	B6
	04:46 PM	Appointment	
	02:28 PM	UserForm	
	02:33 PM	UserForm	
	02:49 PM	Purchase	
	02:49 PM	Purchase	
	02:50 PM	Vitals	
	02:50 PM	Treatment	
	02:59 PM	UserForm	
	03:33 PM	Vitals	
	03:34 PM	Purchase	
	04:08 PM	Purchase	
	04:08 PM	Purchase	
	04:10 PM	Prescription	
	04:10 PM	Purchase	
04:11 PM	Purchase		
04:13 PM	Purchase		

B6

B6

B6

B6 Female (Spayed)

Canine: Great Dane Black

Patient ID: B6

STANDARD CONSENT FORM

B6

B6

Owner's name:

Date: 10/4/2018

Owner's address:

B6

10/4/18
Date

**If the individual admitting the animal is someone other than the legal owner,
please complete the portion below:**

B6

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

B6

B4, B6

Discharge Instructions

Patient

Name: B6

Species: Canine

Black Female (Spayed) Great Dane

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: B6

Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B4, B6

B4, B6

Cardiology Technician:

B4, B6

Student: B6 V19

Admit Date: B6 2:27:50 PM

Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with mitral regurgitation

Clinical Findings:

B6

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.

In general, most dogs 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 you notice fast or labored breathing then a chest x-ray should be performed.

We 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.

Diet Suggestions:

Today we discussed the fact that there seem to be a relationship between grain free diet, diets with exotic protein sources, and DCM. We recommend switching from a grain free diet. At this moment we are unsure of the cause of the connection, some studies have indicated low taurine levels in the food. If taurine is the cause, there is potential for some reversal of her heart disease. We have checked her taurine levels today, and results are pending. If results are low, supplementation long term may be required.

Some Diet Change Recommendations

Canned Options

Hills Science Diet Adult Beef & Barely Entree

Hills Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrots & Spinach Stew

Dry Options

Royal Canin Early Cardiac

Purina Pro Plan Adult Weight Management

A sheet that has suggestions for low sodium, heart healthy, treats and diets can also be found on the HeartSmart web site

B6

Here is a link to a blog by our nutritionist with more information about the association between diet and DCM on Petfoodology.

"A broken heart risk of heart disease in boutique or grain free diets and exotic ingredients"

<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>

If it is possible for you to bring a sample of her food to us for analyzing and reporting to the FDA.

Exercise Recommendations:

B6 can continue with her normal activity level, we recommend that she not exercise to the point of exhaustion.

Recommended Medications:

Finobendan 10mg Tablet - Give 1 tablet by mouth every 12 hours.

Finobendan is a drug that increases the vigor of contraction of the heart. Side effects are uncommon but can include excitability or intestinal upset.

NEXT DOSE DUE: Tonight

Taurine 1000mg by mouth every 12 hours. You can purchase this at your local pharmacy or GNC. We recommend using *Twinklabs, Swanson, NOW or GNC brands of taurine for quality control reasons*

Recheck Visits: B6

B6

Thank you for entrusting us with [B6] care. Please contact our Cardiology liaison at [B6] or email us at [B6] for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

[B6]

Prescription Refill Disclaimer:

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 [B6] 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 [B6]

Case: [B6]

Owner: [B6]

Discharge Instructions

B6

B6

Patient ID: B6

B6 Canine

3.59 Years Old Female (Spayed) Great Dane
Black

Cardiology Appointment Report

Date: B6

Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC (primary)

B6

Cardiology Resident:

B6

B6

Cardiology Technician:

B6

Student: B6 V19

Presenting Complaint: Murmur II/VI

First heard: B6, zero change in behavior, has always been happy and healthy. No other concerns.

Concurrent Diseases: No other diseases

General Medical History:

Other wise normal, UTD on HWP (heartgard) and vaccines.

Diet and Supplements:

Acana, Fromm, dry food, Kongs with peanut butter, carrots
no supplements

Cardiovascular History:

Prior CHF diagnosis? N

Prior heart murmur? Y

Prior ATE? N

Prior arrhythmia? N

Monitoring respiratory rate and effort at home? N

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:

No medications

Cardiac Physical Examination:

General PE: Nervous/excitable

MM Color and CRT: pigmented, moist

BCS (1-9): 5/9

BW (kg): 42.2

Heart rate: 150

Respiratory rate: panting

Temp (if possible): Not taken

Muscle condition:

- Normal
- Moderate cachexia
- Mild muscle loss
- Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

Murmur location/description: Left apical II/VI has a musical component - also heard III/VI on right side
low frequency rumbling murmur

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
- Fair
- Pulse deficits
- Good
- Pulsus paradoxus
- Strong
- Other:

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 airway stridor
- Normal BV sounds

Abdominal exam:

- Normal
- Mild ascites
- Hepatomegaly
- Marked ascites

Abdominal distension

Problems:

Hx: Murmur II/VI (rDVM)

Differential Diagnoses:

Valvular disease (dysplasia vs degenerative) vs pulmonic stenosis vs aortic stenosis vs DCM

Diagnostic plan:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Echocardiogram | <input type="checkbox"/> Dialysis profile |
| <input checked="" type="checkbox"/> Chemistry profile | <input type="checkbox"/> Thoracic radiographs |
| <input type="checkbox"/> ECG | <input type="checkbox"/> NT-proBNP |
| <input type="checkbox"/> Renal profile | <input type="checkbox"/> Troponin I |
| <input type="checkbox"/> Blood pressure | <input type="checkbox"/> Other tests: |

Echocardiogram Findings:

General/2-D findings:

Patient given 5.6mg midazolam and 8.6mg butorphanol IV for echocardiogram. Recommend either gabapentin or trazodone for future visits.

****Echocardiogram performed on the table with butorphanol and midazolam****

Thin LV walls with reduced contractile function (better side to side motion). The LV cavity is moderately to markedly dilated. The LA is moderately to markedly enlarged. The MV is slightly thickened with no obvious prolapse or ruptured chordae. The PA is smaller than the aorta. No obvious subaortic ridge visualize. No ASD, VSD, or PDA. The RH is subjectively enlarged as well. No pleural or pericardial effusion. No B-lines visualized.

Doppler findings:

1-2+ MR although it was hard to visualize due to the constant panting and tachycardia.

No TR

ECG findings:

Sinus tachycardia during the echocardiogram. No evidence of VPCs or APCs.

Assessment and recommendations:

Echocardiogram findings are consistent with dilated cardiomyopathy. The patient was very tachycardiac during the echocardiogram. Because today's findings are consistent with DCM and the patient is on a grain-free diet, the DCM protocol is recommended. Blood was pulled and submitted for a taurine level today. Discussed with the owner that the patient should not be on a grain free diet anymore and taurine supplementation should be started while we are waiting for the result of the test. Pimobendan 10 mg PO BID should be started. Recheck echocardiogram in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease such as increased RR/RE, cough, exercise intolerance, or syncope.

Final Diagnosis:

- Occult DCM r/o genetic vs. diet related.
- Murmur due to secondary mitral regurgitation

Heart Failure Classification Score:

ISACHC Classification:

- | | |
|--|-------------------------------|
| <input type="checkbox"/> Ia | <input type="checkbox"/> IIIa |
| <input checked="" type="checkbox"/> Ib | <input type="checkbox"/> IIIb |

II

ACVIM Classification:

- A
- B1
- B2

- C
- D

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

%FS

Ao Diam

LA Diam

LA/Ao

Max LA

EPSS

M-Mode Normalized

IVSdN

LVIDdN

LVPWdN

IVSsN

LVIDsN

LVPWsN

Ao Diam N

LA Diam N

2D

IVSd

LVIDd

LVPWd

EDV(Teich)

IVSs

LVIDs

LVPWs

ESV(Teich)

EF(Teich)

%FS

SV(Teich)

LVld LAX

LVAd LAX

LVEDV A-L LAX

LVEDV MOD LAX

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{0.29 - 0.52} !

{1.35 - 1.73} !

{0.33 - 0.53}

{0.43 - 0.71}

{0.79 - 1.14} !

{0.53 - 0.78}

{0.68 - 0.89}

{0.64 - 0.90} !

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LVLs LAX
LVA_s LAX
LVESV A-L LAX
LVESV MOD LAX
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX
LV Diameter
LV Length

Doppler

MR Vmax
MR maxPG
AV Vmax
AV maxPG

B6

cm
cm
ml
ml
BPM
%
%
ml
ml
l/min
l/min
cm
cm

m/s
mmHg
m/s
mmHg

B6

B4, B6

B6

B6

B6 Female (Spayed)
Canine Great Dane Black

B6

10/5/2018

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at B6

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: [B6] HQ Pet Food Report Notification; [B6]

Sent: 10/7/2018 1:24:20 AM

Subject: Acana Singles Limited Ingredient Lamb and Apple 25 pound bag; [B6]
- EON-367777

Attachments: 2055744-report.pdf

A PFR Report has been received and PFR Event [EON-367777] has been created in the EON System.

A "PDF" report by name "2055744-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-367777

ICSR #: 2055744

EON Title: PFR Event created for Acana Singles Limited Ingredient Lamb and Apple 25 pound bag; 2055744

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Spaniel - Cocker American		
Age	5 Years		
District Involved	PFR-[B6] DO		

Product information

Individual Case Safety Report Number: 2055744

Product Group: Pet Food

Product Name: Acana Singles Limited Ingredient Lamb and Apple 25 pound bag

Description: He was fine up until approximately [B6] when he developed a cough. He was taken to the emergency vet and was diagnosed with Kennel Cough, which was a misdiagnosis. On [B6] he was seen by his vet [B6] in [B6] where they performed Chest X-ray and bloodwork and it was determined that [B6] heart was enlarged and he was in Congestive Heart Failure. He was given a shot of Lasix, and placed on 3 medications and I was told he should be seen by a cardiologist. On [B6] his symptoms worsened and he was take. Back to the Emergency Vet Hospital and was kept over night. On [B6] he saw [B4, B6] Vet Cardiologist, underwent a history and an echocardiogram where he was Diagnosed with Dilated Cardiomyopathy

and the vet reported that he believed it was related to the grain free diet. He kept him in the hospital in **B4, B6** overnight for treatment and oxygen. He encouraged me to buy Taurine and L-Carnitine and bring up the next day. The next morning, **B6** **B6** was worse and they recommended transferring to the ICU at **B4, B6**. **B4, B6** On **B6** despite all efforts, **B6** was euthanized as he was not responding to treatments.

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Died Euthanized

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Singles Limited Ingredient Lamb and Apple 25 pound bag		

Sender 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:

B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 10/6/2018 5:20:24 AM
Subject: Blue Buffalo Wilderness- High Protein Grain Free -Natures Evolutionary Diet- with Chicken Life Source bits- Senior; [B6] - EON-367745
Attachments: 2055738-report.pdf

A PFR Report has been received and PFR Event [EON-367745] has been created in the EON System.

A "PDF" report by name "2055738-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-367745

ICSR #: 2055738

EON Title: PFR Event created for Blue Buffalo Wilderness- High Protein Grain Free ?Natures Evolutionary Diet- with Chicken Life Source bits- Senior; 2055738

AE Date	[B6]	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Dachshund - Miniature		
Age	13 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2055738

Product Group: Pet Food

Product Name: Blue Buffalo Wilderness- High Protein Grain Free ?Natures Evolutionary Diet- with Chicken Life Source bits- Senior

Description: [B6] has developed canine dilated cardiomyopathy suddenly. His health has been excellent even though he's 13. Up u til now, he had lots of life and energy left in him. Literally in a matter of 48 hours he developed CDM. I have fed him the same kibble brand, Blue Buffalo, the majority of his life. I read an article on the FDA site that you're investigating possible links between CDM and CDM. Please let me know if there's any way I can help.

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: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Blue Buffalo Wilderness- High Protein Grain Free ?Natures Evolutionary Diet- with Chicken Life Source bits- Senior		

Sender 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:

B6

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Report Details - EON-367745

ICSR:	2055738
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
Report Submission Date:	2018-10-06 01:17:04 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 has developed canine dilated cardiomyopathy suddenly. His health has been excellent even though hes 13. Up u til now, he had lots of life and energy left in him. Literally in a matter of 48 hours he developed CDM. I have fed him the same kibble brand, Blue Buffalo, the majority of his life. I read an article on the FDA site that youre investigating possible links between CDM and CDM. Please let me know if theres any way I can help.
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Blue Buffalo Wilderness- High Protein Grain Free Natures Evolutionary Diet- with Chicken Life Source bits- Senior		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	24 Pound		
	Purchase Date:	08/20/2018		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Plastic container		
	Product Use Information:	Description:	Daily food	
		First Exposure Date:	08/20/2018	
		Last Exposure Date:	B6	
		Time Interval between Product Use and Adverse Event:	9 Years	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
Adverse Event Abate After Product Stop:		Not Applicable		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Possibly related		
Other Foods or Products Given to the Animal During This Time Period:	Yes			

	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: Amazon
		Address: United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Dachshund - Miniature
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	14.2 Pound
	Age:	13 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	Practice Name: B6
		Contact: Name: B6
		Phone: B6
		Address: B6 United States
		Type of Veterinarian: Primary/regular veterinarian
		Date First Seen: B6
		Permission to Release Records to FDA: Yes
Sender Information:	Name:	B6
	Address:	B6 United States
	Contact:	Phone: B6
		Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	None
Additional Documents:		

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 10/9/2018 1:12:19 AM
Subject: Core Wellness Ocean Formula: [B6] EON-367873
Attachments: 2055809-report.pdf

A PFR Report has been received and PFR Event [EON-367873] has been created in the EON System.

A "PDF" report by name "2055809-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-367873

ICSR #: 2055809

EON Title: PFR Event created for Core Wellness Ocean Formula; 2055809

AE Date	12/26/2017	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Pug		
Age	11 Years		
District Involved	PFR-Foreign Firms DO		

Product information

Individual Case Safety Report Number: 2055809

Product Group: Pet Food

Product Name: Core Wellness Ocean Formula

Description: I was [B6] owner from 6 mos until her death at age 11 on [B6] I fed her grain free food her entire life (Core Wellness - Ocean formula). Starting around October 2017 I noticed that she would pant a bit more than normal while she was on a walk. I raised it with the vet and we decided to keep an eye on it. On Dec 26, 2017, I noticed her breathing was a bit laboured even while resting. She was taken to my regular vet the next day. She was xrayed, diagnosed with pneumonia and treated with antibiotics. When two different types of ab did not work, she was referred to a specialist clinic (on [B6]) where xrays were repeated, interpreted by another radiologist and heart disease was suspected. I was intending to take her to a cardiologist for an echo on [B6] but she passed away before I was able to take her. Although [B6] did not receive an official diagnosis, by a

cardiologist, of cardiomyopathy, I thought it worth bringing to your attention and I hope it is of some relevance to the FDA's research. **B6** heart was certainly enlarged. She was otherwise in good health. Thank you.

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: Died Naturally

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Core Wellness Ocean Formula		

Sender information

B6

CAN

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-367873

ICSR:	2055809
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
Report Submission Date:	2018-10-08 21:06:09 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I was [B6] owner from 6 mos until her death at age 11 on [B6] I fed her grain free food her entire life (Core Wellness - Ocean formula). Starting around October 2017 I noticed that she would pant a bit more than normal while she was on a walk. I raised it with the vet and we decided to keep an eye on it. On Dec 26, 2017, I noticed her breathing was a bit laboured even while resting. She was taken to my regular vet the next day. She was xrayed, diagnosed with pneumonia and treated with antibiotics. When two different types of ab did not work, she was referred to a specialist clinic (on [B6]) where xrays were repeated, interpreted by another radiologist and heart disease was suspected. I was intending to take her to a cardiologist for an echo on [B6] but she passed away before I was able to take her. Although [B6] did not receive an official diagnosis, by a cardiologist, of cardiomyopathy, I thought it worth bringing to your attention and I hope it is of some relevance to the FDA's research. [B6] heart was certainly enlarged. She was otherwise in good health. Thank you.	
	Date Problem Started:	12/26/2017	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Naturally	
	Date of Death:	[B6]	

Product Information:	Product Name:	Core Wellness Ocean Formula		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Product Use Information:	Description:	Fed to dog for 11+ years	
		Product Use Stopped After the Onset of the Adverse Event:	No	
		Perceived Relatedness to Adverse Event:	Possibly related	
	Manufacturer /Distributor Information:			
Purchase Location Information:	Address:	Canada		

Animal Information:	Name:	[B6]
	Type Of Species:	Dog
	Type Of Breed:	Pug
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	19 Pound
	Age:	11 Years
Assessment of Prior	Good	

	Health:	
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6 Canada
	Contact:	
	Phone:	B6
	Email:	B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Reported to Other Parties:	Other	

Additional Documents:

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 10/8/2018 3:48:32 AM
Subject: Fromm Four Star Salmon a la Veg dog food; [B6] - EON-367810
Attachments: 2055752-report.pdf

A PFR Report has been received and PFR Event [EON-367810] has been created in the EON System.

A "PDF" report by name "2055752-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-367810

ICSR #: 2055752

EON Title: PFR Event created for Fromm Four Star Salmon a la Veg dog food; 2055752

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Retriever - Golden		
Age	7 Years		
District Involved	PFR; [B6] DO		

Product information

Individual Case Safety Report Number: 2055752

Product Group: Pet Food

Product Name: Fromm Four Star Salmon a la Veg dog food

Description: After fetching tennis balls at the park, [B6] had a big drink of water at home and then collapsed. He had difficulty standing and his back legs seemed to not support him. His breathing was labored and we took him to the emergency vet. He was found to have fluid around his heart. The vet drained it but the blood continued to immediately fill again and his breathing was very labored. The recommendation was to euthanize him at that time, about 4 hours from the time that he initially collapsed. We have read articles about Dilated Cardiomyopathy (DCM) in dogs related to diet. We don't know that [B6] had DCM but wanted to report his sudden death. At his annual vet checkup in April 2018, he was found to be an extremely fit and healthy dog with no known health issues or concerns. We were feeding him Fromm 4 Star Salmon a la Veg food two times per day

since he was about a year old.

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: Died Euthanized

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Fromm Four Star Salmon a la Veg dog food		

Sender 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:

B6

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Report Details - EON-367810

ICSR:	2055752
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
Report Submission Date:	2018-10-07 23:42:17 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	After fetching tennis balls at the park, [B6] had a big drink of water at home and then collapsed. He had difficulty standing and his back legs seemed to not support him. His breathing was labored and we took him to the emergency vet. He was found to have fluid around his heart. The vet drained it but the blood continued to immediately fill again and his breathing was very labored. The recommendation was to euthanize him at that time, about 4 hours from the time that he initially collapsed. We have read articles about Dilated Cardiomyopathy (DCM) in dogs related to diet. We don't know that [B6] had DCM but wanted to report his sudden death. At his annual vet checkup in April 2018, he was found to be an extremely fit and healthy dog with no known health issues or concerns. We were feeding him Fromm 4 Star Salmon a la Veg food two times per day since he was about a year old.
	Date Problem Started:	[B6]
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Fromm Four Star Salmon a la Veg dog food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	06/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Unopened - stored in package in garage Open-stored in plastic bin in garage (first couple of years not airtight and last few airtight container)		
	Product Use Information:	Description:	Fed 1 1/2 cups of food two times per day	
		Last Exposure Date:	[B6]	
		Product Use Stopped After the Onset of the Adverse Event:	No	
		Perceived Relatedness to Adverse Event:	Possibly related	
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
Manufacturer /Distributor Information:				
Purchase Location				

	Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	57 Pound	
	Age:	7 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
Contact:		Name:	B6
		Phone:	B6
Address:		B6	
		United States	
Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	None		
Additional Documents:			

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: [B6] HQ Pet Food Report Notification; [B6]

Sent: 10/8/2018 7:28:33 PM

Subject: Pro Plan Savory dry - chicken: Lisa Freeman - EON-367850

Attachments: 2055797-report.pdf; 2055797-attachments.zip

A PFR Report has been received and PFR Event [EON-367850] has been created in the EON System.

A "PDF" report by name "2055797-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 "2055797-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367850

ICSR #: 2055797

EON Title: PFR Event created for Pro Plan Savory dry - chicken beef or lamb (1 cup TID); 2055797

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	7 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055797

Product Group: Pet Food

Product Name: Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)

Description: Presented to ER on [B6] for CHF and DCM (had rads at RDVM for cough). Full echo on [B6] Unlikely to be associated with diet but reporting because he is sometimes fed the lamb formula Pro Plan. 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: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
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:

B6

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Report Details - EON-367850

ICSR: 2055797
 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
 Report Submission Date: 2018-10-08 15:17:24 EDT

Reported Problem:
Problem Description: Presented to ER on **B6** for CHF and DCM (had rads at RDVM for cough). Full echo on **B6** Unlikely to be associated with diet but reporting because he is sometimes fed the lamb formula Pro Plan. Taurine WNL
Date Problem Started: **B6**
Concurrent Medical Problem: Yes
Pre Existing Conditions: Atopy (on Atopica)
Outcome to Date: Stable

Product Information:
Product Name: Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)
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: Retriever - Labrador
Gender: Male
Reproductive Status: Neutered
Weight: 37.7 Kilogram
Age: 7 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** **B6**
Phone: **B6**
Email: **B6**
Address: **B6**
 United States
Healthcare Professional Information: **Practice Name:** Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman
Phone: (508) 887-4523

			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:	compiled medical records	B6 .pdf	
	Description:	Compiled medical records		
	Type:	Medical Records		

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6]; HQ Pet Food Report Notification; [B6]
Sent: 10/8/2018 6:44:41 PM
Subject: Rawz meal free dry food limited recipe wild salmon dry: Lisa Freeman - EON-367845
Attachments: 2055793-report.pdf; 2055793-attachments.zip

A PFR Report has been received and PFR Event [EON-367845] has been created in the EON System.

A "PDF" report by name "2055793-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 "2055793-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367845

ICSR #: 2055793

EON Title: PFR Event created for Rawz meal free dry food limited recipe wild salmon dry; 2055793

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	10 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055793

Product Group: Pet Food

Product Name: Rawz meal free dry food limited recipe wild salmon dry

Description: DCM and atrial fibrillation diagnosed 10/5/18

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
Rawz meal free dry food limited recipe wild salmon dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
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:

B6

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Report Details - EON-367845

ICSR: 2055793
 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
 Report Submission Date: 2018-10-08 14:34:26 EDT

Reported Problem:
 Problem Description: DCM and atrial fibrillation diagnosed 10/5/18
 Date Problem Started: B6
 Concurrent Medical Problem: Yes
 Pre Existing Conditions: Hypothyroidism, skin issues
 Outcome to Date: Stable

Product Information:
 Product Name: Rawz meal free dry food limited recipe wild salmon dry
 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: Mixed (Dog)
 Gender: Male
 Reproductive Status: Neutered
 Weight: 33.2 Kilogram
 Age: 10 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: B6
 Phone: B6
 Email: B6
 Address: B6
 United States
 Healthcare Professional Information: Practice Name: Tufts Cummings School of Veterinary Medicine
 Contact: Name: Lisa Freeman
 Phone: (508) 887-4523
 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:	B6 compiled records; B6 pdf		
	Description:	Compiled records		
	Type:	Medical Records		

B6

B4, B6

All Medical Records

Client: **B6**

Address: **B6**

Patient: **B6**

Breed: Bulldog Cross

DOB: **B6**

Species: Canine

Sex: Male
(Neutered)

Home Phone: **B6**

Work Phone: () -

Cell Phone: **B6**

Referring Information

B6

B6

B6

B6

Client: **B6**

Patient: **B6**

Initial Complaint:

Emergency

SOAP Text **B6** 6:17PM - **B4, B6**

NEW VISIT (ER) - **B6**

Doctor: **B4, B6** DVM

Student: **B4, B6** V'19

Presenting complaint: vomiting, anorexia

Referral visit? Yes

Diagnostics completed prior to visit (approximately 2 PM on **B6**)

-CBC: HCT 36.9%, MCV 61.2 fL, LYMPH 0.89 k/uL, EOS 0.01 k/uL

-Chemistry: ALT 256 U/L

-Abdominal radiographs + 1 VD thoracic view available on ER e-mail

HISTORY

Signalment: 10 yr. M/C Bulldog mix

Current history: Owner states that for the past 3-4 weeks, **B6** has been eating random things out of the garbage (children's crayons, cat food cans) but only become anorexic 3 days ago. **B6** vomited 3 times yesterday and 1 time this morning, consisting of bile and has not been drinking. Owner does not notice any change in behavior or lethargy (owner says patient is typically quiet and sleeps a lot). rDVM performed abdominal radiographs and CBC/chem and referred patient here for further evaluation.

Prior medical history: Ear infections and seasonal atopy managed with shampoos and limited ingredient diet. Adopted from rescue organization when **B6** was approximately 9 months old. Patient is hypothyroid; well controlled.

Client: B6

Patient: B6

Current medications: levothyroxine 0.5 mg PO q 12 hrs

Diet: Raw Limited Ingredient Salmon

EXAM

B6

ASSESSMENT

A1: Arrhythmia - suspect atrial fibrillation secondary to enlarged left atrium

A2: Vomiting - r/o gastritis vs pancreatitis vs neoplasia vs obstruction vs other

PLAN

B6

Client:

Patient:

Resuscitation code (if admitting to ICU): Red

SOAP approved (DVM to sign): DVM

SOAP Text 6:11AM -

B6

HISTORY

Signalment: 10 yr. M/C Bulldog mix

Current history: Owner states that for the past 3-4 weeks, has been eating random things out of the garbage (children's crayons, cat food cans) but only become anorexic 3 days ago. vomited 3 times yesterday and 1 time this morning, consisting of bile and has not been drinking. Owner does not notice any change in behavior or lethargy (owner says patient is typically quiet and sleeps a lot). rDVM performed abdominal radiographs and CBC/chem and referred patient here for further evaluation.

Prior medical history: Ear infections and seasonal atopy managed with shampoos and limited ingredient diet. Adopted from rescue organization when was approximately 9 months old. Patient is hypothyroid; well controlled.

Current medications: levothyroxine 0.5 mg PO q 12 hrs

Diet: Raw Limited Ingredient Salmon - Rawz for about 1.5-2 years, but been on grain free for a long time

Might have tried hydrolyzed food in the past but unsure

EXAM

B6

ASSESSMENT

A1: Arrhythmia - suspect atrial fibrillation secondary to enlarged left atrium

A2: Vomiting - r/o gastritis vs pancreatitis vs neoplasia vs obstruction vs other

Client: **B6**

Patient: **B6**

PLAN

B6

Disposition/Recommendations

Client: B6
Patient: B6

Client: B6

Patient: B6

B4, B6

B4, B6

Client: B6

Veterinarian:

Patient ID: B6

Visit ID:

Patient: B6

Species: Canine

Breed: Bulldog Cross

Sex: Male (Neutered)

Age: 10.02 Years Old

Lab Results Report

Nova Full Panel-ICU

B6 8:52:25 PM

Accession ID: B6

Test	Results	Reference Range	Units
SO2%		94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEeef		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

B6

6/52

B6

B6



Printed Monday, October 08, 2018

Client: B6

Patient: B6

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU **B6** 8:54:03 PM **Accession ID: B6**

Test	Results	Reference Range	Units
HW ANTIGEN-CANINE	B6	0 - 0	
LYME C6		0 - 0	
A.PHAGO/PLATYS		0 - 0	
E CANIS/EWINGI		0 - 0	

Nova Full Panel-ICU **B6** 8:54:13 PM **Accession ID: B6**

Test	Results	Reference Range	Units
WBC (ADVIA)	B6	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)		64.5 - 77.5	fL
MCH(ADVIA)		21.3 - 25.9	pg
MCHC(ADVIA)		31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
PLT(ADVIA)		173 - 486	K/uL
MPV (ADVIA)		8.29 - 13.2	fL
PLTCRT		0.129 - 0.403	%
RETIC(ADVIA)		0.2 - 1.6	%
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL
COMMENTS (HEMATOLOGY)		0 - 0	

Nova Full Panel-ICU **B6** 8:54:27 PM **Accession ID: B6**

Test	Results	Reference Range	Units
GLUCOSE	B6	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



Client: **B6**
 Patient: **B6**

A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	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
6068 Result(s) verified			
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

B6

Nova Full Panel-ICU **B6** 8:54:11 PM Accession ID: **B6**

Test	Results	Reference Range	Units
SEGS%		43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
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
WBC MORPHOLOGY		0 - 0	
Occasional reactive lymphocytes			
ACANTHOCYTES		0 - 0	
KERATOCYTES/BLISTER CELLS		0 - 0	
POIKILOCYTOSIS		0 - 0	
SCHISTOCYTES		0 - 0	
SPHEROCYTES		0 - 0	

B6

Nova Full Panel-ICU **B6** 8:54:00 PM Accession ID: **B6**

Test	Results	Reference Range	Units
CBC Review		0 - 0	

See comment.
 Poikilocytosis can be associated with liver disease and vascular pathology among other causes; it is a nonspecific



Client: B6

Patient: B6

finding: B4, B6 DVM PhD DACVP

Nova Full Panel-ICU B6 3:54:00 PM Accession ID: B6

Test	Results	Reference Range	Units
T4/TOSOH	B6	1 - 4.1	ug/dl

Nova Full Panel-ICU B6 8:58:31 PM Accession ID: B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl



9/52

B6

B6

Printed Monday, October 08, 2018

Client: B6

Patient: B6

RDVM B6 medical records 5/31/18-10/4/18

ID: B6
Owner Name: B6

Address: B6

Cellular Home: B6

Email Address: B6

Patient ID: B6
Name: B6

Species: CANINE
Breed: BULLDOG/MIX
Color: WHITE/YELLOW
Birth Date: B6

Microchip:
Sex: Male *Mentel*

Client Education

Puppy/Kitten Deference	Lyme Rabies	Senior Wellness Dental Disease
Basic Training Aggression	Flea & Tick Obesity	FUS
Heartworm Leptospirosis	Osteoarthritis	Elim. Disorder

Immunization Record

YEAR	B6								
Felv/Fiv Test									
FVRCP									
FELV									
<i>3-5-14</i> Rabies									
<i>3-5-14</i> DA2PP2									
Lepto									
Lyme									
Influenza									
Bordetella									
HW Test									
Lyme Test									
E. Canis Test									
A. Phago Test									
Focal									

u/s 6/18/18

Superficial veins cephalic better

Client: **B6**

Patient: **B6**

RDVM **B6** medical records **B6**

PAGE:

PATIENT
NAME

OWNER'S
NAME

DATE			PROB. NO.	SOAP
MO.	DAY	YR.		

MEDICAL RECORD

B6

Client: B6

Patient: B6

RDVM B6 medical record B6

PAGE:

PATIENT NAME					OWNER'S NAME				
MO.	DATE		PROB.	SOAP	MEDICAL RECORD				
	DAY	YR.	NO.						

B6

Client: **B6**

Patient: **B6**

RDVM **B6** medical records **B6**

PATIENT NAME					OWNER'S NAME	
MO.	DATE		PROB. NO.	SOAP	MEDICAL RECORD	
	DAY	YR.				
B6						

Client: **B6**

Patient: **B6**

RDVM **B6** **medical records** **B6**

PAGE:

PATIENT NAME					OWNER'S NAME	
MO.	DATE DAY	YR.	PROB. NO.	SOAP	MEDICAL RECORD	

B6

Client: B6

Patient: B6

RDVM B6 medical records B6

PAGE:

PATIENT NAME					OWNER'S NAME				
MO.	DATE		PROB. NO.	SOAP	MEDICAL RECORD				
	DAY	YR.							

B6

Client: **B6**

Patient: **B6**

RDVM **B6** medical records **B6**

PATIENT NAME					PAGE:		OWNER'S NAME	
MO.	DATE		PROB. NO.	SOAP	MEDICAL RECORD			
DAY	YR.							

B6

Client: B6

Patient: B6

RDVM

B6

medical records

B6

B6

Client: B6

Patient: B6

RDVM

B6

medical records

B6

B6

Client: **B6**

Patient: **B6**

RDVM **B6** **medical record** **B6**

B6

Client: B6
Patient: B6

RDVM: B6 medical records 5/31/18-10/4/18

Client: B6 Gender: Male/Castrated
B6 Weight: 70.40 lbs
Patient Name: B6 Age: 10 Years
Species: Canine Doctor: B6 DVM
Breed:

Test	Results	Reference Interval	LOW	NORMAL	HIGH
ProCytel D	B6	24 PM)			5/31/18
RBC		5.65 - 8.87			
HCT		37.3 - 61.7	LOW		
HGB		13.1 - 20.5			
MCV		63.6 - 73.9	LOW		
MCH		21.2 - 25.9			
MCHC		32.0 - 37.9			
RDW		13.6 - 21.7			
%RETIC					
RETIC		10.0 - 110.0			
RETIC-HGB		22.3 - 29.6			
WBC		5.05 - 16.76			
%NEU					
%LYM					
%MONO					
%EOS					
%BASO					
NEU		2.85 - 11.64			
LYM		1.05 - 5.10	LOW		
MONO		0.16 - 1.12			
EOS		0.38 - 1.35	LOW		
BASO		0.00 - 0.10			
PLT		148 - 484			
MPV		8.7 - 13.2			
PDW		9.1 - 19.4			
PCT		0.14 - 0.46			

RBC Run WBC Run

B6

B6

B6

Printed: B6 1:32 PM

Page 1 of 2

B6

Client: B6

Patient: B6

RDVM B6 medical records B6

Client: B6 Gender: Male/Castrated
B6 Weight: 70.40 lbs
Patient Name: B6 Age: 10 Years
Species: Canine Doctor: B6 DVM
Breed:

Test	Results	Reference Interval	LOW	NORMAL	HIGH
Catalyst One		8:13:32 PM)			5/31/18
GLU		70 - 143			
CREA		0.5 - 1.8			
BUN		7 - 27			
BUN/CREA					
PHOS		2.5 - 6.8			
CA		7.9 - 12.0			
TP		5.2 - 8.2			
ALB		2.2 - 3.9			
GLOB		2.5 - 4.5			
ALB/GLOB	B6				
ALT		10 - 135	HIGH		
ALKP		23 - 212			
GGT		0 - 11			
TBIL		0.0 - 0.9			
CHOL		110 - 320			
AMY		500 - 1500	LOW		
LIPA		200 - 1800			
Na		144 - 160			
K		3.5 - 5.8			
Na/K					
Cl		109 - 122			
Osm Calc					

Printed: B6 12 PM

Page 2 of 2

B4, B6

Client: B6

Patient: B6

RDVM B6 allergy test results 10/5/16

10/05/2018 17:46

B4, B6

B6

PAGE 02/03

B4, B6

B4, B6

B4, B6

Allergy Test Results

B4, B6

Log#: 256495ER

Patient Name: B6

Diets Recommended

- Iams - Skin & Coat Plus Response FP: Potato, herring meal, catfish, animal fat, beet pulp, fish digest (Dry)
- FirstMate - Grain Free Wild Tuna Formula: Tuna, water, potato, kale (Can)
- FirstMate - Grain Free Salmon Formula: Wild boneless/skinless salmon, water, potato, kale (Can)
- Hill's - d/d Canine Salmon Formula: Water, salmon, potato, potato starch, potato protein, soybean oil, fish oil, powdered cellulose (Can)
- Brothers Complete - Bare Bites: Beef liver (Treat)
- Canine Caviar - Turkey: Turkey, water, turkey liver, guar gum (Can); Can be mixed with potato
- Canine Caviar - Duck: Duck, duck liver, sweet potatoes, water, guar gum (Can)
- Hill's - d/d Canine Duck Formula: Water, duck, potato, duck liver, potato starch, soybean oil, powdered cellulose, fish oil (Can)
- Hill's - d/d Canine Venison Formula: Water, venison, potatoes, potato starch, potato protein, soybean oil, powdered cellulose, fish oil (Can)
- Canine Caviar - Venison: Venison, water, venison tripe, venison liver, guar gum (Can); Can be mixed with potato
- Iams - Response KO: Oat flour, kangaroo, canola meal, animal fat, beet pulp, fish oil (Dry)
- Canine Caviar - Beaver: Beaver, water, guar gum (Can)
- Canine Caviar - Buffalo: Buffalo, water, guar gum (Can)



Websites: alphastrip.com • Evionoba cucinoba.com • Iams iams.com • Hill's hills.com • Nitro nitro.com • Royal Canin royalcanin.us • Wellness wellness.com

B4, B6

Allergy Tests You Can Trust!

Client: B6
Patient: B6

RDVM B6 allergy test results 10/5/16

10/05/2018 17:46

B6

B6

PAGE 03/03

B4, B6

B4, B6

B4, B6

Allergy Test Results

B4, B6

Date Received: 9/30/2016 Date Returned: 10/5/2016 Dr.: B4, B6
Clinic: B6 Account No.: B6
Address: B6
City: B6 State/Province: B6 Zip/Postal Code: B6 Country:
Phone: B6 FAX: B6
Log#: 256495ER Patient Name: B6 Breed: Bulldog Mix Age: 7yr M Species: Dog
Owner's First Name: B6 Owner's Last Name: B6

PRIMARY FOODS

Allergen	Class Score	Allergen	Class Score
Egg		Milk	
Salmon		Wheat	
Corn		Rice	
Soybean		Pork	
Beef		Turkey	
Chicken		Lamb	

EXTENDED FOODS

Allergen	Class Score	Allergen	Class Score
Egg	2	Milk	1
Salmon	0	Wheat	0
Corn	0	Rice	3
Soybean	1	Pork	0
Beef	1	Turkey	0
Chicken	2	Lamb	3
Duck	0	Potato	0
Rabbit	0	Venison	0
Yeast	0	Pea	0
Oat	0	Barley	0

MOLD SPECIAL PANEL

Allergen	Class Score	Allergen	Class Score
Penicillium		Cladosporium	
Aspergillus		Mucor	
Alternaria		Helminthosporium	
Fusarium		Stemphylium	
Rhizopus		Aureobasidium	
Phoma		Epicoccum	

Explanation of Results:

Classes 1, 2, 3, 4, 5 and 6 represent levels of IgE antibody specific for the respective allergen. Consider Class 2 level and greater for allergen immunotherapy.

Class 6- Ultra high level
Class 5- Ultra high level
Class 4- Very high level
Class 3- High level
Class 2- Low level
Class 1- Very low level

Class 0- absent or undetectable

B4, B6

**** VERY IMPORTANT ** Please read**

IF REQUESTED
FOODS AND SPECIAL PANELS ON THIS PAGE

Flea hypersensitivity is a multi-component disease. It is not always totally IgE antibody-mediated. Negative in vitro test probably indicates a Type IV Cell-mediated (Delayed-type Hypersensitivity)

VETERINARIAN

Client: B6

Patient: B6

Vitals Results

4:57:35 PM	Heart Rate (/min)
4:57:36 PM	Respiratory Rate
4:57:37 PM	Temperature (F)
4:57:38 PM	Weight (kg)
7:23:44 PM	Heart Rate (/min)
7:23:45 PM	Temperature (F)
7:23:46 PM	Respiratory Rate
9:34:16 PM	Amount eaten
10:12:31 PM	Cardiac rhythm
10:12:32 PM	Heart Rate (/min)
10:12:52 PM	Respiratory Rate
11:52:54 PM	Cardiac rhythm
11:52:55 PM	Heart Rate (/min)
11:53:07 PM	Eliminations
11:53:16 PM	Respiratory Rate
1:00:47 AM	Cardiac rhythm
1:00:48 AM	Heart Rate (/min)
1:37:16 AM	Catheter Assessment
1:38:12 AM	Respiratory Rate
1:50:37 AM	Cardiac rhythm
1:50:38 AM	Heart Rate (/min)
2:49:03 AM	Cardiac rhythm
2:49:04 AM	Heart Rate (/min)
3:35:48 AM	Respiratory Rate
3:36:03 AM	Cardiac rhythm
3:36:04 AM	Heart Rate (/min)
4:44:11 AM	Cardiac rhythm
4:44:12 AM	Heart Rate (/min)
5:37:23 AM	Weight (kg)
5:37:33 AM	Eliminations
5:38:50 AM	Respiratory Rate
5:39:04 AM	Catheter Assessment
5:39:36 AM	Temperature (F)
6:30:19 AM	Cardiac rhythm
6:30:20 AM	Heart Rate (/min)
7:28:56 AM	Respiratory Rate
8:01:55 AM	Cardiac rhythm
8:01:56 AM	Heart Rate (/min)
8:55:50 AM	Cardiac rhythm

B6

B6

Client: **B6**
Patient: **B6**

Vitals Results

8:55:51 AM	Heart Rate (/min)
8:56:45 AM	Catheter Assessment
10:04:36 AM	Cardiac rhythm
10:04:37 AM	Heart Rate (/min)
10:05:26 AM	Respiratory Rate
11:07:25 AM	Cardiac rhythm
11:07:26 AM	Heart Rate (/min)
11:12:49 AM	Respiratory Rate
11:13:11 AM	Eliminations
12:20:08 PM	Blood Pressure (mmHg)
12:28:05 PM	Cardiac rhythm
12:28:06 PM	Heart Rate (/min)
12:55:30 PM	Cardiac rhythm
12:55:31 PM	Heart Rate (/min)
1:40:43 PM	Cardiac rhythm
1:40:44 PM	Heart Rate (/min)
1:42:42 PM	Respiratory Rate
1:42:50 PM	Catheter Assessment
2:56:24 PM	Cardiac rhythm
2:56:25 PM	Heart Rate (/min)
3:50:38 PM	Cardiac rhythm
3:50:39 PM	Heart Rate (/min)
3:51:17 PM	Respiratory Rate
4:53:34 PM	Cardiac rhythm
4:53:35 PM	Heart Rate (/min)
5:26:51 PM	Weight (kg)
5:27:11 PM	Catheter Assessment
5:27:40 PM	Eliminations
5:28:37 PM	Cardiac rhythm
5:28:38 PM	Heart Rate (/min)
5:31:07 PM	Respiratory Rate
5:31:19 PM	Temperature (F)
5:42:41 PM	Amount eaten
6:26:38 PM	Cardiac rhythm
6:26:39 PM	Heart Rate (/min)
7:11:26 PM	Respiratory Rate
7:33:30 PM	Cardiac rhythm
7:33:31 PM	Heart Rate (/min)
8:37:08 PM	Cardiac rhythm
8:37:09 PM	Heart Rate (/min)
9:04:40 PM	Catheter Assessment

B6

B6

Client: **B6**
Patient: **B6**

Vitals Results

9:04:48 PM	Respiratory Rate
10:11:22 PM	Cardiac rhythm
10:11:23 PM	Heart Rate (/min)
10:36:23 PM	Cardiac rhythm
10:36:24 PM	Heart Rate (/min)
11:20:49 PM	Eliminations
11:20:56 PM	Respiratory Rate
11:21:56 PM	Cardiac rhythm
11:21:57 PM	Heart Rate (/min)
1:40:01 AM	Catheter Assessment
1:40:50 AM	Cardiac rhythm
1:40:51 AM	Heart Rate (/min)
1:41:04 AM	Respiratory Rate
3:26:17 AM	Cardiac rhythm
3:26:18 AM	Heart Rate (/min)
3:26:43 AM	Respiratory Rate
3:30:08 AM	Cardiac rhythm
3:30:09 AM	Heart Rate (/min)
4:27:51 AM	Cardiac rhythm
4:27:52 AM	Heart Rate (/min)
5:53:01 AM	Cardiac rhythm
5:53:02 AM	Heart Rate (/min)
5:55:46 AM	Catheter Assessment
5:55:59 AM	Amount eaten
5:56:30 AM	Respiratory Rate
6:00:21 AM	Weight (kg)
6:00:27 AM	Eliminations
6:00:34 AM	Temperature (F)
6:41:18 AM	Cardiac rhythm
6:41:19 AM	Heart Rate (/min)
7:34:31 AM	Blood Pressure (mmHg)
7:35:00 AM	Cardiac rhythm
7:35:01 AM	Heart Rate (/min)
7:35:25 AM	Respiratory Rate
8:37:50 AM	Cardiac rhythm
8:37:51 AM	Heart Rate (/min)
9:59:36 AM	Cardiac rhythm
9:59:37 AM	Heart Rate (/min)
10:02:17 AM	Respiratory Rate
10:02:31 AM	Catheter Assessment
10:50:27 AM	Cardiac rhythm

B6

B6

Client: **B6**
Patient: **B6**

Vitals Results

B6	10:50:28 AM	Heart Rate (/min)	B6
	11:29:06 AM	Eliminations	
	11:55:39 AM	Cardiac rhythm	
	11:55:40 AM	Heart Rate (/min)	
	11:55:49 AM	Respiratory Rate	
	12:45:30 PM	Cardiac rhythm	
	12:45:31 PM	Heart Rate (/min)	
	1:44:51 PM	Cardiac rhythm	
	1:44:52 PM	Heart Rate (/min)	
	2:07:26 PM	Respiratory Rate	
	2:07:35 PM	Catheter Assessment	
	2:57:59 PM	Cardiac rhythm	
2:58:00 PM	Heart Rate (/min)		

Client: B6
Patient: B6

ECG from Cardio

B6

10/5/2018 11:54:36 AM

B4, B6
Cardiology

B6

Client: **B6**
Patient: **B6**

ECG from Cardio

B6

10/5/2018 11:54:52 AM

B4, B6
Cardiology

B6

Client: B6

Patient: B6

Patient History

	04:57 PM	Vitals
	04:57 PM	Vitals
	04:57 PM	Vitals
	04:57 PM	Vitals
	05:05 PM	UserForm
	05:06 PM	UserForm
	07:23 PM	Vitals
	07:23 PM	Vitals
	07:23 PM	Vitals
	07:23 PM	Vitals
	08:13 PM	UserForm
	08:52 PM	Purchase
	08:53 PM	Purchase
	08:53 PM	Purchase
	08:55 PM	Purchase
	08:58 PM	Labwork
	09:08 PM	Treatment
	09:28 PM	Purchase
	09:28 PM	Purchase
	09:33 PM	Treatment
	09:34 PM	Treatment
B6	09:34 PM	Vitals
	10:12 PM	Treatment
	10:12 PM	Treatment
	10:12 PM	Vitals
	10:12 PM	Vitals
	10:12 PM	Treatment
	10:12 PM	Vitals
	10:46 PM	Purchase
	10:46 PM	Purchase
	10:46 PM	Purchase
	11:52 PM	Treatment
	11:52 PM	Treatment
	11:52 PM	Vitals
	11:52 PM	Vitals
	11:53 PM	Treatment
	11:53 PM	Vitals
	11:53 PM	Treatment
	11:53 PM	Vitals
	01:00 AM	Treatment
	01:00 AM	Vitals
	01:00 AM	Vitals

B6

Client: B6

Patient: B6

Patient History

01:33 AM	Treatment
01:37 AM	Treatment
01:37 AM	Vitals
01:38 AM	Treatment
01:38 AM	Vitals
01:50 AM	Treatment
01:50 AM	Vitals
01:50 AM	Vitals
02:49 AM	Treatment
02:49 AM	Vitals
02:49 AM	Vitals
03:35 AM	Treatment
03:35 AM	Vitals
03:36 AM	Treatment
03:36 AM	Vitals
03:36 AM	Vitals
04:03 AM	Prescription
04:44 AM	Treatment
04:44 AM	Vitals
04:44 AM	Vitals
05:30 AM	Treatment
05:37 AM	Treatment
05:37 AM	Treatment
05:37 AM	Vitals
05:37 AM	Treatment
05:37 AM	Vitals
05:38 AM	Treatment
05:38 AM	Vitals
05:39 AM	Treatment
05:39 AM	Vitals
05:39 AM	Treatment
05:39 AM	Vitals
06:30 AM	Treatment
06:30 AM	Treatment
06:30 AM	Vitals
06:30 AM	Vitals
06:30 AM	Vitals
07:28 AM	Treatment
07:28 AM	Vitals
07:56 AM	Purchase
08:01 AM	Treatment

B6

B6

Client: **B6**
Patient: **B6**

Patient History

B6

08:01 AM	Vitals
08:01 AM	Vitals
08:23 AM	Purchase
08:55 AM	Treatment
08:55 AM	Vitals
08:55 AM	Vitals
08:56 AM	Treatment
08:56 AM	Treatment
08:56 AM	Vitals
09:09 AM	Purchase
09:11 AM	Purchase
10:04 AM	Vitals
10:04 AM	Vitals
10:05 AM	Vitals
10:24 AM	Treatment
10:25 AM	Treatment
10:40 AM	UserForm
11:07 AM	Treatment
11:07 AM	Vitals
11:07 AM	Vitals
11:12 AM	Treatment
11:12 AM	Vitals
11:13 AM	Treatment
11:13 AM	Vitals
11:13 AM	Purchase
11:58 AM	Treatment
11:59 AM	Purchase
11:59 AM	Purchase
12:08 PM	Purchase
12:20 PM	Vitals
12:20 PM	Purchase
12:28 PM	Treatment
12:28 PM	Vitals
12:28 PM	Vitals
12:55 PM	Treatment
12:55 PM	Vitals
12:55 PM	Vitals
01:40 PM	Treatment
01:40 PM	Vitals
01:40 PM	Vitals
01:42 PM	Treatment
01:42 PM	Treatment

B6

Client: B6
Patient: B6

Patient History

01:42 PM	Vitals
01:42 PM	Treatment
01:42 PM	Vitals
02:12 PM	Prescription
02:13 PM	Purchase
02:42 PM	Purchase
02:48 PM	Treatment
02:56 PM	Treatment
02:56 PM	Vitals
02:56 PM	Vitals
02:57 PM	Treatment
03:50 PM	Treatment
03:50 PM	Vitals
03:50 PM	Vitals
03:51 PM	Treatment
03:51 PM	Vitals
04:53 PM	Treatment
04:53 PM	Vitals
04:53 PM	Vitals
05:26 PM	Treatment
05:26 PM	Vitals
05:27 PM	Treatment
05:27 PM	Treatment
05:27 PM	Vitals
05:27 PM	Treatment
05:27 PM	Vitals
05:28 PM	Treatment
05:28 PM	Vitals
05:28 PM	Vitals
05:31 PM	Treatment
05:31 PM	Vitals
05:31 PM	Treatment
05:31 PM	Vitals
05:32 PM	Prescription
05:42 PM	Treatment
05:42 PM	Vitals
05:49 PM	Prescription
06:24 PM	Treatment
06:24 PM	Treatment
06:26 PM	Treatment
06:26 PM	Vitals

B6

B6

Client: **B6**

Patient: **B6**

Patient History

06:26 PM	Vitals
07:11 PM	Treatment
07:11 PM	Vitals
07:33 PM	Treatment
07:33 PM	Vitals
07:33 PM	Vitals
08:37 PM	Treatment
08:37 PM	Vitals
08:37 PM	Vitals
08:59 PM	Treatment
09:04 PM	Treatment
09:04 PM	Treatment
09:04 PM	Vitals
09:04 PM	Treatment
09:04 PM	Vitals
09:13 PM	Purchase
09:13 PM	Purchase
10:11 PM	Treatment
10:11 PM	Vitals
10:11 PM	Vitals
10:36 PM	Treatment
10:36 PM	Vitals
10:36 PM	Vitals
10:38 PM	Treatment
11:20 PM	Treatment
11:20 PM	Vitals
11:20 PM	Treatment
11:20 PM	Vitals
11:21 PM	Treatment
11:21 PM	Vitals
11:21 PM	Vitals
01:39 AM	Treatment
01:40 AM	Treatment
01:40 AM	Vitals
01:40 AM	Treatment
01:40 AM	Vitals
01:40 AM	Vitals
01:41 AM	Treatment
01:41 AM	Vitals
03:26 AM	Treatment
03:26 AM	Vitals

B6

B6

Client: **B6**
Patient: **B6**

Patient History

03:26 AM	Vitals
03:26 AM	Treatment
03:26 AM	Vitals
03:30 AM	Treatment
03:30 AM	Vitals
03:30 AM	Vitals
04:27 AM	Treatment
04:27 AM	Vitals
04:27 AM	Vitals
05:52 AM	Treatment
05:53 AM	Treatment
05:53 AM	Vitals
05:53 AM	Vitals
05:55 AM	Treatment
05:55 AM	Vitals
05:55 AM	Treatment
05:55 AM	Vitals
05:56 AM	Treatment
05:56 AM	Treatment
05:56 AM	Vitals
06:00 AM	Treatment
06:00 AM	Vitals
06:00 AM	Treatment
06:00 AM	Vitals
06:00 AM	Treatment
06:00 AM	Vitals
06:00 AM	Treatment
06:00 AM	Vitals
06:41 AM	Treatment
06:41 AM	Vitals
06:41 AM	Vitals
07:24 AM	Treatment
07:34 AM	Vitals
07:34 AM	Treatment
07:35 AM	Treatment
07:35 AM	Vitals
07:35 AM	Vitals
07:35 AM	Treatment
07:35 AM	Vitals
08:37 AM	Treatment
08:37 AM	Vitals
08:37 AM	Vitals
09:11 AM	Purchase

B6

B6

Client: B6

Patient: B6

Patient History

09:59 AM	Treatment
09:59 AM	Vitals
09:59 AM	Vitals
10:02 AM	Treatment
10:02 AM	Vitals
10:02 AM	Treatment
10:02 AM	Treatment
10:02 AM	Vitals
10:33 AM	UserForm
10:50 AM	Treatment
10:50 AM	Vitals
10:50 AM	Vitals
11:29 AM	Treatment
11:29 AM	Vitals
11:47 AM	Deleted Reason
11:55 AM	Treatment
11:55 AM	Vitals
11:55 AM	Vitals
11:55 AM	Treatment
11:55 AM	Vitals
11:57 AM	Purchase
12:05 PM	Prescription
12:05 PM	Prescription
12:06 PM	Purchase
12:45 PM	Treatment
12:45 PM	Vitals
12:45 PM	Vitals
01:43 PM	Treatment
01:44 PM	Treatment
01:44 PM	Vitals
01:44 PM	Vitals
02:07 PM	Treatment
02:07 PM	Vitals
02:07 PM	Treatment
02:07 PM	Vitals
02:57 PM	Treatment
02:57 PM	Vitals
02:57 PM	Vitals
02:59 PM	Treatment

B6

B6

B4, B6

B6

B6

B6

Male (Neutered)

Canine: Bulldog Cross White/Yellow

Patient ID:

B6

STANDARD CONSENT FORM

B6

B6

Owner's name: **B6**

Date: **B6**

Owner's address: **B6**

B6

B6

OWNER'S PRINTED SIGNATURE

DATE

**If the individual admitting the animal is someone other than the legal owner,
please complete the portion below:**

B6

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City

State

Zip

B4, B6

B6

Patient ID: **B6**

B6 Canine

10.01 Years Old Male (Neutered) Bulldog
Cross

Body Weight: Weight (kg) 0.00

Brachycephalic Consent Form
Anesthesia, Sedation and Hospitalization

B6

B6

B6

B6

Owner signature:

Date:

B6

B4, B6

B4, B6

Treatment Plan

Estimated Charges

B6

B6

This estimate is based upon our preliminary examination. This is an estimate and is not the final bill. Every effort will be made to keep you informed of the current status of your bill throughout your animal's hospitalization. The final fee may vary considerably from this estimated cost.

Patient	Description	Low Qty	Low Extended	High Qty	High Extended
B6	This estimate includes hospitalization, medication, cardiology consult, bloodwork. It does not include surgery, if indicated.	B6			

B6

Doctor of Record: **B4, B6**

I understand that no guarantee of successful treatment is made. I certify that I have read and fully understand the authorization for medical and/or surgical treatment, the reason for why such medical and/or surgical treatment is considered necessary, as well as its advantages and possible complications, if any. I also assume financial responsibility for all charges incurred to this patient(s). I agree to pay 75% of the estimated cost at the time of admission. Additional deposits will be required if additional care or procedures are required. I further agree to pay the balance of the charges when this patient(s) is released.

Procedural billing is inclusive up to and including the estimated duration of hospitalization. There will be additional expenses if hospitalization extends beyond the specified duration.

I have read, understand, and agree to accept the conditions of this treatment plan.

Thank you for entrusting us with your pet's care.

High Total
Low Total
75% Deposit

B6

B4, B6

B6

Patient ID: B6

B6 Canine

1002 years Old Male (Neutered) Bulldog
Cross

White/Yellow BW: Weight (kg) 32.00

Cardiology Consultation

Date: B6

Weight: Weight (kg) 32.00

Requesting Clinician: B6 DVM (Emergency & Critical Care Resident)

Attending Cardiologist:

B4, B6

Cardiology Resident:

B4, B6

Thoracic radiographs available for review?

- Yes - in SS
- Yes - in PACS
- No

Patient location:

ICU Run

Presenting complaint and important concurrent diseases:

Acute onset of V x 24 hours, anorexia for 3 days. Does get into trash and things at home. History of hypothyroidism, skin issues. On Rawz diet at home (grain free).

Current medications and doses:

Soloxine

Cerenia 1 mg/kg IV q 24 hr in hospital

At-home diet: (name, form, amount, frequency)

Rawz limited ingredient wild salmon

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.)

Afib on telemetry (rate 120-140 bpm) with occasional monomorphic VPCs

Suspect DCM based on TFAST

Questions to be answered: Cause of arrhythmia

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)

- Yes (explain):
- No

STOP - remainder of form to be filled out by Cardiology

Physical Examination

Heart rate: 120-150
MM Color and CRT: pink

Respiratory rate: 30-40
BCS (1-9): 6

Muscle condition:

- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam

Murmur Grade:

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

Murmur location/description: left systolic 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
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

Arrhythmia: irregularly irregular

- 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
- Abdominal distension

Hepatomegaly

Mild ascites

Echocardiogram Findings:

General/2-D findings: There is decreased LV wall thicknesses. The LV cavity size is moderately increased. The LA is moderately enlarged. The contractile function is markedly reduced. Subjectively the PA is dilated. There is no pleural or pericardial effusion. No ascited.

Doppler findings: 1-2 + MR, Trace TR

Blood Pressure (mmHg):

Cuff size: #4

Limb: RH

70mmHg

ECG findings:

atrial fibrillation with occasional isolated LV origin VPCs

Radiographic findings:

No signs of pulmonary edema

Assessment and recommendations:

DCM with atrial fibrillation and hypotension. The radiographics and physical exam does not suggest that the patient is currently in CHF, but the LA is enlarged enough that I would be worried that he could go into CHF shortly. The patient is also hypotensive. Recommend starting pimobendan 10mg TID, recheck BP tonight to see BP is improved and if dose needs to be increased. Also recheck T4 level. Ideally we can get a taurine level (Whole blood). Start taurine supplementation 1000mg BID. Change diet to non-grain free. Monitor RR/RE at home. Because of the hypotension, I hesitate to start diltiazem at this time. The dog's HR is not that high at this time, so we can wait until BP is improved become considering diltiazem. Recheck ECG and BP 1 week after discharge.

Final Diagnosis:

DCM, atrial fibrillation

Heart Failure Classification Score:

ISACHC Classification:

Ia

Ib

II

IIIa

IIIb

ACVIM CHF Classification:

A

B1

B2

C

D

M-Mode

IVSd
LVlDd
LVPWd
IVSs
LVlDs
LVPWs
%FS
Ao Diam
LA Diam
LA/Ao
Max LA
EPSS

cm
cm
cm
cm
cm
cm
%
cm
cm

cm
cm

M-Mode Normalized

IVSdN
LVlDdN
LVPWdN
IVSsN
LVlDsN
LVPWsN
Ao Diam N
LA Diam N

B6

2D

SA LA
Ao Diam
SA LA / Ao Diam
LVlA A4C
LVEDV MOD A4C
LVlA A4C
LVESV MOD A4C
LVEF MOD A4C
SV MOD A4C

cm
cm

cm
ml
cm
ml
%
ml

Doppler

MR Vmax
MR maxPG
MV E Vel
PV Vmax
PV maxPG
AV Vmax
AV maxPG

m/s
mmHg
m/s
m/s
mmHg
m/s
mmHg

B4, B6

B4, B6

Emergency & Critical Care **B4, B6**

Patient

Name:

B6

Signalment:

10.02 Years Old White/Yellow
Male (Neutered) Bulldog Cross

Owner

Name:

Address:

B6

Patient ID:

B6

Emergency Clinician:

B4, B6

DVM (Resident - Cardiology)

Consulting Clinician:

ER Supervisor:

B6

Discharge Instructions

Admit Date: **B6** 4:55:40 PM

Check Out Date: **B6**

Case Summary

B6

B6

Recommended Medications:

Pimobendan 10mg - give 1 tablet every 8 hours.

Pimobendan is a drug that has been shown to improve both quality and of life and survival time of dogs with heart failure. The drug increases the vigor of contraction of the heart. Side effects are uncommon but can include excitability or intestinal upset.

NEXT DOSE DUE: tonight.

Taurine 1000mg - give 1 tablet (1000mg) orally every 12 hours. Taurine is an amino acid that its deficiency has been shown to be associated with heart disease.

NEXT DOSE DUE: tonight.

Cerenia 60mg - give 1/2 tablet (30mg) every 24 hours.

Cerenia is an anti-nausea medication.

NEXT DOSE DUE: tonight.

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 [B6](#)

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:

B6

Thank you for entrusting us with [B6] care. Please contact our Cardiology liaison at [B4, B6] or email us at [B4, B6] for scheduling and non-emergent questions or concerns.

Please visit our [B4, B6] website for more information
[B4, B6]

Prescription Refill Disclaimer:

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 [B4, B6] 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: [B4, B6]

Case: [B6]

Owner: [B6]

Discharge Instructions

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6] com
Sent: 10/8/2018 6:20:46 PM
Subject: Taste of the Wild High Forest dry; [B4, B6] EON-367841
Attachments: 2055791-report.pdf; 2055791-attachments.zip

A PFR Report has been received and PFR Event [EON-367841] has been created in the EON System.

A "PDF" report by name "2055791-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 "2055791-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367841

ICSR #: 2055791

EON Title: PFR Event created for Taste of the Wild High Forest dry; 2055791

AE Date	01/25/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	3.18 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055791

Product Group: Pet Food

Product Name: Taste of the Wild High Forest dry

Description: Feeding Taste of the Wild High Prairie Grain Free (Pine Forest before that). Diagnosed with DCM and CHF this past winter. Owner willing to provide additional information. Our records do not include echo from [B6] ([B6]) from Feb, 2018. They also ran taurine at [B6] which was reported to be normal. I am getting those records from [B6] and will submit as soon as I have them.

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
Taste of the Wild High Forest dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
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:

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.

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-367841

ICSR: 2055791
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
Report Submission Date: 2018-10-08 14:14:30 EDT

Reported Problem:

Problem Description:	Feeding Taste of the Wild High Prairie Grain Free (Pine Forest before that). Diagnosed with DCM and CHF this past winter. Owner willing to provide additional information. Our records do not include echo from: B6 B6 B6) from Feb, 2018. They also ran taurine at B6 which was reported to be normal. I am getting those records from B6 and will submit as soon as I have them.
Date Problem Started:	01/25/2018
Concurrent Medical Problem:	No
Outcome to Date:	Stable

Product Information:

Product Name:	Taste of the Wild High Forest dry
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Product Use Information:	Description: See diet history in medical records. Owner can provide additional info First Exposure Date: 12/01/2017
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Mixed (Dog)
Gender:	Female
Reproductive Status:	Neutered
Weight:	34.1 Kilogram
Age:	3.18 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: B6 Phone: B6 Email: B6
Address:	B6 United States
Healthcare Professional	

	Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine	
		Contact:	Name:	Lisa Freeman
			Phone:	(508) 887-4523
			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:	B6	compiled medical records.pdf	
	Description:	Compiled medical records		
	Type:	Medical Records		

B4, B6

B4, B6

Client:

B6

Address:

All Medical Records

Patient:

B6

Breed: Hound Cross

DOB:

B6

Species: Canine

Sex: Female
(Spayed)

Home Phone:

B6

Work Phone: () -

Cell Phone:

B6

Referring Information

UNKNOWN RDVM **UNKNOWN RDVM** ,
UNKNOWN RDVM **UNKNOWN RDVM** ,

Client:

B6

Patient:

B6

Initial Complaint:

Scanned Record

Initial Complaint:

Nutrition Phone/In person

SOAP Text

B4, B6

5:09PM -

B4, B6

Subjective

Nutrition Phone Consult Notes

PHONE CONSULTATION - NO EXAM PERFORMED

(See Diet History Form and information from referring veterinarian in Documents for additional details)

History: DCM and CHF diagnosed Jan, 2018; history of environmental allergies (ears/skin). Taurine WNL.

Meds: Pimobendan, enalapril, furosemide, spironolactone

Current Diet: (See Diet History Form in Documents and comm log for additional information)

- Current diet: Taste of the Wild High Prairie dry (1 ¾ cup [10 oz cup] or 17.5 oz twice daily). Occasional canned (I and love and you Clucking Good Stew or Wellness Beef Stew)

Client: B6

Patient: B6

- Previous: Taste of the Wild Pine Forest dry (20 oz twice daily)
- Treats/human foods: Homemade dried cooked beef liver or kidneys (dried in oven – keep in freezer); Occasional “I and love and you” jerky treats – venison and lamb but none recently.
- Medication administration: Galbani ricotta cheese ½ teaspoon twice daily

Supplements:

- Supplements: Taurine (Nutricost) – 1000 mg twice daily

Owner Goals:

Diet to help with DCM

Assessment: Possible diet-associated DCM and CHF

Plan: Change diet

- Avoid BEG diets (boutique, exotic ingredient, or grain-free)
- Adequate calories to maintain body weight at 75 pounds
- Reduced sodium from all sources (diet, treats, table food)
- Moderate protein to help maintain muscle mass
- Supplements: Taurine, omega-3 fatty acids
- Owner is ok to have me report to FDA and willing to answer their questions

****PHONE CONSULTATION - NO EXAM PERFORMED****

Disposition/Recommendations

Client: **B6**
Patient: **B6**

Client: B6
Patient: B6

B4, B6

B4, B6

Client: B6
Veterinarian:
Patient ID: B6
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Hound Cross
Sex:	Female (Spayed)
Age:	3.18 Years Old

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units
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4/74

B6

B6

Printed Monday, October 08, 2018

Client: B6

Patient: B6

Nutrition Diet Hx Form

Client Diet History Form

Submitted: 09/04/2018

PET INFORMATION

Pet Name B6
Pet Last Name B6
Pet Species/Breed Dog / Hound (Bloodhound Redbone mix)
Pet's Color Tan
Pet's Age (Best Guess) Probably born B6
Pet's Sex Female
Spayed or Neutered? Yes

CLIENT INFORMATION

Client Name B6
Client Address B6
Client Phone B6 (Mobile)
Client Email B6
Co-Owner Name B6
Co-Owner Phone B6
Co-Owner Email B6

CONSULT INFORMATION

Type of Consult Phone
HCD Being Requested? No

Reasons & Goals for Consult On 1/25/18 B6 was diagnosed with DCM. I read the "A broken heart" article about the possible association between grain-free diet and DCM. B6 has been on a grain-free diet, and I'm hoping that a change of diet will help with her condition.
As of her weight, she might be just a tad overweight but most likely not by much, perhaps a pound or two.

Attachments [Additional relevant diagnostics](#)
[IMG_4818.jpeg](#)

PRIMARY VETERINARIAN INFORMATION

rDVM Name B6
rDVM Clinic B6
rDVM Phone B6
rDVM Fax B6
rDVM Email B6

Client: B6
Patient: B6

Nutrition Diet Hx Form

Diet History Form - updated

Agree to Terms

Date Submitted
09/04/2018

Information to Gather

About You, Your Veterinarian(s) and Your Pet

What type of appointment are you requesting?
Phone

Has your pet been seen at Tufts in the last 6 months?
No

About the Pet Owner

Pet owner name
B6

Pet owner email
B6

Address
B6
United States

Preferred Phone
B6

Preferred Phone Type
Mobile

Alternate Phone

Is there another phone number you would like to give us in case we can't reach you at one of the above?
No

Spouse/partner/co-owner's name
B6

Spouse/partner/co-owner's email
B6

Spouse/partner/co-owner's phone
B6

How did you hear about our service?
Media - interview, article, etc

Client: B6
Patient: B6

Nutrition Diet Hx Form

Your Pet's Primary Veterinarian
Primary veterinarian B6
Primary veterinarian's clinic name B6
Primary veterinarian's clinic phone B6
Primary veterinarian's clinic fax B6
Primary veterinarian's clinic email B6
Is your pet currently being (or has your pet been) seen by any other veterinarians in relation to her/his current health issues or other health issues that you'd like to discuss with us? Yes
Information About Your Second Veterinarian
Name of 2nd veterinarian B6
Clinic name of 2nd veterinarian B6
Phone for 2nd veterinarian's clinic B6
Fax for 2nd veterinarian's clinic B6
Email for 2nd veterinarian's clinic B6
What is this second veterinarian's role in your pet's care? To get an expert opinion on B6 treatment
Should this 2nd veterinarian receive a copy of any written reports that result from working with our service? No
Is your pet being seen by a 3rd veterinarian? No
About Your Pet
Pet's name B6
What is your pet's species? Dog

Client: B6

Patient: B6

Nutrition Diet Hx Form

Breed
Hound (Bloodhound Redbone mix)
Color
Tan
Sex
Female
Spayed/neutered?
Yes
Do you know your pet's exact birthdate?
No
Pet's Age
Probably born Aug 2015
What is your pet's current weight
75
Pounds or kilograms?
lbs
Has your pet gained or lost weight within the past 6 months?
Stayed the same
Which category best describes your pet?
ideal weight
Reason and goals for consultation
On 1/25/18 B6 was diagnosed with DCM. I read the "A broken heart" article about the possible association between grain-free diet and DCM. B6 has been on a gain-free diet, and I'm hoping that a change of diet will help with her condition. As of her weight, she might be just a tad overweight but most likely not by much, perhaps a pound or two.
Details About Your Pet's Habits
Questions about your pet
Is your pet housed:
· Indoors
Please describe your pet's activity level:
Moderate
Do you have any other pets?
Yes
What are your other pets?
Species How many?
Dogs two additional dogs

Client: B6
 Patient: B6

Nutrition Diet Hx Form

Do any pets have access to other pets' food?
No

How many people (including yourself) live in your household?
3

Who feeds your pet?
Me

How many times per day do you feed your pet?
Twice

Does your pet finish all food that is offered?
Yes

Does your pet have any difficulty with the following?

Does your pet have any of the following?
· Environmental allergies

Please explain about your pet's conditions
Seasonal allergies only. Her underbelly gets dark, and she gets ear infections.

Have you observed any changes in any of the following?

Have you made any recent changes in diet (last 4 weeks)?
No

Your Pet's Diet

Do you feed your pet DRY (e.g., kibble) pet food?
Yes

Please list each kind of DRY petfood individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Taste of the Wild High Prairie Grain-Free	1 ¾ cup (cup size 10 oz)	2x/day	Dec 2017
Taste of the Wild Pine Forest Grain-Free	2 cups (cup size 10 oz)	2x/day	Feb 2016

Do you feed your pet WET (e.g., canned or pouched) pet food?
Yes

Please list each kind of WET (e.g., canned or pouched) petfood individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
"I and love and you" Clucking Good Stew	Perhaps ½ can	Rarely	Several cans at most since late 2016
Wellness Beef Stew	Perhaps ½ can	Rarely	Several cans at most since late 2016

Do you feed your pet HOME-COOKED food?
No

Client: B6

Patient: B6

Nutrition Diet Hx Form

Do you feed your pet TREATS?
Yes

Please list each kind of TREAT individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Homemade dried beef liver and kidneys	2-3 small pieces	Perhaps 4 times a week, if that	Not sure, probably less than a year
"I and love and you", Natural Jerky Dog Treats, Venison & Lamb	Small pieces	Not sure, infrequently	Not sure, probably several bags since early 2016
Happy Howie's Premium Turkey Roll	Tiny pieces	Infrequent, a 2 bl log lasted a long time	May 2017 only
Merrick Texas Hold'em's Premium Lamb (or beef) Lung Filets Dog Treats	A little bit, not sure	Infrequently, 2-3 8 oz bag lasted several months	Mid 2016 to early 2017 only
Merrick Lamb Lung Training Dog Treats	A little bit, not sure	Infrequently, the 5 oz bag lasted a while	June-July 2016 only
Stewart Pro-Treat Beef Liver Freeze-Dried Dog Treats	A little bit, not sure	Infrequently, the 21 oz tub lasted a good few months	June-July 2016 only
Beef Marrow Bone Dog Treat & Beef Knee Caps Dog Treats	One piece	Once a month	March & April 2017 only

Is there any OTHER kind of food you feed your pet?
No

Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, herbs, or any other supplements)?
Yes

Please list any dietary supplements

Product Name	Amount	Frequency
Nutricost Taurine	1000mg	2x daily

Is your pet receiving any medications?
Yes

Please list your pet's medications

Drug Name	Dosage
Furosemide	60mg 2x daily
Spironolactone	37.5mg 2x daily
Enalapril	15mg 2x daily
Vetmedin	15mg 3x daily

Do you use food (e.g., Pill Pockets, cheese, bread, peanut butter, etc.) to administer medications?
Yes

Lists foods used to administer medication

What kind?	Amount?	How often?
Ricotta cheese	½ teaspoon	2x daily

Regarding commercial diets (pet foods and treats not made in your home) your pet may have received

Client: **B6**

Patient: **B6**

Nutrition Diet Hx Form

in the past, please select the following statement that is most accurate:

I have never fed other commercial diets to my pet

Home-cooked Diets

Is a home-cooked diet being requested? (Please note that this option is only available for phone or in-person consults, not for consults directly with veterinarians.)

No

Medical Records & Test Results**Requested Items**

- Additional relevant diagnostics (e.g., urine culture, T4, ultrasound reports)
- Last 6 months' medical records or as appropriate (all consults)

Do you have any of the above in electronic format?

Yes

Additional relevant diagnostics

- [Archive.zip](#)

Last 6 months' medical records

Would you like to upload and attach anything else to this form?

- [IMG_4818.jpeg](#)

Client: B6
Patient: B6

RDVM B6 records

Patient Chart

B6
B6

Printed: 09-05-18 at 6:47p

CLIENT INFORMATION

Name Address B6 Spouse B6

PATIENT INFORMATION

Name B6 (Record - 18741) Species Canine
Sex Female, Spayed Breed Bloodhound Mix
Birthday B6 Age 3y
ID Rabies 011425
Color Red Weight 75.00 lbs
Reminded 10-01-16 Codes

Reminders for B6 Last done

B6

HEALTH HISTORY SUMMARY

Date	Diagnosis
02-22-18	Heartworm 4DX Neg -Spoke to owner
11-21-16	Heartworm 4DX Neg -Spoke to owner

B6 weight history (in lbs)

B6

MEDICAL HISTORY

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 2

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6.47p

Client: B6

Page: 3

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 4

Date	By	Code	Description	Qty (Variance)
B6				

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 5

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 6

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 7

Date	By	Code	Description	Qty (Variance)
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<h1>B6</h1>				
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Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6** Page: 8

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM: B6 records

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 9

Date	By	Code	Description	Qty (Variance)
<h1>B6</h1>				

Client: B6
Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6 Page: 10

Date	By	Code	Description	Qty (Variance)
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<h1>B6</h1>				
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Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 11

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 12

Date	By	Code	Description	Qty (Variance)
B6				

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6.47p

Client: B6 Page: 13

Date	By	Code	Description	Qty (Variance)
B6				

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 14

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 15

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 17

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**
Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6** Page: 18

Date	By	Code	Description	Qty (Variance)
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B6				
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Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 19

Date	By	Code	Description	Qty (Variance)
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B6				
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Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 20

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 21

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6.47p

Client: **B6** Page: 22

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6
Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 23

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6
Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6.47p

Client: B6

Page: 24

Date	By	Code	Description	Qty (Variance)
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B6				
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Client: **B6**
Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6** Page: 25

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 26

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**
Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6** Page: 27

Date	By	Code	Description	Qty (Variance)
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B6				
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Client: **B6**

Patient: **B6**

RDVM **B6** records

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B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 28

Date	By	Code	Description	Qty (Variance)
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B6				
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Client: **B6**
Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6** Page: 29

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**
Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 30

Date	By	Code	Description	Qty (Variance)
B6				

Client: B6
Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 31

Date	By	Code	Description	Qty (Variance)
B6				

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for: **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 32

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**
Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6** Page: 33

Date	By	Code	Description	Qty (Variance)
B6				

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 34

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 35

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6

Page: 36

Date	By	Code	Description	Qty (Variance)
B6				

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for B6
Date: 09-05-18, Time: 6.47p

Client: B6

Page: 37

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 38

Date	By	Code	Description	Qty (Variance)
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B6

Client: **B6**

Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6**

Page: 39

Date	By	Code	Description	Qty./Variance
B6				

Client: **B6**
Patient: **B6**

RDVM **B6** records

B6

Patient Chart for **B6**
Date: 09-05-18, Time: 6:47p

Client: **B6** Page: 40

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 records

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 41

Date	By	Code	Description	Qty (Variance)
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B6

Client: B6

Patient: B6

RDVM B6 echo results 5/2/18

B4, B6

REFERRING DOCTOR / HOSPITAL:

B6

PATIENT INFORMATION

PATIENT'S NAME: B6

SIGNALMENT 2015, FS, mixed breed [canine]

RECORD #: B6 2018-5-2

WEIGHT: 75 pounds; [34.1 kg]

DATE OF EXAM: Wednesday, May 2, 2018

HISTORY: severe DCM

ECHOCARDIOGRAM

Left Inflow

Right Inflow

Left Outflow

Right Outflow

Echo Summary

Echo Discussion

B6

Client: B6

Patient: B6

RDVM B6 echo results 5/2/18

B4, B6

PATIENT'S NAME: B6

GROSS ECHO MEASUREMENTS

IVSd	B6	normal range
LVIDd		(0.68 - 1.38 cm)
LVPWd		(3.58 - 5.22cm)
IVSs		(0.66 - 1.36cm)
LVIDs		(1 - 1.84cm)
LVPWs		(2.16 - 3.83cm)
%FS		(1.05 - 1.9cm)
HR		(33.7 - 45.9%)
LAmx		(1.99 - 3.28)
LA/Ao (boon)		< 1.3
TRmax (m/s)		
TRmax (mmHg)		
MRmax (m/s)		
MRmax (mmHg)		
PA max (m/s)		(<2.5m/s)
PI max (m/s)		
AOmax (m/s)	(<2.5m/s)	
Ai max (m/s)		

B4, B6

Client: B6
Patient: B6

Nutrition RDVM Consult Request Form

Referring Veterinarian Nutrition Consult Form - Updated
Date Submitted 09/29/2018
Veterinarian's Name B6
Practice Name B6
Practice Address B6 United States
Email B6
Phone B6
Fax B6
Preferred Method of Contact Email
How did you hear about our service? - Your client
Client Name B6
Client Email B6
Pet Name B6
Pet Species Dog
Pet weight 75
Pounds or kilograms lbs
Body condition score 5

Client: B6

Patient: B6

Nutrition RDVM Consult Request Form

On what scale?

out of 9

Does this pet have any generalized muscle loss?

No

Type of consult

Client consultation or appointment

Reason for consult

See attached AMC report

Is a home-cooked diet recipe being requested?

No

Current medical concerns

See attached AMC report

Is this pet currently on medication?

Yes

Current medications

Drug	Route	Dose	Frequency
Spirolactone	Oral	37.5mg	Every 12 hours
Enalapril	Oral	15mg	Every 12 hours
Vetmedin	Oral	15mg	Every 8 hours
Eurosemide	Oral	60mg	Every 12 hours

Previous medical history

Diagnosed January 2018. Initially brought in for coughing. Owner was feeding Taste of the Wild Bison Formula.

Medical Records

How will you provide the required records?

I will upload now via this form

File(s)

B6

Client: B6

Patient: B6

Nutrition RDVM Consult Request Form

B6

Diet History

Client: B6

Patient: B6

Vitals Results

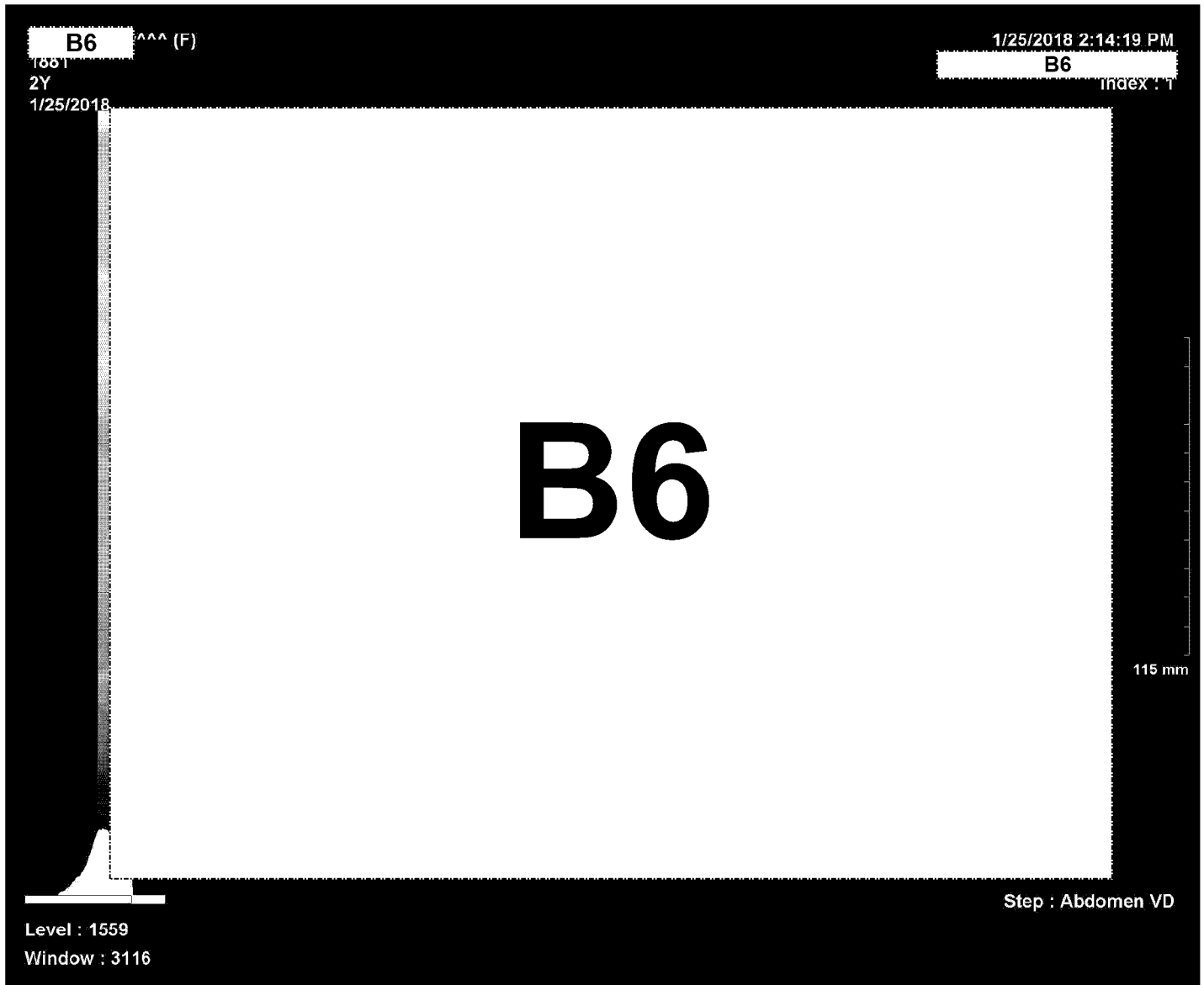
10/2/2018 5:09:37 PM	Muscle Condition Score (MCS)
10/2/2018 5:09:38 PM	Body Condition Score (BCS)
10/2/2018 5:09:39 PM	Weight (kg)

B6

Client: B6

Patient: B6

RDVM: B6 Rads 1/28/18



Client: **B6**

Patient: **B6**

RDVM **B6** Rads 1/28/18

B6

Client: **B6**

Patient: **B6**

RDVM **B6** Rads 1/28/18

B6

Client: **B6**

Patient: **B6**

RDVM **B6** Rads 1/28/18

B6

Client: B6

Patient: B6

RDVM **B6** Rads 1/28/18

B6

Client: B6

Patient: B6

RDVM B6 Rads 1/28/18

B6

Client: B6

Patient: B6

RDVM B6 **Rads 1/28/18**

B6

Client: **B6**

Patient: **B6**

RDVM **B6** **Rads 1/28/18**

B6

Client: **B6**

Patient: **B6**

RDVM **B6** Rads 1/28/18

B6

Client: **B6**

Patient: **B6**

RDVM **B6** Rads 11/6/17

B6

Client: **B6**
Patient: **B6**

RDVM **B6** Rads 11/6/17

B6

Client: **B6**
Patient: **B6**

RDVM **B6** **Rads 11/6/17**

B6

Client: **B6**

Patient: **B6**

RDVM **B6** Rads 11/3/16

B6

Client: **B6**

Patient: **B6**

RDVM **B6** Rads 11/3/16

B6

Client: **B6**
Patient: **B6**

Patient History

10/01/2018 10:58 AM	Appointment
10/02/2018 05:09 PM	Vitals
10/02/2018 05:09 PM	Vitals
10/02/2018 05:09 PM	Vitals
10/02/2018 05:18 PM	Purchase

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 10/8/2018 7:12:54 PM
Subject: Taste of the Wild Pacific Stream (dry): Lisa Freeman - EON-367849
Attachments: 2055795-report.pdf; 2055795-attachments.zip

A PFR Report has been received and PFR Event [EON-367849] has been created in the EON System.

A "PDF" report by name "2055795-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 "2055795-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367849

ICSR #: 2055795

EON Title: PFR Event created for Taste of the Wild Pacific Stream (dry); 2055795

AE Date	02/02/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	9.76 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055795

Product Group: Pet Food

Product Name: Taste of the Wild Pacific Stream (dry)

Description: DCM and CHF diagnosed 2/2/18. Owner did not change diet after diagnosis. Just rechecked echo and no improvement. Taurine levels pending and will echo other dog in household on same diet to screen.

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 Pacific Stream (dry)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
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:

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.

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-367849			
ICSR:	2055795		
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		
Report Submission Date:	2018-10-08 15:05:04 EDT		
Reported Problem:	Problem Description: DCM and CHF diagnosed 2/2/18. Owner did not change diet after diagnosis. Just rechecked echo and no improvement. Taurine levels pending and will echo other dog in household on same diet to screen.		
	Date Problem Started: 02/02/2018		
	Concurrent Medical Problem: Yes		
	Pre Existing Conditions: hypothyroid - on soloxine		
	Outcome to Date: Stable		
Product Information:	Product Name: Taste of the Wild Pacific Stream (dry)		
	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: Doberman Pinscher		
	Gender: Female		
	Reproductive Status: Neutered		
	Weight: 26.8 Kilogram		
	Age: 9.76 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
			Phone: B6
			Email: B6
		Address: B6 United States	
Healthcare Professional Information:	Practice Name: Tufts Cummings School of Veterinary Medicine		
	Contact:	Name: Lisa Freeman	
		Phone: (508) 887-4523	

			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:	B6	compiled records smaller.pdf	
	Description:	B6	compiled records	
	Type:	Medical Records		

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Queen, Jackie L; Palmer, Lee Anne; Carey, Lauren
CC: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica; Nemser, Sarah
Sent: 4/23/2018 2:31:39 PM
Subject: DCM cases-food-iodine screening results
Attachments: 800.261-MSU-iodine results.pdf

FYI-Iodine < 10ppm for the foods tested. Exogenous thyrotoxicosis unlikely a cause of the DCM
Multiple EONs Involved:

- 800.218
 - EON-323515
 - EON-345822
- 800.261
 - EON-350158

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>





MICHIGAN STATE UNIVERSITY
**VETERINARY DIAGNOSTIC
LABORATORY**

Director: B6
4125 Beaumont Road
Lansing, MI 48910-8104
Phone: 517-353-1683
Fax: 517-353-5096
www.animalhealth.msu.edu

REPORT OF LABORATORY EXAMINATION

Client: RC107973/ U.S. Food & Drug Adm (71095)
Center for Veterinary Medicine
8401 Muirkirk Rd, G202 HFV 500
Laurel, MD 20708

Owner: FDA Vet-LIRN, -

Report #: C18103012
Received: 04/13/18 11:43
Printed: 04/20/18 14:32

Admit: Jones, Dr.
Herd:
Species: Non-Animal

Sex: Unknown
Age:

Page 1 of 1

Animal ID	Iodine Feed Wet or Dry?	Iodine, Feed (ug/g)
800261DOGKIBBLE	Dry	4.20
800218SUB2DOGKIBBLE	Dry	4.04
800218SUB6DOGKIBBLE	Dry	1.87
800218SUB5DOGKIBBLE	Dry	3.19
800218SUB4DOGKIBBLE	Dry	1.58

Case Comments

Method: ICP-MS

B6

Clinical Toxicologist

4/20/2018 2:27:48 PM EDT

L = Low Result, H = High Result, @ = Critical Result, ▲ = Corrected Result

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Hartogensis, Martine; McDermott, Patrick; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Edwards, David; Conway, Charlotte
CC: DeLancey, Siobhan
Sent: 7/12/2018 1:13:44 PM
Subject: DCM Comms going live today at 2:00 pm
Attachments: CVMU_DCM_GrainFree_FINAL.docx; FDA In Brief_DCM_grainfree_FINAL.docx

Hi all,

The DCM comms will be going live at 2:00 pm today! Attached are the final versions. I'll shoot you links when they're live. Thanks so much for everyone's cooperation. Hopefully getting the message out will help us get more/better reports to aid in the investigation.

Anne

Anne Norris

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: B6
Anne.Norris@fda.hhs.gov



FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease

July 12, 2018

The U.S. Food and Drug Administration is alerting pet owners and veterinary professionals about reports of canine dilated cardiomyopathy (DCM) in dogs eating certain pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients. These reports are unusual because DCM is occurring in breeds not typically genetically prone to the disease. The FDA's Center for Veterinary Medicine and the Veterinary Laboratory Investigation and Response Network, a collaboration of government and veterinary diagnostic laboratories, are investigating this potential association.

Canine DCM is a disease of a dog's heart muscle and results in an enlarged heart. As the heart and its chambers become dilated, it becomes harder for the heart to pump, and heart valves may leak, leading to a buildup of fluids in the chest and abdomen. DCM often results in congestive heart failure. Heart function may improve in cases that are not linked to genetics with appropriate veterinary treatment and dietary modification, if caught early.

The underlying cause of DCM is not truly known, but is thought to have a genetic component. Breeds that are typically more frequently affected by DCM include large and giant breed dogs, such as Great Danes, Boxers, Newfoundlands, Irish Wolfhounds, Saint Bernards and Doberman Pinschers. It is less common in small and medium breed dogs, except American and English Cocker Spaniels. However, the cases that have been reported to the FDA have included Golden and Labrador Retrievers, Whippets, a Shih Tzu, a Bulldog and Miniature Schnauzers, as well as mixed breeds.

Diets in cases reported to the FDA frequently list potatoes or multiple legumes such as peas, lentils, other "pulses" (seeds of legumes), and their protein, starch and fiber derivatives early in the ingredient list, indicating that they are main ingredients. Early reports from the veterinary cardiology community indicate that the dogs consistently ate these foods as their primary source of nutrition for time periods ranging from months to years. High levels of legumes or potatoes appear to be more common in diets labeled as "grain-free," but it is not yet known how these ingredients are linked to cases of DCM. Changes in diet, especially for dogs with DCM, should be made in consultation with a licensed veterinarian.

In the reports the FDA has received, some of the dogs showed signs of heart disease, including decreased energy, cough, difficulty breathing and episodes of collapse. Medical records for four atypical DCM cases, three Golden Retrievers and one Labrador Retriever, show that these dogs had low whole blood levels of the amino acid taurine. Taurine deficiency is well-documented as potentially leading to DCM. The Labrador Retriever with low whole blood taurine levels is recovering with veterinary treatment, including taurine supplementation, and a diet change. Four other cases of DCM in atypical dog breeds, a Miniature Schnauzer, Shih Tzu and two Labrador Retrievers, had normal blood taurine levels. The FDA continues to work with board certified veterinary cardiologists and veterinary nutritionists to better understand the clinical presentation of these dogs. The agency has also been in contact with pet food manufacturers to discuss these reports and to help further the investigation.

The FDA encourages pet owners and veterinary professionals to report cases of DCM in dogs suspected of having a link to diet by using the electronic [Safety Reporting Portal](#) or calling their state's [FDA Consumer Complaint Coordinators](#). Please see the link below about "[How to Report a Complaint about Pet Food](#)" for additional instructions.

Additional Information

- [How to Report a Complaint about Pet Food](#)
- [Veterinary Laboratory Investigation and Response Network \(Vet-LIRN\)](#)

Document properties

Author: Norris, Anne
Template: Normal.dotm
Page count: 2
Paragraph count: 11
Line count: 51
Word count: 602
Character count (spaces excluded): 3293
Character count (spaces included): 3891

FDA In Brief

METADATA

Title: FDA investigates cases of canine heart disease potentially linked to diet

Description: FDA investigates dilated cardiomyopathy in dogs that ate certain pet foods labeled as “grain-free.”

Short Title: FDA investigates canine heart disease cases potentially linked to diet

For Immediate Release: July 12, 2018

Media Inquiries: Juli Putnam, 240-402-0537, juli.putnam@fda.hhs.gov

FDA In Brief: FDA investigates cases of canine heart disease potentially linked to diet

“We are concerned about reports of canine heart disease, known as dilated cardiomyopathy (DCM), in dogs that ate certain pet foods containing peas, lentils, other legumes or potatoes as their main ingredients. These reports are highly unusual as they are occurring in breeds not typically genetically prone to the disease,” said Martine Hartogensis, D.V.M., deputy director of the FDA’s Center for Veterinary Medicine’s Office of Surveillance and Compliance. “The FDA is investigating the potential link between DCM and these foods. We encourage pet owners and veterinarians to report DCM cases in dogs who are not predisposed to the disease.”

The U.S. Food and Drug Administration’s Center for Veterinary Medicine and the [Veterinary Laboratory Investigation and Response Network](#), a collaboration of government and veterinary diagnostic laboratories, are investigating the potential association between reports of canine dilated cardiomyopathy (DCM) in dogs and certain pet foods containing peas, lentils, other legume seeds or potatoes as main ingredients. Canine DCM is a disease of a dog’s heart muscle and often results in congestive heart failure. In cases that are not linked to genetics, heart function may improve with appropriate veterinary treatment and dietary modification if caught early.

A genetic predisposition for DCM is typically seen in large and giant breed dogs, such as Great Danes, Newfoundlands, Irish Wolfhounds, Saint Bernards and Doberman Pinschers. The disease is less common in small and medium breed dogs, except American and English Cocker Spaniels. However, recently reported atypical cases have included Golden and Labrador Retrievers, a Whippet, a Shih Tzu, a Bulldog, and Miniature Schnauzers as well as mixed breeds. Early reports from the veterinary cardiology community indicate that the impacted dogs consistently ate foods containing peas, lentils, other legume seeds or potatoes as main ingredients as their primary source of nutrition for time periods ranging from months to years. That’s why the FDA is conducting an investigation into this potential link. In the meantime, the FDA continues to recommend that changes in diet, especially for dogs with DCM, should be made in consultation with a licensed veterinary professional.

Cases of DCM in dogs suspected of having a link to diet can be reported to the FDA's electronic [Safety Reporting Portal](#). For additional instructions, see "[How to Report a Complaint about Pet Food](#)."

As part of its investigation, the FDA has been in contact with the pet food manufacturers and the veterinary community to discuss these reports and will provide updates as more information becomes available.

#

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Document properties

Author: Putnam, Juli
Template: Normal.dotm
Page count: 2
Paragraph count: 15
Line count: 57
Word count: 549
Character count (spaces excluded): 3091
Character count (spaces included): 3626

From: Shaw, Courtney </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8FAB2A952A2D4349A0CB0B87B99205D5-COSHAW>
To: Palmer, Lee Anne; Jones, Jennifer L
Sent: 8/22/2019 5:19:41 PM
Subject: DCM food discussions

Hi Lee Ann and Jennifer,

I was presenting in a recent division meeting about some talks I attended at ACVIM regarding the issue with diet and DCM in dogs and we started discussing the work that is being done at the FDA level. I saw your names in the CVM news that you presented at AVMA. I am the cardiology subject matter expert for our division and I would be interested in learning more about the work you are doing.

Thanks,

Courtney Shaw

From: Joshua A Stern <jstern@ucdavis.edu>
To: Jones, Jennifer L; Reimschuessel, Renate
Sent: 10/19/2018 5:11:29 PM
Subject: DCM question

Hi Jennifer & Renate -

I'm giving a presentation at the ACVIM Cardiology conference (all board certified vet cardiologists will be the audience) and I'm giving an update on our work in golden retrievers. I will however be

B5

B5

I was hoping I could get a tiny bit of general info from you to update my slides. I'm happy to chat by phone if that is easier.

Here a few questions - that I would love to know if you are able to answer:

B5

I really appreciate your help if possible. The cardiologists would love to have a tiny bit more info and I'm in a position to pass this on to a captive audience tomorrow afternoon.

Also I'll be reviewing the recommendations for reporting and necropsy info too - so this will hopefully give the investigation a bit of a boost.

Best

Josh

Joshua Stern, DVM, PhD, DACVIM (Cardiology)
Associate Professor of Cardiology
Department of Medicine & Epidemiology
University of California Davis; CCAH Room 258
B6 (530) 752.2475 office
jstern@ucdavis.edu

Associate Editor - Journal of Veterinary Cardiology
www.journals.elsevier.com/journal-of-veterinary-cardiology

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6
Sent: 4/5/2018 3:55:43 PM
Subject: FDA Case investigation for [REDACTED] B6 -8 yr MI Bull Terrier (EON-350263)
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf

Good morning [REDACTED] B6

Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about [REDACTED] B6 illness. As part of our investigation, we'd like to request:

- **Full Medical Records**
 - Please email (preferred) or fax (301-210-4685) a copy of [REDACTED] B6 entire medical history (not just this event).
- Do you have any information on the Grain Free Food, including lot or best by date?
 - Additionally, is there any open or unopened product available?

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.

Please respond to this email so that we can initiate our investigation.

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>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6
Sent: 1/23/2018 6:53:51 PM
Subject: FDA Case Investigation for [REDACTED] B6 dogs (800.218)
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf

Good afternoon [REDACTED] B6

Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about the dogs' illnesses. As part of our investigation, we'd like to request:

- **Test Remaining OPEN product from** [REDACTED] B6
 - Testing for Co, Ca, P, Mg, Cu, Fe, Mg, Se, Zn, Taurine, Methionine, and Cysteine.
 - Please send me the size of the bag/approximate weight.
 - We will coordinate the testing through your office.

In the unfortunate event that any of the dogs from these reports die or are euthanized, we may be able to offer cardiac histopathology (fixed formalin) and metals/aminoacids (fresh frozen) testing. Please contact me if this occurs and the owners are interested.

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.

Please respond to this email so that we can initiate our investigation.

Thank you kindly,
Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
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Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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.*



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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):



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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.



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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.



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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.

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [B6]@cvcavets.com'
Sent: 4/5/2018 4:36:07 PM
Subject: FDA Case Investigation for [B6] (11 yr FS Afghan Hound)

Good afternoon Dr. [B6]
Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about [B6]'s illness.
As part of our investigation, we'd like to request:

- **Full Medical Records**
 - Please email (preferred) or fax (301-210-4685) a copy of [B6] **entire** medical history (not just this event).
- Do you have any information on the Grain Free Food, including lot or best by date?
 - Additionally, is there any open or unopened product available?

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.

Please respond to this email so that we can initiate our investigation.

Thank you kindly,
Dr. Jones

Jennifer L. A. Jones, DVM

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Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: [REDACTED] B6
CC: Ceric, Olgica; Nemser, Sarah
Sent: 6/7/2016 11:30:46 AM
Subject: FDA Follow-up for 5 [REDACTED] B6 Cats-DCM & low Taurine
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf.html; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf.html

Good morning Dr. [REDACTED] B6

We received your pet food reports for Mr. and Mrs. [REDACTED] B6 5 cats. Thank you for submitting the reports. We'd like to request the following:

- Full medical records for each cat-Please email or fax (301-210-4685) a copy to attention: Dr. Jones
- Owner interview-We'd like to speak with the owner about the cats' diet and environment just prior to the illness. The phone interview usually lasts less than 30 minutes. Please let me know if it would be okay to contact the owner.

Attached are a copy of our network procedures. They describe how veterinarians help with our case investigations. An owner friendly version is also attached.

Thank you for reporting your case to FDA.

Please email or call with questions.

Kind regards,
Jennifer

Jennifer L. A. Jones, DVM

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