

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

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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

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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

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: 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-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 inappetent 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:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>No</td> </tr> </table>	Owner Information provided:	No						
Owner Information provided:	No									
Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>University of Florida</td> </tr> <tr> <td rowspan="4">Contact:</td> <td>Name: Darcy Adin</td> </tr> <tr> <td>Phone: (614) 582-9798</td> </tr> <tr> <td>Other Phone: 3522948606</td> </tr> <tr> <td>Email: adind@ufl.edu</td> </tr> <tr> <td>Address:</td> <td>2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States</td> </tr> </table>	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
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:										

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:	<p>Problem Description: B6 was 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.</p> <p>Date Problem Started: 04/03/2019</p> <p>Concurrent Medical Problem: Yes</p> <p>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.</p> <p>Outcome to Date: Stable</p>
Product Information:	<p>Product Name: Cosequin DS</p> <p>Product Type: Other</p> <p>Lot Number:</p> <p>Product Use Information: Description: 1/2 tablet once daily as joint supplement</p> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p> <p>Product Name: Smart Bones Smart Sticks (peanut butter)</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Product Use Information: Description: 5 inch treat given once per week First Exposure Date: 01/01/2016</p> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p> <p>Product Name: Dr. Lyon's dental treat (mint)</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Product Use Information: Description: 3 inch treat fed once per week First Exposure Date: 01/01/2018</p> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p> <p>Product Name: Pedigree chicken and rice</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Product Use Information: Description: 1/4 cup fed once per day First Exposure Date: 01/01/2012</p>

		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 <ppreventcreation@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, Chondroitin, 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:	<table border="1"> <tr> <td>Problem Description:</td> <td>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.</td> </tr> <tr> <td>Date Problem Started:</td> <td>03/19/2019</td> </tr> <tr> <td>Concurrent Medical Problem:</td> <td>Yes</td> </tr> <tr> <td>Pre Existing Conditions:</td> <td>Previously diagnosed with Wobblers disease in 2012, but is not currently clinical. Patient receives Glucosamine nutramax 800mg daily, MSM nutramax 700mg daily, Chondroitin nutramax 300mg daily, and ASU nutramax 75mg daily.</td> </tr> <tr> <td>Outcome to Date:</td> <td>Stable</td> </tr> </table>	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, Chondroitin nutramax 300mg daily, and ASU nutramax 75mg daily.	Outcome to Date:	Stable																																															
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Product Information:	<table border="1"> <tr> <td>Product Name:</td> <td colspan="2">Dasuquin (Nutramax) Glucosamine, MSM, Chondroitin, ASU</td> </tr> <tr> <td>Product Type:</td> <td colspan="2">Other</td> </tr> <tr> <td>Lot Number:</td> <td colspan="2"></td> </tr> <tr> <td>Product Use Information:</td> <td>Description:</td> <td>joint supplement daily</td> </tr> <tr> <td>Manufacturer /Distributor Information:</td> <td colspan="2"></td> </tr> <tr> <td>Purchase Location Information:</td> <td colspan="2"></td> </tr> <tr> <td>Product Name:</td> <td colspan="2">Origins 6 Fish Grain Free dry</td> </tr> <tr> <td>Product Type:</td> <td colspan="2">Pet Food</td> </tr> <tr> <td>Lot Number:</td> <td colspan="2"></td> </tr> <tr> <td>Product Use Information:</td> <td>Description:</td> <td>2 cups fed twice per day</td> </tr> <tr> <td></td> <td>First Exposure Date:</td> <td>03/01/2013</td> </tr> <tr> <td></td> <td>Last Exposure Date:</td> <td>03/19/2019</td> </tr> <tr> <td></td> <td>Time Interval between Product Use and Adverse Event:</td> <td>6 Years</td> </tr> <tr> <td></td> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td></td> <td>Adverse Event Abate After Product Stop:</td> <td>Unknown</td> </tr> <tr> <td></td> <td>Product Use Started Again:</td> <td>No</td> </tr> <tr> <td></td> <td>Perceived Relatedness to Adverse Event:</td> <td>Possibly related</td> </tr> <tr> <td></td> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> <tr> <td></td> <td>Manufacturer</td> <td></td> </tr> </table>	Product Name:	Dasuquin (Nutramax) Glucosamine, MSM, Chondroitin, ASU		Product Type:	Other		Lot Number:			Product Use Information:	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:	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	
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	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 cattledog)		
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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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.

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From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification: B6

Sent: 3/19/2019 8:56:56 PM

Subject: Natural Balance LID High Protein Grain-free Lamb or Beef flavors: Lisa Freeman - EON-382772

Attachments: 2064292-report.pdf; 2064292-attachments.zip

A PFR Report has been received and PFR Event [EON-382772] has been created in the EON System.

A "PDF" report by name "2064292-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 "2064292-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382772

ICSR #: 2064292

EON Title: PFR Event created for Natural Balance LID High Protein Grain-free Lamb or Beef flavors; 2064292

AE Date	03/17/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	9 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2064292

Product Group: Pet Food

Product Name: Natural Balance LID High Protein Grain-free Lamb or Beef flavors

Description: DCM and CHF diagnosed 3/17/19 Eating BEG diet Owners have given permission to report and are willing to answer questions Changing to new diet and will recheck in 3 months Taurine and troponin 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: 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 LID High Protein Grain-free Lamb or Beef flavors		

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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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 12/27/2018 3:33:42 PM
Subject: B6

Hi Jen
B6 was euthanized on 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 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

Attending DVM: ACCESSION, NON						Order							
Client #	Client Name	Patient Name	Sex	Batch #	Invoice #	Number	Type	St	Opened Date	Time	Closed Date	Time	Current Charges
B6													

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. --

Join WebEx meeting

Meeting number (access code): [B6]

Meeting password: [B6]

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

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Can't join the meeting?

If you are a host, [go here](#) to view host information.

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

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]
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:

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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: Likley 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

x = examined

lg = liver glycogen

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- Organ
- t - testis
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- i - immature
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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 #	800.04-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/Hepatobiliary			
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

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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 synechiae 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"/>

x = examined

lg = liver glycogen

Severity codes:

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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

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/Abdominal Adipose			<input type="checkbox"/>
Salivary Gland			<input type="checkbox"/>
Pancreas			<input type="checkbox"/>
Hematopoietic/ Lymphoreticular			
Spleen	NSF	A-5-2	<input type="checkbox"/>

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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: Leptospiriosis spp.)

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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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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

Word count: 285

Character count (spaces excluded): 1825

Character count (spaces included): 1999

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			
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Cardiopulmonary			
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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"/>
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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"/>
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Salivary Gland			<input type="checkbox"/>
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Organ	Diagnosis	Slide #	Photo
Thymus			<input type="checkbox"/>
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Repro			<input type="checkbox"/>
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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: Leptospiriosis spp.)

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Date	NA	Study #	800	Initial dsr	
12/11/2015					

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Comments:

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

B6

Company: US FDA

Template: Normal.dotm

Page count: 2

Paragraph count: 117

Line count: 258

Word count: 285

Character count (spaces excluded): 1825

Character count (spaces included): 1999

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

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: [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: 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:

Lab Results Report

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

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

7/1/17

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:

3955550

B6

ER Supervisor:

B6

Discharge Instructions

Admit Date: B6 12:12:26 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:

Arrhythmias:

- ☒ 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:

- | | |
|----------------------------------------------------|-----------------------------------------------|
| <input checked="" type="checkbox"/> Echocardiogram | <input type="checkbox"/> Dialysis profile |
| <input 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:

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:

- | | |
|---------------------------------------------|---------------------------------------|
| <input type="checkbox"/> Summated | <input type="checkbox"/> Pseudonormal |
| <input type="checkbox"/> Normal | <input type="checkbox"/> Restrictive |
| <input type="checkbox"/> Delayed relaxation | |

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:

- | | |
|----------------------------------------|-------------------------------|
| <input checked="" type="checkbox"/> Ia | <input type="checkbox"/> IIIa |
| <input type="checkbox"/> Ib | <input type="checkbox"/> IIIb |
| <input type="checkbox"/> II | |

ACVIM Classification:

- | | |
|------------------------------------------|----------------------------|
| <input checked="" type="checkbox"/> A vs | <input type="checkbox"/> C |
| <input checked="" type="checkbox"/> B1 | <input type="checkbox"/> D |
| <input type="checkbox"/> B2 | |

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	
LVID LAX	cm
LVAd LAX	cm
LVEDV A-L LAX	ml

B6

LVEDV MOD LAX
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
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=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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From: RFR Event [mailto:rpreventcreation@fda.hhs.gov]
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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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 Veg 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

=====

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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:	<table border="1"> <tr> <td>Name:</td><td>Lisa Freeman</td></tr> <tr> <td>Phone:</td><td>(508) 887-4523</td></tr> <tr> <td>Email:</td><td>lisa.freeman@tufts.edu</td></tr> </table>	Name:	Lisa Freeman	Phone:	(508) 887-4523
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					
Additional Documents:	Preferred Method Of Contact:	Email					
	Attachment:	B6	compiled records.pdf				
	Description:	B6	compiled medical records				
	Type:	Medical Records					

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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you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

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:	<p>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.</p> <p>Date Problem Started: B6</p> <p>Concurrent Medical Problem: No</p> <p>Outcome to Date: Worse/Declining/Deteriorating</p>																		
Product Information:	<p>Product Name: Blue Buffalo Wilderness- High Protein Grain Free Natures Evolutionary Diet- with Chicken Life Source bits- Senior</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Package Type: BAG</p> <p>Package Size: 24 Pound</p> <p>Purchase Date: 08/20/2018</p> <p>Possess Unopened Product: No</p> <p>Possess Opened Product: No</p> <p>Storage Conditions: Plastic container</p> <p>Product Use Information:</p> <table> <tr> <td>Description:</td><td>Daily food</td></tr> <tr> <td>First Exposure Date:</td><td>08/20/2018</td></tr> <tr> <td>Last Exposure Date:</td><td>B6</td></tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td><td>9 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>Not Applicable</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:	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
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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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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-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:	<table><tr><td>Problem Description:</td><td colspan="2">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.</td></tr><tr><td>Date Problem Started:</td><td colspan="2">12/26/2017</td></tr><tr><td>Concurrent Medical Problem:</td><td colspan="2">No</td></tr><tr><td>Outcome to Date:</td><td colspan="2">Died Naturally</td></tr><tr><td>Date of Death:</td><td colspan="2">[B6]</td></tr></table>			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]																			
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Product Information:	<table><tr><td>Product Name:</td><td colspan="2">Core Wellness Ocean Formula</td></tr><tr><td>Product Type:</td><td colspan="2">Pet Food</td></tr><tr><td>Lot Number:</td><td colspan="2"></td></tr><tr><td>Package Type:</td><td colspan="2">BAG</td></tr><tr><td>Possess Unopened Product:</td><td colspan="2">No</td></tr><tr><td>Possess Opened Product:</td><td colspan="2">No</td></tr><tr><td>Product Use Information:</td><td colspan="2"><table><tr><td>Description:</td><td>Fed to dog for 11+ years</td></tr><tr><td>Product Use Stopped After the Onset of the Adverse Event:</td><td>No</td></tr><tr><td>Perceived Relatedness to Adverse Event:</td><td>Possibly related</td></tr></table></td></tr><tr><td>Manufacturer /Distributor Information:</td><td colspan="2"></td></tr><tr><td>Purchase Location Information:</td><td>Address:</td><td>Canada</td></tr></table>			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:	<table><tr><td>Description:</td><td>Fed to dog for 11+ years</td></tr><tr><td>Product Use Stopped After the Onset of the Adverse Event:</td><td>No</td></tr><tr><td>Perceived Relatedness to Adverse Event:</td><td>Possibly related</td></tr></table>		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
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Perceived Relatedness to Adverse Event:	Possibly related																																			
Manufacturer /Distributor Information:																																				
Purchase Location Information:	Address:	Canada																																		
Animal Information:	<table><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Type Of Species:</td><td>Dog</td></tr><tr><td>Type Of Breed:</td><td>Pug</td></tr><tr><td>Gender:</td><td>Female</td></tr><tr><td>Reproductive Status:</td><td>Neutered</td></tr><tr><td>Weight:</td><td>19 Pound</td></tr><tr><td>Age:</td><td>11 Years</td></tr><tr><td>Assessment of Prior</td><td>Good</td></tr></table>			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																	
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Type Of Species:	Dog																																			
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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:	<div style="border: 1px solid black; padding: 5px; text-align: center;"> <h1>B6</h1> </div> 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:		

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:
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:		

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:	<table><tr><td>Problem Description:</td><td colspan="2">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</td></tr><tr><td>Date Problem Started:</td><td colspan="2">B6</td></tr><tr><td>Concurrent Medical Problem:</td><td colspan="2">Yes</td></tr><tr><td>Pre Existing Conditions:</td><td colspan="2">Atopy (on Atopica)</td></tr><tr><td>Outcome to Date:</td><td colspan="2">Stable</td></tr></table>			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																																																	
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Animal Information:	<table><tr><td>Name:</td><td colspan="2">B6</td></tr><tr><td>Type Of Species:</td><td colspan="2">Dog</td></tr><tr><td>Type Of Breed:</td><td colspan="2">Retriever - Labrador</td></tr><tr><td>Gender:</td><td colspan="2">Male</td></tr><tr><td>Reproductive Status:</td><td colspan="2">Neutered</td></tr><tr><td>Weight:</td><td colspan="2">37.7 Kilogram</td></tr><tr><td>Age:</td><td colspan="2">7 Years</td></tr><tr><td>Assessment of Prior Health:</td><td colspan="2">Good</td></tr><tr><td>Number of Animals Given the Product:</td><td colspan="2">1</td></tr><tr><td>Number of Animals Reacted:</td><td colspan="2">1</td></tr><tr><td>Owner Information:</td><td colspan="2"><table><tr><td>Owner Information provided:</td><td colspan="2">Yes</td></tr><tr><td>Contact:</td><td colspan="2"><table><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td>B6</td></tr><tr><td>Email:</td><td>B6</td></tr></table></td></tr><tr><td>Address:</td><td colspan="2"><table><tr><td>B6</td></tr><tr><td>United States</td></tr></table></td></tr></table></td></tr><tr><td>Healthcare Professional Information:</td><td colspan="2"><table><tr><td>Practice Name:</td><td colspan="2">Tufts Cummings School of Veterinary Medicine</td></tr><tr><td>Contact:</td><td colspan="2"><table><tr><td>Name:</td><td>Lisa Freeman</td></tr><tr><td>Phone:</td><td>(508) 887-4523</td></tr></table></td></tr></table></td></tr></table>			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:	<table><tr><td>Owner Information provided:</td><td colspan="2">Yes</td></tr><tr><td>Contact:</td><td colspan="2"><table><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td>B6</td></tr><tr><td>Email:</td><td>B6</td></tr></table></td></tr><tr><td>Address:</td><td colspan="2"><table><tr><td>B6</td></tr><tr><td>United States</td></tr></table></td></tr></table>		Owner Information provided:	Yes		Contact:	<table><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td>B6</td></tr><tr><td>Email:</td><td>B6</td></tr></table>		Name:	B6	Phone:	B6	Email:	B6	Address:	<table><tr><td>B6</td></tr><tr><td>United States</td></tr></table>		B6	United States	Healthcare Professional Information:	<table><tr><td>Practice Name:</td><td colspan="2">Tufts Cummings School of Veterinary Medicine</td></tr><tr><td>Contact:</td><td colspan="2"><table><tr><td>Name:</td><td>Lisa Freeman</td></tr><tr><td>Phone:</td><td>(508) 887-4523</td></tr></table></td></tr></table>		Practice Name:	Tufts Cummings School of Veterinary Medicine		Contact:	<table><tr><td>Name:</td><td>Lisa Freeman</td></tr><tr><td>Phone:</td><td>(508) 887-4523</td></tr></table>		Name:	Lisa Freeman	Phone:	(508) 887-4523
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			Email: lisa.freeman@tufts.edu
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Sender Information:	Name:	Lisa Freeman	
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	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	

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)																																																																
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Report Submission Date:	2018-10-08 14:34:26 EDT																																																																
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			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	

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:			
Animal Information:	Purchase Location 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	
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	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		

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	
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	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	



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

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



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: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 8/5/2018 1:32:12 AM
Subject: Acana Pork and Squash; B6 EON-361371
Attachments: 2053236-report.pdf

A PFR Report has been received and PFR Event [EON-361371] has been created in the EON System.

A "PDF" report by name "2053236-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-361371

ICSR #: 2053236

EON Title: PFR Event created for Acana Pork and Squash; 2053236

AE Date	04/12/2016	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2053236

Product Group: Pet Food

Product Name: Acana Pork and Squash

Description: This is not an event that suddenly occurred. My dog was diagnosed with dilated cardiomyopathy at 2 years old. I enrolled him in the taurine deficient study done by Dr. Joshua Stern at UC Davis. He was eating Acana Pork & Squash since he was a puppy. His taurine was tested (4-18) and his whole blood is 135 and plasma 28. Since his taurine level is low, I was told to supplement him with taurine and take him off the current dog food. I was told his food could cause taurine deficient dilated cardiomyopathy. He will be re-tested in the upcoming months. It is not know at this time if the dog food contributed to his disease or caused it. The study is still on going.

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: Unknown

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Pork and Squash		

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-361371

ICSR:	2053236		
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:	2018-08-04 21:25:50 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	This is not an event that suddenly occurred. My dog was diagnosed with dilated cardiomyopathy at 2 years old. I enrolled him in the taurine deficient study done by Dr. Joshua Stern at UC Davis. He was eating Acana Pork & Squash since he was a puppy. His taurine was tested (4-18) and his whole blood is 135 and plasma 28. Since his taurine level is low, I was told to supplement him with taurine and take him off the current dog food. I was told his food could cause taurine deficient dilated cardiomyopathy. He will be re-tested in the upcoming months. It is not know at this time if the dog food contributed to his disease or caused it. The study is still on going.	
	Date Problem Started:	04/12/2016	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Unknown	
Product Information:	Product Name:	Acana Pork and Squash	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	05/29/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	The product is stored in it's original bag and then placed in a air tight container.	
	Product Use Information:	Description:	The product was feed 2xs per day.
		Last Exposure Date:	07/15/2018
		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:	Name:	Pet Valu
		Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div> United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	67 Pound	
	Age:	4 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: Phone:
		Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div> United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	04/19/2016
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div> United States	
	Contact:	Phone: Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Store/Place of Purchase Manufacturer	
Additional Documents:			

Report Details - EON-367777

ICSR:	2055744																																												
Type Of Submission:	Initial																																												
Report Version:	FPSR.FDA.PETF.V.V1																																												
Type Of Report:	Both																																												
Reporting Type:	Voluntary																																												
Report Submission Date:	2018-10-06 21:13:52 EDT																																												
Reporter is the Animal Owner:	Yes																																												
Reported Problem:	<p>Problem 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] On [B6] despite all efforts, [B6] was euthanized as he was not responding to treatments.</p> <p>Date Problem Started: [B6]</p> <p>Concurrent Medical Problem: Yes</p> <p>Pre Existing Conditions: He has seasonal and indoor allergies and was on Apoquel and Allergy injections. He may have had food allergies. He was placed on the grain free food 3-4 years ago. He was health and active. He was on ACANA SINGLES LIMITED INGREDIENT LAMB AMD APPLE AND SOMETIMES DUCK AND PEAR FOR THE PAST 3-4 YEARS EXCLUSIVELY.</p> <p>Outcome to Date: Died Euthanized</p> <p>Date of Death: [B6]</p>																																												
Product Information:	<table><tr><td>Product Name:</td><td colspan="2">Acana Singles Limited Ingredient Lamb and Apple 25 pound bag</td></tr><tr><td>Product Type:</td><td colspan="2">Pet Food</td></tr><tr><td>Lot Number:</td><td colspan="2"></td></tr><tr><td>Package Type:</td><td colspan="2">BAG</td></tr><tr><td>Package Size:</td><td colspan="2">25 Pound</td></tr><tr><td>Purchase Date:</td><td colspan="2">07/25/2018</td></tr><tr><td>Number Purchased:</td><td colspan="2">1</td></tr><tr><td>Possess Unopened Product:</td><td colspan="2">No</td></tr><tr><td>Possess Opened Product:</td><td colspan="2">Yes</td></tr><tr><td>Storage Conditions:</td><td colspan="2">The product was stored in an airtight and waterproof container in the basement. A weeks worth of food was put in an airtight container on the kitchen.</td></tr><tr><td>Product Use Information:</td><td>Description:</td><td>[B6] ate 1 1/4 cup divided into two meals per day.</td></tr><tr><td></td><td>Last Exposure Date:</td><td>[B6]</td></tr><tr><td></td><td>Time Interval between Product Use and Adverse Event:</td><td>4 Years</td></tr><tr><td></td><td>Product Use Stopped After the Onset of the Adverse Event:</td><td>Yes</td></tr></table>			Product Name:	Acana Singles Limited Ingredient Lamb and Apple 25 pound bag		Product Type:	Pet Food		Lot Number:			Package Type:	BAG		Package Size:	25 Pound		Purchase Date:	07/25/2018		Number Purchased:	1		Possess Unopened Product:	No		Possess Opened Product:	Yes		Storage Conditions:	The product was stored in an airtight and waterproof container in the basement. A weeks worth of food was put in an airtight container on the kitchen.		Product Use Information:	Description:	[B6] ate 1 1/4 cup divided into two meals per day.		Last Exposure Date:	[B6]		Time Interval between Product Use and Adverse Event:	4 Years		Product Use Stopped After the Onset of the Adverse Event:	Yes
Product Name:	Acana Singles Limited Ingredient Lamb and Apple 25 pound bag																																												
Product Type:	Pet Food																																												
Lot Number:																																													
Package Type:	BAG																																												
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Possess Unopened Product:	No																																												
Possess Opened Product:	Yes																																												
Storage Conditions:	The product was stored in an airtight and waterproof container in the basement. A weeks worth of food was put in an airtight container on the kitchen.																																												
Product Use Information:	Description:	[B6] ate 1 1/4 cup divided into two meals per day.																																											
	Last Exposure Date:	[B6]																																											
	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:	Not Applicable
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Perflow.com
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Spaniel - Cocker American	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	28 Pound	
	Age:	5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
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:	Phone	
	Reported to Other Parties:	Other	
Additional Documents:			

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6].com
Sent: 10/26/2018 11:32:24 AM
Subject: Blue Wilderness; [B6] EON-369415
Attachments: 2058021-report.pdf

A PFR Report has been received and PFR Event [EON-369415] has been created in the EON System.

A "PDF" report by name "2058021-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-369415

ICSR #: 2058021

EON Title: PFR Event created for Blue Wilderness; 2058021

AE Date	01/01/2016	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Retriever - Labrador		
Age	11 Years		
District Involved	PFR; [B6] DO		

Product information

Individual Case Safety Report Number: 2058021

Product Group: Pet Food

Product Name: Blue Wilderness

Description: When the dog was 9 years old she started limping periodically. Had some gas. I looked for a grain free, soy free food with glucosamine. We decided on Blue Wilderness. In two years the dog had to be Euthanized for a enlarged heart/congestive heart failure.

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
Blue Wilderness		

Sender information

B6

USA

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B6

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Report Details - EON-369415		
ICSR:	2058021	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-10-26 07:25:05 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description:	When the dog was 9 years old she started limping periodically. Had some gas. I looked for a grain free, soy free food with glucosamine. We decided on Blue Wilderness. In two years the dog had to be Euthanized for a enlarged heart /congestive heart failure.
	Date Problem Started:	01/01/2016
	Concurrent Medical Problem:	Unknown
	Outcome to Date:	Died Euthanized
	Date of Death:	B6
Product Information:	Product Name:	Blue Wilderness
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BOX
	Package Size:	35 Pound
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Dog food container
	Product Use Information:	Description: Fed 2x's per day total of 4 cups
		Perceived Relatedness to Adverse Event: Probably related
Animal Information:	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Labrador
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	70 Pound
	Age:	11 Years
	Assessment of Prior Health:	Good
Sender Information:	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
	Name:	B6

	Address:	<div>B6</div> <div>United States</div>	
	Contact:	Phone:	<div>B6</div>
		Email:	<div>B6</div>
	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: Cleary, Michael *; HQ Pet Food Report Notification; [B6] com

Sent: 10/25/2018 8:01:06 PM

Subject: Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb-Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free-Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato [B6] - EON-369375

Attachments: 2057993-report.pdf; 2057993-attachments.zip

A PFR Report has been received and PFR Event [EON-369375] has been created in the EON System.

A "PDF" report by name "2057993-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 "2057993-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-369375

ICSR #: 2057993

EON Title: PFR Event created for Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato; 2057993

AE Date	10/02/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	4 Years		
District Involved	PFR- [B6] DO		

Product information

Individual Case Safety Report Number: 2057993

Product Group: Pet Food

Product Name: Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato

Description: 02 Oct 2018 - presented for routine exam. A new grade II/VI murmur was noted. 13 Oct 2018 -

presented to a different veterinarian for 2nd opinion for the heart murmur. Chest rads revealed cardiomegaly but no signs of heart failure. A limited cardiac ultrasound revealed dilatation of all 4 heart chambers with poor myocardial contractility. Suspected grain free diet DCM. Changed diet to Purina Pro Plan Lamb and Rice. Rx: L-Carnitine 1 g BID, Taurine 500 mg BID and referred to **B6** for further work up. 17 Oct 2018: Grade II/VI left apical systolic murmur ausculted; no arrhythmias. Echocardiogram revealed mildly dilated left and right atria, moderately dilated left ventricle, decreased LV systolic function. Elevated left filling pressures based on doppler. Blood pressure, thyroid panel, platelet count and troponin levels all normal. Blood submitted for taurine level sent to **B6** still pending 25 Oct 2018. Diagnosis: Dilated Cardiomyopathy.

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

Product Name	Lot Number or ID	Best By Date
Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato		

Sender information

B6

USA

Owner information

B6

USA

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

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Report Details - EON-369375						
ICSR:	2057993					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Both					
Reporting Type:	Voluntary					
Report Submission Date:	2018-10-25 15:47:25 EDT					
Reported Problem:	Problem Description:	02 Oct 2018 - presented for routine exam. A new grade II/VI murmur was noted. 13 Oct 2018 - presented to a different veterinarian for 2nd opinion for the heart murmur. Chest rads revealed cardiomegaly but no signs of heart failure. A limited cardiac ultrasound revealed dilatation of all 4 heart chambers with poor myocardial contractility. Suspected grain free diet DCM. Changed diet to Purina Pro Plan Lamb and Rice. Rx: L-Carnitine 1 g BID, Taurine 500 mg BID and referred to [B6] for further work up. 17 Oct 2018: Grade II/VI left apical systolic murmur ausculted; no arrhythmias. Echocardiogram revealed mildly dilated left and right atria, moderately dilated left ventricle, decreased LV systolic function. Elevated left filling pressures based on doppler. Blood pressure, thyroid panel, platelet count and troponin levels all normal. Blood submitted for taurine level sent to [B6] still pending 25 Oct 2018. Diagnosis: Dilated Cardiomyopathy.				
	Date Problem Started:	10/02/2018				
	Concurrent Medical Problem:	No				
	Outcome to Date:	Stable				
Product Information:	Product Name:	Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov 2017-Aug 2018: Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato				
	Product Type:	Pet Food				
	Lot Number:					
	Package Type:	BAG				
	Package Size:	14 Pound				
	Possess Unopened Product:	No				
	Possess Opened Product:	Yes				
	Storage Conditions:	Room temperature in kitchen pantry				
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>Oral administration</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> </table>	Description:	Oral administration	Perceived Relatedness to Adverse Event:	Probably related
	Description:	Oral administration				
Perceived Relatedness to Adverse Event:	Probably related					
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:	15.9 Kilogram				
	Age:	4 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:	<div style="border: 1px solid black; padding: 10px; text-align: center;"> <h1>B6</h1> </div> United States		
Healthcare Professional Information:	Practice Name:	B6		
	Contact:	Name:	B6	
		Phone:	B6	
	Type of Veterinarian:	Primary/regular veterinarian		
	Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6		
	Address:	<div style="border: 1px solid black; padding: 10px; text-align: center;"> <h1>B6</h1> </div> 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:	Attachment:	B6 10.21.2018.pdf		
	Description:	All medical records		
	Type:	Medical Records		

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 10/25/2018 5:16:28 PM
Subject: taste of the wild grain free pacific stream-taste of the wild prey trout limited ingredients: [B6] EON-369346
Attachments: 2057985-report.pdf; 2057985-attachments.zip

A PFR Report has been received and PFR Event [EON-369346] has been created in the EON System.

A "PDF" report by name "2057985-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 "2057985-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-369346

ICSR #: 2057985

EON Title: PFR Event created for taste of the wild grain free pacific stream taste of the wild prey trout limited ingredients; 2057985

AE Date	[B6]	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Dogue de Bordeaux		
Age	8 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2057985

Product Group: Pet Food

Product Name: taste of the wild grain free pacific stream taste of the wild prey trout limited ingredients

Description: [B4, B6] .Has been eating Taste of the wild grain free for about 5 years. [B6] had to be rushed to cardiologist and diagnosed with dcm dilated cardiomyopathy. Have full vet report and findings. He is still not recovered and we are unsure where this is going to end up

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: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
taste of the wild grain free pacific stream taste of the wild prey trout limited ingredients		

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-369346

ICSR:	2057985		
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:	2018-10-25 13:10:59 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	B6 Has been eating Taste of the wild grain free for about 5 years. 10/24/18 had to be rushed to cardiologist and diagnosed with dcm dilated cardiomyopathy. Have full vet report and findings. He is still not recovered and we are unsure where this is going to end up	
	Date Problem Started:	B6	
	Date of Recovery:	10/24/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	taste of the wild grain free pacific stream taste of the wild prey trout limited ingredients	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Purchase Date:	10/02/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Cool dry place	
	Product Use Information:	Description:	Recommended feeding for all three of our dogs
		First Exposure Date:	10/03/2018
		Last Exposure Date:	10/23/2018
		Time Interval between Product Use and Adverse Event:	5 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:	Probably related
		Other Foods or Products Given to the Animal During This Time Period:	Yes

	Manufacturer /Distributor Information:			
	Purchase Location Information:	Name:	B6	
		Address:	United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Dogue de Bordeaux		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Age:	8 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	3		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact: Name:	B6	
		Phone:	B6	
		Email:	B6	
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	10/24/2018	
		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		
Additional Documents:	Preferred Method Of Contact:	Email		
	Attachment:	B6	102418_5.pdf	
	Description:	vet finding		
	Type:	Article		
	Attachment:	B6	102418_4.pdf	
	Description:	vet findings		
	Type:	Article		

Attachment:

B6

102418_1.pdf

Description: vet findings

Type: Article

B4, B6

♥ Health Status

Date/Time

B6 2:44:01pm

Weight (lb)

B6

Heart Rate

Attitude

QAR

*** PLEASE DO NOT RUN OUT OF MEDICATIONS ***

Date/Time

B6

Drug Name

Qty Instructions

Prescribed By

B4, B6 DVM, MS,
DACVIM, DECVIM

B6

B4, B6 DVM, MS,
DACVIM, DECVIM

B6

B4, B6 DVM, MS,
DACVIM, DECVIM

B6

👤 Diagnostic Result

ECG - Electrocardiogram - 10 lead (Ref: US10393-DR6381)

Normal sinus rhythm

No evidence of supra and ventricular arrhythmia

Left ventricle enlargement pattern

Echocardiogram by cardiologist (Ref: US10393-DR6377)

Decreased systolic function, dilated Left Ventricle

Mild to moderate Mitral Valve Regurgitation due to dilatation, with mild left atrial enlargement

Mild tricuspid regurgitation with mild right atrial enlargement and no pulmonary hypertension

No Pericardial effusion

Report Details - EON-369325

ICSR:	2057945		
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:	2018-10-25 07:45:50 EDT		
Reported Problem:	Problem Description:	DCM, CHF, atrial fibrillation WB taurine = 260 Dog's diet previously submitted to FDA Note: this may be a duplicate submission	
	Date Problem Started:	02/20/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Naturally	
	Date of Death:	B6	
Product Information:	Product Name:	Taste of the Wild High Prairie	
	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:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	74 Kilogram	
	Age:	9 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:	B4, B6
		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:	Records
	Type:	Medical Records

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 10/25/2018 7:36:40 PM
Subject: WELLNESS CORE GRAIN FREE: [B6] - EON-369373
Attachments: 2057992-report.pdf

A PFR Report has been received and PFR Event [EON-369373] has been created in the EON System.

A "PDF" report by name "2057992-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-369373

ICSR #: 2057992

EON Title: PFR Event created for WELLNESS CORE GRAIN FREE, NULO GRAIN FREE, BLUE BUFFALO GRAIN FREE; 2057992

AE Date	10/22/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Schnauzer - Miniature		
Age	10.5 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2057992

Product Group: Pet Food

Product Name: WELLNESS CORE GRAIN FREE, NULO GRAIN FREE, BLUE BUFFALO GRAIN FREE

Description: CHEST RADIOGRAPHS REVEALED AN ENLARGED HEART

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
BLUE BUFFALO GRAIN FREE		
WELLNESS CORE GRAIN FREE		
NULO GRAIN FREE		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

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Report Details - EON-369373

ICSR:	2057992		
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:	2018-10-25 15:26:17 EDT		
Reported Problem:	Problem Description:	CHEST RADIOGRAPHS REVEALED AN ENLARGED HEART	
	Date Problem Started:	10/22/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	BLUE BUFFALO GRAIN FREE	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	Unknown	
	Possess Opened Product:	Unknown	
	Storage Conditions:	UNKNOWN	
	Product Use Information:	Description:	ORALLY
		Product Use Stopped After the Onset of the Adverse Event:	Unknown
		Perceived Relatedness to Adverse Event:	Possibly related
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	NULO GRAIN FREE	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	Unknown	
	Possess Opened Product:	Unknown	
	Storage Conditions:	UNKNOWN	
	Product Use Information:	Description:	ORALLY
		Product Use Stopped After the Onset of the Adverse Event:	Unknown
		Perceived Relatedness to Adverse Event:	Possibly related
	Manufacturer /Distributor Information:		
	Purchase Location Information:		

	Product Name:	WELLNESS CORE GRAIN FREE		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	Unknown		
	Possess Opened Product:	Unknown		
	Storage Conditions:	UNKNOWN		
	Product Use Information:	Description:	ORALLY	
		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:	Unknown	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
	Animal Information:	Name:	B6	
Type Of Species:		Dog		
Type Of Breed:		Schnauzer - Miniature		
Gender:		Female		
Reproductive Status:		Neutered		
Weight:		16.3 Pound		
Age:		10.5 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:				
Sender Information:	Name:	B6		
	Address:	B6		

		<div>B6</div> United States	
	Contact:	Phone: <div>B6</div>	
		Other Phone: <div>B6</div>	
		Email: <div>B6</div>	
	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 <pfrpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]

Sent: 12/5/2018 4:44:22 PM

Subject: Acana dog food. Varying diet/formulas over the past [B6] years. [B6]
EON-372923

Attachments: 2059678-report.pdf

A PFR Report has been received and PFR Event [EON-372923] has been created in the EON System.

A "PDF" report by name "2059678-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-372923

ICSR #: 2059678

EON Title: PFR Event created for Acana dog food. Varying diet/formulas over the past [B6] years.; 2059678

AE Date	09/01/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Mastiff		
Age	[B6] Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2059678

Product Group: Pet Food

Product Name: Acana dog food. Varying diet/formulas over the past [B6] years.

Description: Since approximately Sept 2018, we noticed [B6] had an occasional cough/throat clearing noise.

We mentioned this during vet visits, but our vets didn't seem concerned. On [B6] we rushed

[B6] to the emergency vet due to weakness and inability to stand and while there he had chest X-rays taken which showed "an extremely large heart?". The on duty vet performed an ultrasound and noted how hard his heart was working to pump blood. He inquired about the food we feed him and if it was grain free. After finding out it was, he alerted us to new findings regarding grain free diets and dilated cardiomyopathy. He suggested we contact the FDA to report the findings. Unfortunately, [B6] did not recover and passed away early [B6]

B6

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: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana dog food. Varying diet/formulas over the past B6 years.		

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-372923

ICSR:	2059678																																					
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:	2018-12-05 11:36:30 EST																																					
Reporter is the Animal Owner:	Yes																																					
Reported Problem:	<table><tr><td>Problem Description:</td><td colspan="2">Since approximately Sept 2018, we noticed [B6] had an occasional cough /throat clearing noise. We mentioned this during vet visits, but our vets didnt seem concerned. On [B6] we rushed [B6] to the emergency vet due to weakness and inability to stand and while there he had chest X-rays taken which showed an extremely large heart. The on duty vet performed an ultrasound and noted how hard his heart was working to pump blood. He inquired about the food we feed him and if it was grain free. After finding out it was, he alerted us to new findings regarding grain free diets and dilated cardiomyopathy. He suggested we contact the FDA to report the findings. Unfortunately, [B6] did not recover and passed away early [B6]</td></tr><tr><td>Date Problem Started:</td><td colspan="2">09/01/2018</td></tr><tr><td>Concurrent Medical Problem:</td><td colspan="2">Yes</td></tr><tr><td>Pre Existing Conditions:</td><td colspan="2">Prednisone</td></tr><tr><td>Outcome to Date:</td><td colspan="2">Died Euthanized</td></tr><tr><td>Date of Death:</td><td colspan="2">[B6]</td></tr></table>			Problem Description:	Since approximately Sept 2018, we noticed [B6] had an occasional cough /throat clearing noise. We mentioned this during vet visits, but our vets didnt seem concerned. On [B6] we rushed [B6] to the emergency vet due to weakness and inability to stand and while there he had chest X-rays taken which showed an extremely large heart. The on duty vet performed an ultrasound and noted how hard his heart was working to pump blood. He inquired about the food we feed him and if it was grain free. After finding out it was, he alerted us to new findings regarding grain free diets and dilated cardiomyopathy. He suggested we contact the FDA to report the findings. Unfortunately, [B6] did not recover and passed away early [B6]		Date Problem Started:	09/01/2018		Concurrent Medical Problem:	Yes		Pre Existing Conditions:	Prednisone		Outcome to Date:	Died Euthanized		Date of Death:	[B6]																		
Problem Description:	Since approximately Sept 2018, we noticed [B6] had an occasional cough /throat clearing noise. We mentioned this during vet visits, but our vets didnt seem concerned. On [B6] we rushed [B6] to the emergency vet due to weakness and inability to stand and while there he had chest X-rays taken which showed an extremely large heart. The on duty vet performed an ultrasound and noted how hard his heart was working to pump blood. He inquired about the food we feed him and if it was grain free. After finding out it was, he alerted us to new findings regarding grain free diets and dilated cardiomyopathy. He suggested we contact the FDA to report the findings. Unfortunately, [B6] did not recover and passed away early [B6]																																					
Date Problem Started:	09/01/2018																																					
Concurrent Medical Problem:	Yes																																					
Pre Existing Conditions:	Prednisone																																					
Outcome to Date:	Died Euthanized																																					
Date of Death:	[B6]																																					
Product Information:	<table><tr><td>Product Name:</td><td colspan="2">Acana dog food. Varying diet/formulas over the past [B6] years.</td></tr><tr><td>Product Type:</td><td colspan="2">Pet Food</td></tr><tr><td>Lot Number:</td><td colspan="2"></td></tr><tr><td>Package Type:</td><td colspan="2">BAG</td></tr><tr><td>Package Size:</td><td colspan="2">25 Pound</td></tr><tr><td>Storage Conditions:</td><td colspan="2">Sealed container</td></tr><tr><td>Product Use Information:</td><td colspan="2"><table><tr><td>First Exposure Date:</td><td>03/17/2014</td></tr><tr><td>Last Exposure Date:</td><td>[B6]</td></tr><tr><td>Perceived Relatedness to Adverse Event:</td><td>Probably related</td></tr><tr><td>Other Foods or Products Given to the Animal During This Time Period:</td><td>No</td></tr></table></td></tr><tr><td>Manufacturer /Distributor Information:</td><td colspan="2"></td></tr><tr><td>Purchase Location Information:</td><td colspan="2"></td></tr></table>			Product Name:	Acana dog food. Varying diet/formulas over the past [B6] years.		Product Type:	Pet Food		Lot Number:			Package Type:	BAG		Package Size:	25 Pound		Storage Conditions:	Sealed container		Product Use Information:	<table><tr><td>First Exposure Date:</td><td>03/17/2014</td></tr><tr><td>Last Exposure Date:</td><td>[B6]</td></tr><tr><td>Perceived Relatedness to Adverse Event:</td><td>Probably related</td></tr><tr><td>Other Foods or Products Given to the Animal During This Time Period:</td><td>No</td></tr></table>		First Exposure Date:	03/17/2014	Last Exposure Date:	[B6]	Perceived Relatedness to Adverse Event:	Probably related	Other Foods or Products Given to the Animal During This Time Period:	No	Manufacturer /Distributor Information:			Purchase Location Information:		
Product Name:	Acana dog food. Varying diet/formulas over the past [B6] years.																																					
Product Type:	Pet Food																																					
Lot Number:																																						
Package Type:	BAG																																					
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Product Use Information:	<table><tr><td>First Exposure Date:</td><td>03/17/2014</td></tr><tr><td>Last Exposure Date:</td><td>[B6]</td></tr><tr><td>Perceived Relatedness to Adverse Event:</td><td>Probably related</td></tr><tr><td>Other Foods or Products Given to the Animal During This Time Period:</td><td>No</td></tr></table>		First Exposure Date:	03/17/2014	Last Exposure Date:	[B6]	Perceived Relatedness to Adverse Event:	Probably related	Other Foods or Products Given to the Animal During This Time Period:	No																												
First Exposure Date:	03/17/2014																																					
Last Exposure Date:	[B6]																																					
Perceived Relatedness to Adverse Event:	Probably related																																					
Other Foods or Products Given to the Animal During This Time Period:	No																																					
Manufacturer /Distributor Information:																																						
Purchase Location Information:																																						
Animal Information:	<table><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Type Of Species:</td><td>Dog</td></tr><tr><td>Type Of Breed:</td><td>Mastiff</td></tr><tr><td>Gender:</td><td>Male</td></tr><tr><td>Reproductive Status:</td><td>Neutered</td></tr><tr><td>Weight:</td><td>200 Pound</td></tr><tr><td>Age:</td><td>[B6] years</td></tr><tr><td>Assessment of Prior</td><td>Good</td></tr></table>			Name:	[B6]	Type Of Species:	Dog	Type Of Breed:	Mastiff	Gender:	Male	Reproductive Status:	Neutered	Weight:	200 Pound	Age:	[B6] years	Assessment of Prior	Good																			
Name:	[B6]																																					
Type Of Species:	Dog																																					
Type Of Breed:	Mastiff																																					
Gender:	Male																																					
Reproductive Status:	Neutered																																					
Weight:	200 Pound																																					
Age:	[B6] years																																					
Assessment of Prior	Good																																					

	Health:		
	Number of Animals Given the Product:	3	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6 Phone: B6
	Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	None	
Additional Documents:			

From: PFR Event <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification B6
Sent: 12/4/2018 10:17:32 PM
Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372804
Attachments: 2059619-report.pdf; 2059619-attachments.zip

A PFR Report has been received and PFR Event [EON-372804] has been created in the EON System.

A "PDF" report by name "2059619-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 "2059619-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372804

ICSR #: 2059619

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059619

AE Date	11/21/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2059619

Product Group: Pet Food

Product Name: Earthborn Meadow Feast dry

Description: Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

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: 5

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

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

=====

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Report Details - EON-372804				
ICSR:	2059619			
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:	2018-12-04 17:08:36 EST			
Reported Problem:	Problem Description:	Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months		
	Date Problem Started:	11/21/2018		
	Concurrent Medical Problem:	Yes		
	Pre Existing Conditions:	History of resection of jejunum and ileum due to intussusception as puppy		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Earthborn Meadow Feast dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	Description:	See diet history	
		First Exposure Date:	02/01/2018	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Boxer (German Boxer)		
	Gender:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not pregnant		
	Lactation Status:	Not lactating		
	Weight:	27.4 Kilogram		
	Age:	3 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	5		
	Number of Animals Reacted:	4		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name:	B6
			Phone:	
Email:				
Address:		B6		
	United States			

	Healthcare Professional Information:	Practice Name: Tufts Cummings School of Veterinary Medicine Contact: <table border="1"> <tr> <td>Name:</td> <td>Lisa Freeman</td> </tr> <tr> <td>Phone:</td> <td>(508) 887-4523</td> </tr> <tr> <td>Email:</td> <td>lisa.freeman@tufts.edu</td> </tr> </table> Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States	Name:	Lisa Freeman	Phone:	(508) 887-4523	Email:	lisa.freeman@tufts.edu
Name:	Lisa Freeman							
Phone:	(508) 887-4523							
Email:	lisa.freeman@tufts.edu							
Sender Information:	Name: Address: Contact: Permission To Contact Sender: Preferred Method Of Contact:	Lisa Freeman 200 Westboro Rd North Grafton Massachusetts 01536 United States Phone: 5088874523 Email: lisa.freeman@tufts.edu Yes Email						
Additional Documents:	Attachment: Description: Type:	compiled medical records B6 pdf Medical records Medical Records						

B6

Client:

Address:

B6

All Medical Records

Patient:

B6

Breed: Boxer

DOB:

B6

Species: Canine

Sex: Female

Home Phone:

Work Phone:

Cell Phone: (

B6

Referring Information

B6

Initial Complaint:

Scanned Record

SOAP Text Nov 20 2018 12:24PM - Clinician, Unassigned

B6

Initial Complaint:

DCM study

SOAP Text Nov 20 2018 1:12PM -

B6

Disposition/Recommendations

Client:
Patient:

B6

Client:
Patient:

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Client: **B6**
Veterinarian:
Patient ID: 345628
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Boxer
Sex:	Female
Age:	B6 years Old

Lab Results Report

11/20/2018 5:45:57 PM

Accession ID: **B6**

Test	Results	Reference Range	Units
Troponin I Research -	B6	0 - 0.08	mg/dl



stringsoft

3/12

B6

Printed Tuesday, December 04, 2018

Client: **B6**
Patient:

B4 BNP - 11/20/2018

B4 Reference Laboratories

Client: **B6**

Client: **B6**
Patient:
Species: CANINE
Breed: BOXER
Gender: FEMALE
Age: 3Y

Date: 11/20/2018
Requisition #: 354628
Accession: **B6**
Ordered by: **B6**

B4 VetConnect 1-888-433-9967
TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395
Account #88933

CARDIOPET proBNP - CANINE

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

Comments:

1. Cardiopet proBNP 901 - 1500 pmol/L

B6

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

Client:
Patient:

B6

Gastrointestinal Lab Texas A&M 11/20/18



Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474



Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

B6
Tufts University-Clinical Pathology Lab
Attn: **B6**
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name: **B6**
Owner Name:
Species: Canine
Date Received: Nov 27, 2018

Tufts University-Clinical Pathology Lab
Tracking Number: 1811200085

GI Lab Accession: **B6**

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	11/27/18

Interpretation:

B6

B6

Comments:

B6

345628 Canine
11/20/2018 1:14 PM
CARDIAC TROPONIN/TEXGI
SST

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

Client: **B6**
Patient:

Gastrointestinal Lab Texas A&M 11/20/18



Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474



**Important
Notices:**

Ongoing studies

B4, B6

Phone: (979) 862-2861
Fax: (979) 862-2864

GI Lab Contact Information

Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

Client:
Patient:

B6

Diet hx

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name **B6** Owner's name **B6** Today's date: 20 Nov 2018

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 your pet is eating.

Examples are shown in the table – please provide enough detail that we could go to 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 ½ cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
Pupperoni original beef flavor	treat	½	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
EARTHBOUN - MEADOW FEAST	dry	~1 ½ c.	2x/day	FEB 2016

*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 type="checkbox"/> No	_____
Carnitine	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Antioxidants	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Multivitamin	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Fish oil	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Coenzyme Q10	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Other (please list):	_____	_____
Example: Vitamin C	Nature's Bounty	500 mg tablets - 1 per day
SUPPLEMENT	NUPRO - DOG SUPPLEMENT	1 scoop (~1 TBSP) 1-2x/day

6. 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): salad or cheese

Client:
Patient:

B6

Client:
Patient:

B6

ECG from Cardio

B6

11/20/2018 2:45:12 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from Cardio

B6

11/20/2018 2:45:12 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

Patient History

09/27/2018 02:02 PM

11/14/2018 05:13 PM

11/19/2018 06:05 PM

11/20/2018 12:38 PM

11/20/2018 01:10 PM

11/20/2018 04:05 PM

11/20/2018 04:05 PM

11/20/2018 04:06 PM

11/20/2018 04:56 PM

11/20/2018 05:46 PM

11/20/2018 05:46 PM

11/21/2018 11:19 AM

11/26/2018 11:33 AM

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6

11/22/2018

Dear

B6

Thank you for referring

B6

with their pet

B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6

DVM, DACVIM (Cardiology)

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 12/4/2018 11:04:49 PM
Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372828
Attachments: 2059621-report.pdf; 2059621-attachments.zip

A PFR Report has been received and PFR Event [EON-372828] has been created in the EON System.

A "PDF" report by name "2059621-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 "2059621-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372828

ICSR #: 2059621

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059621

AE Date	11/20/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2059621

Product Group: Pet Food

Product Name: Earthborn Meadow Feast dry

Description: Eating BEG diet (Earthborn) Echo had subjectively reduced contractility; elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

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: 5

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

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

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Report Details - EON-372828				
ICSR:	2059621			
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:	2018-12-04 17:59:30 EST			
Reported Problem:	Problem Description:	Eating BEG diet (Earthborn) Echo had subjectively reduced contractility, elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months		
	Date Problem Started:	11/20/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Earthborn Meadow Feast dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	Description:	See diet history in records for more details	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Boxer (German Boxer)		
	Gender:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not pregnant		
	Lactation Status:	Not lactating		
	Weight:	30.3 Kilogram		
	Age:	3 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	5		
	Number of Animals Reacted:	4		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name:	B6
			Phone:	
			Email:	
	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:	rpt_medical_record_preview.pdf
	Description:	Medical records
	Type:	Medical Records

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/4/2018 11:12:44 PM
Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372831
Attachments: 2059622-report.pdf; 2059622-attachments.zip

A PFR Report has been received and PFR Event [EON-372831] has been created in the EON System.

A "PDF" report by name "2059622-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 "2059622-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372831

ICSR #: 2059622

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059622

AE Date	11/15/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2059622

Product Group: Pet Food

Product Name: Earthborn Meadow Feast dry

Description: Daughter diagnosed with reduced cardiac contractility ([B6] is mother of [B6] and [B6] Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

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: 5

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

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

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Report Details - EON-372831				
ICSR:	2059622			
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:	2018-12-04 18:08:14 EST			
Reported Problem:	Problem Description:	Daughter diagnosed with reduced cardiac contractility (B6) is mother of B6 Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months		
	Date Problem Started:	11/15/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Earthborn Meadow Feast dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	Description:	See diet history in medical record for more info	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Boxer (German Boxer)		
	Gender:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not pregnant		
	Lactation Status:	Not lactating		
	Weight:	29.1 Kilogram		
	Age:	3 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	5		
	Number of Animals Reacted:	4		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name:	B6
			Phone:	
		Email:		
	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:	rpt_medical_record_preview	B6 pdf
	Description:	Medical records	
	Type:	Medical Records	

Report Details - EON-372834

ICSR:	2059624		
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:	2018-12-04 18:12:06 EST		
Reported Problem:	Problem Description:	Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Subjectively reduced contractility on echo and elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months	
	Date Problem Started:	11/20/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Earthborn Meadow Feast dry	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Description:	See diet history in medical record for more info
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	30.3 Kilogram	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	5	
	Number of Animals Reacted:	4	
	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	records.pdf
	Description:	Medical records	
	Type:	Medical Records	

B6

B6

All Medical Records

B6

Breed: Boxer

B6

Species: Canine

Sex: Male
(Neutered)

Referring Information

B6

Initial Complaint:

Scanned Record

SOAP Text Nov 20 2018 12:22PM -

B6

Initial Complaint:

DCM Study

SOAP Text Nov 20 2018 1:10PM -

B6

Disposition/Recommendations

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6

Veterinarian:

B6

Visit ID:

B6

Species:	Canine
Breed:	Boxer
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

11/20/2018 5:45:23 PM

Accession ID: 448860

Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl

B4

3/13

B6

Printed Tuesday, December 04, 2018

B6

B4

11/20/2018

B4

Reference Laboratories

B6

B4

B6

Species: CANINE
Breed: BOXER
Gender: MALE NEUTERED
Age: 3Y

Date: 11/20/2018

B6

Ordered by: NOT SPECIFIED

TIFFS UNIVERSITY

B6

CARDIOPET proBNP - CANINE

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

Comments:

1. Cardiopet proBNP 901 - 1500 pmol/L

B6

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

B6

CARDIAC TROPONIN/TEXGI SST 11/20/18



Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474



Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

B6
Tufts University-Clinical Pathology Lab
Attn: **B6**
200 Westboro Road
North Grafton, MA 01536
USA

B6

Species: Canine
Date Received: Nov 27, 2018

Tufts University-Clinical Pathology Lab
Tracking Number: 1811200093

GI Lab Accession: **B6**

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	11/27/18

B6

Comments:

B6

Phone: (979) 862-2861
Fax: (979) 862-2864

GI Lab Contact Information

Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

B6

CARDIAC TROPONIN/TEXGI SST 11/20/18



Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474



**Important
Notices:**

B4, B6

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

B6

Diet hx

CARDIOLOGY DIET HISTORY FORM
Please answer the following questions about your pet

B6Today's date: 20 NOV 2018

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 your pet is eating.

Examples are shown in the table – please provide enough detail that we could go to 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
EARTHBOEN - MEADOWFEAST	dry	~ 1 1/2c +	2x day	FEB 2016

*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 type="checkbox"/> No	_____
Carnitine	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Antioxidants	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Multivitamin	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Fish oil	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Coenzyme Q10	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
Other (please list):	_____	_____
Example: Vitamin C	Nature's Bounty	500 mg tablets – 1 per day
SUPPLEMENT	NUPRO - DOG SUPPLEMENT	1 SCOOP (~ 1 TBSP) 1-2x DAY

6. 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): BOLOGNA or CHEESE

B6

B6

ECG from Cardio

B6

11/20/2018 3:27:51 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

B6

ECG from Cardio

B6

11/20/2018 3:28:15 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

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ECG from Cardio

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11/20/2018 3:28:15 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

B6

Patient History

11/20/2018 11:45 AM

11/20/2018 12:23 PM

11/20/2018 01:11 PM

11/20/2018 04:04 PM

11/20/2018 04:04 PM

11/20/2018 04:04 PM

11/20/2018 04:55 PM

11/20/2018 05:45 PM

11/20/2018 05:46 PM

11/21/2018 11:25 AM

11/26/2018 11:33 AM

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6

B6

Male (Neutered)

Canine Boxer Fawn

433149

11/22/2018

B6

Thank you for referring

B6

with their

B6

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

B6

Thank you,

B6

From: PFR Event <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 12/5/2018 12:00:38 AM
Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372842
Attachments: 2059630-report.pdf; 2059630-attachments.zip

A PFR Report has been received and PFR Event [EON-372842] has been created in the EON System.

A "PDF" report by name "2059630-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 "2059630-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372842

ICSR #: 2059630

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059630

AE Date	11/29/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	8 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2059630

Product Group: Pet Food

Product Name: Earthborn Meadow Feast dry

Description: DCM and CHF (cough developed earlier but diagnosed 11/29/18) Eating BEG diet Taurine pending Owner changing diet and we will recheck Note: listed as **B6** in medical record

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
Earthborn Meadow Feast 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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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: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/5/2018 1:37:23 AM
Subject: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs: [B6] - EON-372864
Attachments: 2059643-report.pdf

A PFR Report has been received and PFR Event [EON-372864] has been created in the EON System.

A "PDF" report by name "2059643-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-372864

ICSR #: 2059643

EON Title: PFR Event created for Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs; 2059643

AE Date	09/01/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Poodle - Miniature		
Age	13 Years		
District Involved	PFR-[B6] DO		

Product information

Individual Case Safety Report Number: 2059643

Product Group: Pet Food

Product Name: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs

Description: [B6] started coughing and passing out. The vet found that he has an enlarged heart.

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: 2

Product Name	Lot Number or ID	Best By Date
Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs		

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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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.

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Report Details - EON-372864

ICSR:	2059643																																																									
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:	2018-12-04 20:27:27 EST																																																									
Reporter is the Animal Owner:	Yes																																																									
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	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	10 Pound		
	Age:	13 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	2		
	Number of Animals Reacted:	2		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
Phone:			B6	
Address:		B6 United States		
Sender Information:	Name:	B6		
	Address:	B6 United States		
	Contact:	Phone:	B6	
		Email:		
	Reporter Wants to Remain Anonymous:	No		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-372839

ICSR:	2059627																																																				
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)																																																				
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	Information:	Address:	B6	United States
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Other Canine/dog		
	Gender:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not Pregnant		
	Lactation Status:	Not lactating		
	Weight:	8 Pound		
	Age:	8 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Reacted:	1		
	Owner Information:			
Healthcare Professional Information:				
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:			

Report Details - EON-372851

ICSR:	2059636		
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:	2018-12-04 19:24:26 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	2 years ago my dog was diagnosed with canine dilated cardiomyopathy. All of my pets had been on wellness grain free food because the vet said it was good for their skin.	
	Date Problem Started:	01/01/2016	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish, Herring & Salmon	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	26 Pound	
	Purchase Date:	01/01/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in dog food container	
	Product Use Information:	Description:	Fed daily to pets
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Chewy.com
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Chihuahua	
	Gender:	Mixed Population of Female and Male	
	Reproductive Status:	Neutered	
	Weight:	6 Pound	
	Age:	15 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	6	

	Number of Animals Reacted:		2	
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
		Address:	B6	
		United States		
		Type of Veterinarian:	Primary/regular veterinarian	
		Date First Seen:	11/29/2018	
	Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
		Email:		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-370708				
ICSR:	2058678			
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:	2018-11-09 16:57:32 EST			
Reported Problem:	Problem Description:	Diagnosed with DCM, CHF, and atrial fibrillation. B6 Currently hospitalized. Taurine submitted to UC Davis. Unclear if related to diet, given breed but eating boutique, grain-free diet. Only prior history is traumatic injury in 2015.		
	Date Problem Started:	B6		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Earthborn grain free weight management 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:	Male		
	Reproductive Status:	Neutered		
	Weight:	45.2 Kilogram		
	Age:	B6		
	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:	
			Email:	
Address:		B6		
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 record	B6 .pdf
	Description:	Medical records	
	Type:	Medical Records	

B6

B6

Medical Record for **B6**

Patient: **B6**
Breed: Doberman Pinscher
DOB: **B6**

Species: Canine
Sex: Male
(Neutered)

Referring Information

B6

Initial Complaint:

Emergency

SOAP Text **B6** 6:41PM - Clinician, Unassigned FHSA

Subjective

NEW VISIT (ER)

B6

HISTORY:

Signalment: 8 yo NM Doberman

Current history:

Patient presented as referral from rDVM for CHF and suspected DCM. Yesterday, owner noted that when playing fetch, patient yelped while running back and immediately went inside to lay down. Patient was lethargic remainder of evening, but went on 30 minute walk and was willing to eat dinner. Owners noticed he was intermittently breathing

B6

heavier last night with a dry cough which owners mistook initially as him attempting to vomit. This morning, patient not willing to eat breakfast or go for walk. Maintains thirst.

Was evaluated by rDVM today, **B6** or clinical signs. Radiographs showed cardiomegaly and an arrhythmia was ausculted. ECG indicated atrial fibrillation. Patient was given 2 doses of furosemide (4mg/kg total) and referred here for cardiology workup.

Patient has no known history of heart disease, collapse, weakness, or respiratory changes. Patient diagnosed with idiopathic head shake 1 year ago.

Prior medical history: No known heart disease until today.

Current medications: Desaquin

Diet: earth borne grain free mixed with wellness diet wet food.

Vaccination status/flea & tick preventative use: HW and F&T preventatives.

Travel history: unknown

EXAM:

B6

ASSESSMENT:

A1: CHF secondary to DCM

PLAN:

B6

B6

B6

Diagnostics completed:

ECG on intake-- Atrial fibrillation

AFAST/TFAST-- no FF, enlargement of chambers, consistent with DCM

NOVA-- no significant findings

PCV/TS-- 65/7

Diagnostics pending:

B6

Client communication:

Confirmed history with owners. Discussed that on presentation arrhythmia is still present. Recommended hospitalization with bloodwork, monitoring, initiating medications, and echocardiogram. O ok with plan. Discussed resuscitation code, o hesitant but settled on red code. Discussed that new dr would take over in AM and that no updates between now and then is good news.

Introduced o to Dr. Freeman, o intersted in being enrolled in DCM study.

Deposit & estimate status: 2500

Resuscitation code (if admitting to ICU): Red

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

SOAP Text **B6** 7:16AM - Clinician, Unassigned FHSA

Subjective

History

B6 is an 8yo MN Dobie presented as referral yesterday for CHF and suspected DCM. Owner took to rDVM after a day of lethargy, inappetance and possible coughing episode. Evaluated by rDVM **B6** at that time radiographs showed cardiomegaly and ECG indicated atrial fibrillation. Patient was given 2 doses of furosemide (4mg/kg total) and referred here. Patient has no known history of heart disease, collapse, weakness, or respiratory changes. Patient diagnosed with idiopathic head shake 1 year ago. Current diet: Earth borne grain-free mixed with wellness diet wet food. Medications include Dasequin, HW and F&T preventatives.

B6

B6

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SOAP Text

B6

7:19AM - Clinician, Unassigned FHSA

Subjective

B6

B6

B6

Disposition/Recommendations

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6

Veterinarian:

B6

Visit ID:

Lab Results Report

B6

Species:

Canine

Breed:

Doberman Pinscher

Sex:

Male (Neutered)

Age:

B6 Years Old

CBC, Comprehensive, Sm Animal

B6

8:12:13 PM

B6

Test	Results	Reference Range	Units
MPV (ADVIA)	B6	8.29 - 13.2	fL
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL
HCT(ADVIA)		39 - 55	%
WBC (ADVIA)		4.4 - 15.1	K/uL
PLTCRT		0.129 - 0.403	%
PLT(ADVIA)		173 - 486	K/uL
MCV(ADVIA)		64.5 - 77.5	fL
MCHC(ADVIA)		31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
MCH(ADVIA)		21.3 - 25.9	pg
RETIC(ADVIA)		0.2 - 1.6	%
COMMENTS (HEMATOLOGY)		0 - 0	
HGB(ADVIA)		13.3 - 20.5	g/dL
RBC(ADVIA)		5.8 - 8.5	M/uL

Chemistry Profile - Small Animal (Pa

B6

8:12:13 PM

B6

Test	Results	Reference Range	Units
TRIGLYCERIDES	B6	30 - 338	mg/dl
CHOLESTEROL		82 - 355	mg/dL

B4

8/49

B6

Printed Friday, November 09, 2018

B6

SODIUM	B6	140 - 150	mEq/L
CALCIUM2		9.4 - 11.3	mg/dL
GLOBULINS		2.3 - 4.2	g/dL
POTASSIUM		3.7 - 5.4	mEq/L
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
PHOSPHORUS		2.6 - 7.2	mg/dL
T BILIRUBIN		0.1 - 0.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
ALBUMIN		2.8 - 4	g/dL
GLUCOSE		67 - 135	mg/dL
CK		22 - 422	U/L
CHLORIDE		106 - 116	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
GGT		0 - 10	U/L
ALT		14 - 86	U/L
tCO2 (BICARB)		14 - 28	mEq/L
AMYLASE		409 - 1250	U/L
D.BILIRUBIN		0 - 0.1	mg/dL
NA/K		29 - 40	
AGAP		8 - 19	
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
AST		9 - 54	U/L
CREATININE		0.6 - 2	mg/dL
A/G RATIO		0.7 - 1.6	
UREA		8 - 30	mg/dL

Microscopic Exam of Blood Smear (A**B6**

8:12:13 PM

B6

Test	Results	Reference Range	Units
MONOS (ABS)ADVIA	B6	0.1 - 1.5	K/uL
L YMPHS%		7 - 47	%
MONOS%		1 - 15	%
SEGS%		43 - 86	%
L YMPHS (ABS)ADVIA		1 - 4.8	K/uL
WBC MORPHOLOGY		0 - 0	
No Morphologic Abnormalities			
SEGS (AB)ADVIA		2.8 - 11.5	K/ul

B4

9/49

B6

Printed Friday, November 09, 2018

B6

POIKILOCYTOSIS

Occasional

0 - 0

Nova Full Panel-ICU**B6**

8:12:13 PM

B6

Test	Results	Reference Range	Units
nMG	B6	0 - 0	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
TCO2 (POC)		0 - 0	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
MG (POC)		0.1 - 0.4	mmol/L
HCT (POC)		38 - 48	%
CREAT (POC)		0.2 - 2.1	mg/dL
SO2%		94 - 100	%
K (POC)		3.6 - 4.8	mmol/L
FiO2		0 - 0	%
NOVA SAMPLE		0 - 0	
CA/MG		0 - 0	mol/mol
BUN (POC)		12 - 28	mg/dL
NA (POC)		140 - 154	mmol/L
LACTATE		0 - 2	mmol/L
GAP		0 - 0	mmol/L
nCA		0 - 0	mmol/L
CL(POC)		109 - 120	mmol/L
HB (POC)		12.6 - 16	g/dL
A		0 - 0	mmHg
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

None**B6**

8:12:13 PM

B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%

B4

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B6

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B6

TS (FHSA)

7

0 - 0

g/dl

B6

8:12:13 PM

B6

Test	Results	Reference Range	Units
Troponin I (i-STAT) Cardiology - FHSA	B6	0 - 0	ng/ml

Chemistry 21 (Cobas)**B6**

8:12:13 PM

Accession ID:

B6

Test	Results	Reference Range	Units
AST	B6	9 - 54	U/L
UREA		8 - 30	mg/dL
A/G RATIO		0.7 - 1.6	
CHOLESTEROL		82 - 355	mg/dL
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
GLUCOSE		67 - 135	mg/dL
ALBUMIN		2.8 - 4	g/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
POTASSIUM		3.7 - 5.4	mEq/L
I BILIRUBIN		0 - 0.2	mg/dL
SODIUM		140 - 150	mEq/L
ALT		14 - 86	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
ALK PHOS		12 - 127	U/L
CHLORIDE		106 - 116	mEq/L
GLOBULINS		2.3 - 4.2	g/dL
CREATININE		0.6 - 2	mg/dL

None**B6**

8:12:13 PM

B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

B4

11/49

B4

Printed Friday, November 09, 2018

B6

B4

B4

B6

B4

B6

Species: CANINE
Breed: DOBERMAN_PINSCH
Gender: MALE
Age: 8Y

Date: **B6**
Requisition #: 1A
Ordered by: **B6**

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395

Account #88933

CARDIOPET proBNP - CANINE

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

Comments:

1. Cardiopet proBNP >1800pmol/L

B6

Please Note: Complete Interpretive Comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

B6

Vitals Results

B6

7:10:41 PM
7:15:25 PM
7:15:26 PM
7:15:27 PM
7:15:28 PM
8:50:18 PM
8:59:52 PM
9:00:02 PM
9:00:03 PM
9:00:07 PM
9:04:11 PM
9:41:42 PM
9:42:35 PM
9:42:36 PM
11:05:47 PM
11:05:48 PM
11:05:58 PM
11:27:54 PM
11:28:35 PM
11:28:49 PM
12:16:11 AM
12:16:12 AM
12:16:24 AM
12:25:01 AM
1:03:51 AM
1:03:52 AM
1:04:30 AM
1:57:40 AM
1:58:50 AM
1:58:51 AM
1:59:44 AM
3:04:07 AM
3:04:08 AM
3:06:27 AM
3:32:24 AM
3:34:43 AM
4:06:30 AM
4:06:31 AM
4:06:49 AM
5:00:14 AM

B6

B6

B6

Vitals Results

5:24:57 AM
5:24:58 AM
5:25:15 AM
5:46:22 AM
5:46:49 AM
5:46:50 AM
6:31:20 AM
6:31:21 AM
6:31:40 AM
7:12:38 AM
7:12:54 AM
7:13:08 AM
7:13:09 AM
7:13:51 AM
7:13:59 AM
7:16:21 AM
7:16:22 AM
7:16:23 AM
9:19:06 AM
9:36:24 AM
9:36:25 AM
9:58:09 AM
9:58:10 AM
10:06:41 AM
10:07:04 AM
10:15:59 AM
10:16:39 AM
11:31:33 AM
11:31:34 AM
11:33:55 AM
11:37:52 AM
12:02:52 PM
12:02:53 PM
12:03:56 PM
1:11:16 PM
1:13:44 PM
1:13:45 PM
1:16:08 PM
1:38:13 PM
1:51:30 PM
1:51:31 PM

B6

B6

B6

Vitals Results

3:03:10 PM
3:10:58 PM
3:10:59 PM
3:36:48 PM
3:37:03 PM
4:33:09 PM
4:33:31 PM
4:33:32 PM
5:08:41 PM
5:08:42 PM
5:18:43 PM
6:31:11 PM
6:31:46 PM
6:31:47 PM
6:31:55 PM
6:32:03 PM
9:01:47 PM
9:02:04 PM
9:02:15 PM
9:32:43 PM
9:32:57 PM
9:33:11 PM
9:33:12 PM
9:45:07 PM
11:17:03 PM
11:18:05 PM
11:18:06 PM
11:58:17 PM
11:58:18 PM
11:59:06 PM
12:45:06 AM
12:45:29 AM
12:45:30 AM
1:53:36 AM
1:53:49 AM
1:54:14 AM
1:54:15 AM
2:49:27 AM
2:49:28 AM
2:50:03 AM
3:26:42 AM

B6

B6

B6

Vitals Results

B6

4:00:38 AM
4:00:39 AM
4:01:06 AM
5:12:19 AM
5:12:20 AM
5:12:33 AM
5:19:34 AM
5:21:05 AM
5:34:53 AM
5:35:01 AM
5:54:55 AM
5:55:09 AM
5:55:10 AM
6:27:18 AM
6:27:19 AM
6:27:52 AM
7:18:19 AM
7:18:32 AM
7:18:33 AM
7:19:29 AM
7:19:30 AM
7:19:31 AM
7:19:32 AM
7:42:35 AM
8:47:36 AM
8:47:37 AM
8:47:47 AM
8:50:11 AM
9:09:21 AM
11:08:26 AM
11:08:27 AM
11:20:51 AM
11:21:02 AM
12:06:15 PM
12:06:16 PM
12:06:28 PM
12:39:17 PM
1:03:57 PM
1:03:58 PM
1:04:22 PM
1:20:21 PM

B6

B6

Vitals Results

B6

1:20:22 PM
1:20:59 PM
1:21:06 PM
3:15:43 PM
3:15:44 PM
3:16:26 PM
3:48:16 PM
3:48:26 PM
3:48:27 PM
3:48:41 PM
5:47:11 PM

B6

B6

ECG from Cardio

B6

B6

11:06:07 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement

B6

B6

ECG from Cardio

B6

B6

11:06:48 AM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

B6

B6

ECG from Cardio

B6

B6

11:06:48 AM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

B6

ECG from Cardio

B6

B6

11:07:04 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

B6

B6

ECG from Cardio

B6

B6

11:07:15 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement

B6

B6

Patient History

07:05 PM
07:07 PM
07:10 PM
07:15 PM
07:15 PM
07:15 PM
07:15 PM
07:23 PM
07:23 PM
07:23 PM
08:12 PM
08:12 PM
08:13 PM
08:36 PM
08:38 PM
08:50 PM

08:50 PM

08:50 PM
08:59 PM
08:59 PM
09:00 PM

09:00 PM
09:00 PM
09:00 PM
09:04 PM
09:04 PM
09:19 PM
09:41 PM
09:41 PM
09:42 PM

09:42 PM
09:42 PM
09:42 PM
11:05 PM

11:05 PM
11:05 PM
11:05 PM
11:05 PM
11:27 PM
11:28 PM
11:28 PM

B6

B6

B6

Patient History

11:28 PM
11:28 PM
11:28 PM
12:16 AM

12:16 AM
12:16 AM
12:16 AM
12:16 AM
12:25 AM
01:03 AM

01:03 AM
01:03 AM
01:04 AM
01:04 AM
01:57 AM
01:57 AM
01:58 AM

01:58 AM
01:58 AM
01:59 AM
03:04 AM

03:04 AM
03:04 AM
03:06 AM
03:06 AM
03:31 AM
03:32 AM
03:32 AM
03:34 AM

03:34 AM
03:34 AM
04:06 AM

04:06 AM
04:06 AM
04:06 AM
04:06 AM
05:00 AM
05:00 AM
05:24 AM

05:24 AM
05:24 AM
05:25 AM
05:25 AM

B6

B6

B6

Patient History

05:46 AM
05:46 AM
05:46 AM

05:46 AM
05:46 AM
06:31 AM

06:31 AM
06:31 AM
06:31 AM
06:31 AM

07:12 AM
07:12 AM
07:12 AM
07:12 AM
07:13 AM

07:13 AM

B6

07:13 AM
07:13 AM
07:13 AM

07:13 AM
07:13 AM
07:13 AM
07:13 AM
07:14 AM
07:16 AM

07:16 AM
07:16 AM
08:10 AM
08:38 AM

08:44 AM
08:44 AM
09:19 AM
09:19 AM
09:33 AM

09:36 AM

09:36 AM

09:36 AM

09:44 AM

B6

09:44 AM

09:44 AM

09:57 AM

B6

B6

Patient History

B6

B6

B6

09:58 AM
09:58 AM
09:58 AM
10:06 AM
10:07 AM
10:07 AM
10:07 AM
10:15 AM
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10:19 AM
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10:19 AM
10:19 AM

10:43 AM
11:03 AM

11:25 AM
11:31 AM

11:31 AM
11:31 AM
11:33 AM
11:33 AM
11:37 AM

11:37 AM
12:02 PM

12:02 PM
12:02 PM
12:03 PM
12:03 PM
12:55 PM
12:57 PM

12:58 PM

01:10 PM
01:11 PM
01:11 PM
01:13 PM

01:13 PM
01:13 PM
01:16 PM
01:16 PM

B6

Patient History

01:30 PM
01:30 PM
01:38 PM
01:38 PM
01:43 PM

01:51 PM

01:51 PM
01:51 PM
03:03 PM
03:03 PM
03:10 PM

03:10 PM
03:10 PM
03:36 PM
03:37 PM
03:37 PM
03:37 PM

04:33 PM
04:33 PM
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04:33 PM
05:08 PM

05:08 PM
05:08 PM
05:18 PM
05:18 PM
06:29 PM
06:31 PM

06:31 PM

06:31 PM

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06:31 PM
06:31 PM

06:31 PM
06:31 PM
06:31 PM
06:31 PM
06:32 PM
06:32 PM
09:01 PM

B6

B6

B6

Patient History

B6

09:01 PM
09:01 PM
09:02 PM
09:02 PM
09:32 PM

09:32 PM

09:32 PM
09:32 PM
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09:32 PM
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09:44 PM
09:45 PM
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B6

B6

Patient History

B6

B6

02:49 AM
02:50 AM
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03:26 AM
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B6

Patient History

07:19 AM
07:19 AM
07:19 AM
07:42 AM
07:42 AM
08:47 AM

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B6

B6

Patient History

B6

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05:47 PM

B6

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B6

Radiology Request & Report

B6

Species: Canine
Black/Tan Male (Neutered)
Doberman Pinscher
Birthdate: B6

B6

B6

Date of request: B6

B6

Student:

Date of exam: B6

Patient Location: Ward/Cage:

Weight (kg) 45.20

- ☐ Inpatient
- ☐ Outpatient Time:
- ☐ Waiting
- ☐ Emergency

Sedation

- ☐ BAG
- ☐ OBAG
- ☐ 1/2 dose OBAG
- ☐ DexDomitor/Butorphanol
- ☐ Anesthesia to sedate/anesthetize

Examination Desired: 1 view thoracic radiograph (lateral) - to be done standing in large animal, please.

Presenting Complaint and Clinical Questions you wish to answer:

Emergency

Pertinent History: B6 is an 8yo MN Dober presented as referral yesterday for CHF and suspected DCM. Evaluated by rDVM B6 at that time radiographs showed cardiomegaly, pulmonary edema and ECG indicated atrial fibrillation. Patient was given 2 doses of furosemide (4mg/kg total) and referred here. 1 dose of Furosemide overnight.

Findings:

B6

Conclusions:

- Resolving pulmonary edema and unchanged cardiomegaly consistent with diagnosed DCML. A complete thoracic series may be considered for full evaluation.

B6**Dates****Reported:****Finalized:****B6**

B6

Discharge Instructions

B6

Species: Canine
Black/Tan Male (Neutered) Doberman
Pinscher
Birthdate: B6

B6

B6

B6

Admit Date: B6 6:19:57 PM

Discharge Date: B6

Diagnoses:

1. Dilated cardiomyopathy (DCM) with congestive heart failure
2. Atrial fibrillation with ventricular beats
3. Mild degenerative mitral valve disease

Case summary:

Thank you for bringing B6 into Tufts! He is a lovely boy!

On presentation, Bode was quiet but alert. His heart rate was elevated and irregular, and an EKG confirmed atrial fibrillation as well. He was on telemetry (continuous EKG) and received supportive care in the ICU and was started on cardiac medications in order to help decrease his heart rate and pump better.

B6

B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is

more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Doberman pinschers are predisposed to developing this disease. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs or belly. Unfortunately this is a progressive disease and we cannot reverse the changes to the heart muscle, however we can use cardiac medications and some changes to the diet to make your dog comfortable and have him breathing easier.

Monitoring at home:

B6

Recommended Medications:

B6

B6

B6

B6

Discharge Instructions

B6

Alivacor/Kardia Handout

B4, B6

B4, B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

B6 Canine
B6 Years Old Male (Neutered)
Doberman Pinscher
Black/Tan BW: Weight (kg) 45.20

Cardiology Inpatient

Date: B6
Weight: Weight (kg) 45.20

B6

STOP - remainder of form to be filled out by Cardiology

Physical Examination

B6

Muscle condition:

- | | |
|--------------------------------------------|--------------------------------------------|
| <input checked="" type="checkbox"/> Normal | <input type="checkbox"/> Moderate cachexia |
| <input type="checkbox"/> Mild muscle loss | <input type="checkbox"/> Marked cachexia |

Cardiovascular Physical Exam

Murmur Grade:

- | | |
|------------------------------------------|--------------------------------|
| <input type="checkbox"/> None | <input type="checkbox"/> IV/VI |
| <input checked="" type="checkbox"/> I/VI | <input type="checkbox"/> V/VI |
| <input type="checkbox"/> II/VI | <input type="checkbox"/> VI/VI |
| <input type="checkbox"/> III/VI | |

Murmur location/description: left apical systolic

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:

- ☐ None
- ☐ Sinus arrhythmia
- ☐ Premature beats

- ☐ Bradycardia
- ☒ Tachycardia - atrial fibrillation

Gallop:

- ☐ Yes
- ☒ No
- ☐ Intermittent

- ☐ Pronounced
- ☐ Other:

Pulmonary assessments:

- ☐ Eupneic
- ☒ Mild dyspnea
- ☐ Marked dyspnea
- ☐ Normal BV sounds

- ☐ Pulmonary Crackles
- ☐ Wheezes
- ☐ Upper airway stridor
- ☐ Other auscultatory findings:

Abdominal exam:

- ☒ Normal
- ☐ Hepatomegaly

- ☐ Abdominal distension
- ☐ Mild ascites

Echocardiogram Findings:

B6

Doppler findings:

Mitral inflow:

- ☐ Summated
- ☐ Normal
- ☐ Delayed relaxation

- ☐ Pseudonormal
- ☐ Restrictive

Blood Pressure (mmHg):

Cuff size:

Limb:

ECG findings:

Heart rate: **B6**

B6

☐ B1
☐ B2

☐ D

B6

Notice of Patient Admit

Date: B6 6:19:57 PM

Case No: 329174

B6

B6

Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.

B6

The reason for admission to the FHSA is: DCM, Afib

If you have any questions regarding this particular case, please call B6 to reach the Cardiology Service. Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6

B6 Male (Neutered)
Canine Doberman Pinscher
Black/Tan
329174

Daily Update From the Cardiology Service

Today's date: B6

Dear B4, B6

Thank you for referring patients to B6 at the Cummings School of Tufts University.

Your patient B6 was admitted and is being cared for by the Cardiology Service.

Today B6

- ☒ is in stable condition
- ☐ is still in the oxygen cage
- ☐ is critically ill
- ☒ discharged from the hospital

B6

Today's treatments include:

- ☒ bloodwork planned/pending
- ☒ echocardiography
- ☐ cardiac catheter procedure planned
- ☒ treatment for CHF secondary to DCM
- ☐ ongoing treatment for thrombosis
- ☒ ongoing treatment for arrhythmia (atrial fibrillation)

Additional plans:

Please allow 3-5 business days for reports to be finalized upon patient discharge.

Please call (508) 887-4696 before 5pm or email us at cardiovet@tufts.edu if you have any questions.
Thank you!

Attending Clinician:

Faculty Clinician:

Senior student:

B6

Appears this way on original

Report Details - EON-370712

ICSR:	2058680		
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:	2018-11-09 17:18:34 EST		
Reported Problem:	Problem Description:	DCM and CHF diagnosed 9/17/18. Unclear if this is a diet-associated DCM because this is not boutique company or grain free but some properties of diet could be suspicious (lamb, rice bran, etc). Owner has fed this same food since dog was a puppy. Has since changed to Pro plan adult sensitive skin and stomach dry plus Science beef/barley canned. Plasma taurine: B6 WB: B6	
	Date Problem Started:	09/17/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Nutro Ultra adult dry dog food the superfood plate (chicken, lamb, salmon)	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Description:	2 scoops twice daily (scoop is ~1.5 cups)
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Setter - Irish Red	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	28.8 Kilogram	
	Age:	11 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
	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:	taurine.pdf	
	Description:	Taurine	
	Type:	Laboratory Report	
	Attachment:	compiled records:	B6 pdf
	Description:	Records	
	Type:	Medical Records	

Report Details - EON-370760				
ICSR:	2058697			
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:	2018-11-10 15:28:40 EST			
Reported Problem:	Problem Description:	DCM and CHF diagnosed 10/31/18. On BEG diet. Taurine pending		
	Date Problem Started:	10/31/2018		
	Concurrent Medical Problem:	Yes		
	Pre Existing Conditions:	Dermatitis		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Taste of the Wild High Prairie dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	Description:	Fed for last 3 months until 2 weeks ago when changed to Beneful Salmon dry	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
	Product Name:	Pure Balance Salmon and Pea dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	Description:	Fed for past 6 years until about 3 months ago	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	25.5 Kilogram		
	Age:	B6		
	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:	B6	
	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:	Records		
	Type:	Medical Records		

Report Details - EON-370720			
ICSR:	2058685		
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:	2018-11-09 18:09:56 EST		
Reported Problem:	Problem Description:	DCM and arrhythmias diagnosed at time of GDV surgery so unclear if sepsis/post-op or true DCM. Had recheck echo 10/31/18 and still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer	
	Date Problem Started:	10/06/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	GDV 10/6/18	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Rachel Ray peak open range recipe (beef, venison, lamb)	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Description:	Rachael Ray's since about 2017- prior to that it has been Purina One chicken and rice. The Rachael Ray that I fed him was "PEAK- open range receipt some with chicken some with lamb or beef. The dry was served with one half a can of newman's organic chicken and brown rice. I also cooked chicken breasts and rice as well as hamburger and rice every other week and used cup of this instead of the canned food. Mixed it in with the dry food. I have as of last Thursday switched him to Royal Canin dry food for Boxers with 1/2 can of science diet healthy cusine-roasted chicken, carrots and spinach stew mixed with about two cups of this dry food..
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	34.8 Kilogram	
	Age:	B6 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: 2px dashed black; padding: 10px; text-align: center; font-size: 2em; font-weight: bold;">B6</div>	
	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 record.pdf		
	Description:	Records		
	Type:	Medical Records		

Report Details - EON-370715

ICSR:	2058683		
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:	2018-11-09 17:46:50 EST		
Reported Problem:	Problem Description:	Older housemate diagnosed with DCM and CHF. Screening B6 because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation	
	Date Problem Started:	11/07/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Zignature trout & salmon dry	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Description:	B6 is four and was born on B6 . He ate Zignature trout & salmon from 09/30/15-10/01/18. 1.25 cups twice daily of Zignature. The primary cookies he ate was Earthborn Holistic Grain-Free, all varieties, and he might have had 3-4 cookies per day. The only other cookies he would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give medication, we always used the Greenies Pill Pockets.
	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:	25.9 Kilogram	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	3	
	Number of Animals Reacted:	2	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address:	B6

			B6
	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 record.pdf	
	Description:	Records	
	Type:	Medical Records	

From: PFR Event <ppreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**

Sent: 11/10/2018 10:52:28 PM

Subject: Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food; **B6** EON-370762

Attachments: 2058699-report.pdf; 2058699-attachments.zip

A PFR Report has been received and PFR Event [EON-370762] has been created in the EON System.

A "PDF" report by name "2058699-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 "2058699-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370762

ICSR #: 2058699

EON Title: PFR Event created for Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food; 2058699

AE Date	04/24/2017	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	8 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2058699

Product Group: Pet Food

Product Name: Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food

Description: **B6** has been eating Zignature Trout & Salmon kibble (1c. 2x/day) for over three years, since approximately August 2014. **B6** was diagnosed with a heart murmur in April 2017. Our regular vet said that it was not of concern if **B6** was not experiencing concerning symptoms, like being short of breath. In September 2018, **B6** started refusing to eat. She was also coughing and vomiting. On **B6** she collapsed and was

unconscious and not breathing for several minutes. She was resuscitated with CPR. She was brought to a veterinary emergency hospital, where her blood was collected for taurine testing at University of California-Davis, and an echocardiogram diagnosed a severe case of Dilated Cardiomyopathy. She has since been enrolled in a study program for diet-related Dilated Cardiomyopathy in dogs at [B6] Our younger dog, [B6] was diagnosed with DCM on [B6] and I will be making a separate report regarding him.

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 Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry 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]

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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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-370762			
ICSR:	2058699		
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:	2018-11-10 17:44:49 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	<p>B6 has been eating Zignature Trout & Salmon kibble (1c. 2x/day) for over three years, since approximately August 2014. B6 was diagnosed with a heart murmur in April 2017. Our regular vet said that it was not of concern if B6 was not experiencing concerning symptoms, like being short of breath. In B6 B6 started refusing to eat. She was also coughing and vomiting. On B6 B6 she collapsed and was unconscious and not breathing for several minutes. She was resuscitated with CPR. She was brought to a veterinary emergency hospital, where her blood was collected for taurine testing at University of California-Davis, and an echocardiogram diagnosed a severe case of Dilated Cardiomyopathy. She has since been enrolled in a study program for diet-related Dilated Cardiomyopathy in dogs at B6. Our younger dog, B6, was diagnosed with DCM on B6 and I will be making a separate report regarding him.</p>	
	Date Problem Started:	04/24/2017	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	08/01/2014	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	The food was stored in an airtight plastic container after the bag was opened.	
	Product Use Information:	Description:	I fed my two dogs exactly 1 cup each of this food twice per day.
		First Exposure Date:	08/02/2014
		Last Exposure Date:	B6
Time Interval between Product Use and Adverse Event:		27 Months	
Product Use Stopped After the Onset of the Adverse Event:		Yes	
Adverse Event Abate After Product Stop:		Yes	
Product Use		No	

		Started Again:		
		Perceived Relatedness to Adverse Event:	Definitely related	
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
		Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6	
		Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	57 Pound		
	Age:	8 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	2		
	Number of Animals Reacted:	2		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
			Email:	
		Address:	B6	
		Type of Veterinarian:	Referred veterinarian	
Date First Seen:		10/08/2018		
Permission to Release Records to FDA:		Yes		
Practice Name:		B6		
Contact:		Name:	B6	
		Phone:		
		Email:		
Address:		B6		
Type of		Primary/regular veterinarian		

		Veterinarian:							
		Date First Seen:	04/27/2018						
		Permission to Release Records to FDA:	Yes						
		Practice Name:	B6						
		Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:	
		Name:	B6						
		Phone:							
		Email:							
Address:	B6								
Type of Veterinarian:	Referred veterinarian								
Date First Seen:	B6								
		Permission to Release Records to FDA:	Yes						
Sender Information:	Name:								
	Address:	B6							
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Phone:	B6	Email:				
	Phone:	B6							
	Email:								
	Permission To Contact Sender:	Yes							
Preferred Method Of Contact:	Email								
Reported to Other Parties:	None								
Additional Documents:	Attachment:	4800_001.pdf							
	Description:	Records from B6 & taurine testing results							
	Type:	Echocardiogram							

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: B6
Sent: 11/9/2018 10:36:55 PM
Subject: Zignature trout and salmon dry: Lisa Freeman - EON-370713
Attachments: 2058681-report.pdf; 2058681-attachments.zip

A PFR Report has been received and PFR Event [EON-370713] has been created in the EON System.

A "PDF" report by name "2058681-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 "2058681-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370713

ICSR #: 2058681

EON Title: PFR Event created for Zignature trout and salmon dry; 2058681

AE Date	10/08/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	8 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2058681

Product Group: Pet Food

Product Name: Zignature trout and salmon dry

Description: DCM and CHF. From late-2014 through 09/30/18, B6 ate about 1 cup of Zignature trout & salmon dry food twice per day. Then, from 10/01-10/14/18, she ate Nature's Variety Instinct Raw beef & barley dryg food (1.5c. 2x/day). The primary cookies she ate was Earthborn Holistic Grain-Free, all varieties, and she might have had 3-4 cookies per day. The only other cookies she would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give her medication, we always used the Greenies Pill Pockets. Taurine for B6 - 327 whole blood Owners' other Golden, B6 is four and

was born on 08/03/15. He ate Zignature trout & salmon from 09/30/15-10/01/18 (see separate report). We also have a Golden puppy **B6** who was born on **B6** and ate the same Zignature from 07/23-10/01/18.

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: 3

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Zignature trout and salmon dry		

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

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Report Details - EON-370713		
ICSR:	2058681	
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:	2018-11-09 17:31:06 EST	
Reported Problem:	Problem Description:	DCM and CHF. From late-2014 through 09/30/18, B6 ate about 1 cup of Zignature trout & salmon dry food twice per day. Then, from 10/01-10/14/18, she ate Natures Variety Instinct Raw beef & barley dryg food (1.5c. 2x/day). The primary cookies she ate was Earthborn Holistic Grain-Free, all varieties, and she might have had 3-4 cookies per day. The only other cookies she would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give her medication, we always used the Greenies Pill Pockets. Taurine for B6 - 327 whole blood Owners' other Golden, B6 is four and was born on B6. He ate Zignature trout & salmon from 09/30/15-10/01/18 (see separate report). We also have a Golden puppy, B6 who was born on B6 and ate the same Zignature from 07/23-10/01/18.
	Date Problem Started:	10/08/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	Product Name:	Zignature trout and salmon dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: From late-2014 through 09/30/18, B6 ate about 1 cup of Zignature trout & salmon dry food twice per day. Then, from 10/01-10/14/18, she ate Natures Variety Instinct Raw beef & barley dryg food (1.5c. 2x/day). The primary cookies she ate was Earthborn Holistic Grain-Free, all varieties, and she might have had 3-4 cookies per day. The only other cookies she would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give her medication, we always used the Greenies Pill Pockets.
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	B6 (will report other dog separately)
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	27.7 Kilogram
	Age:	8 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	3
	Number of Animals Reacted:	2
Owner Information:	Owner Information provided:	Yes

		Contact:	Name:	B6
			Phone:	
			Email:	
			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 records.pdf		
	Description:	Medical records		
	Type:	Medical Records		

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 3/19/2019 1:48:37 PM
Subject: Fromm's Four Star Grain Free Salmon and Tunalini; [B6] EON-382722
Attachments: 2064246-report.pdf; 2064246-attachments.zip

A PFR Report has been received and PFR Event [EON-382722] has been created in the EON System.

A "PDF" report by name "2064246-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 "2064246-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382722

ICSR #: 2064246

EON Title: PFR Event created for Fromm's Four Star Grain Free Salmon and Tunalini; 2064246

AE Date	03/06/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	3 Years		
District Involved	PFR- [B6] DO		

Product information

Individual Case Safety Report Number: 2064246

Product Group: Pet Food

Product Name: Fromm's Four Star Grain Free Salmon and Tunalini

Description: [B6] was seemingly healthy and given an echocardiogram to collect "normal" values for training purposes. Echo results were not normal, but revealed he had early stages of Dilated Cardiomyopathy. He was adopted in March 2016 at age 12 weeks and was started on Fromm Gold Puppy Dry kibble until age 1, when he was transitioned to Fromm Four Star Grain Free Salmon and Tunalini kibble diet. He ate that food until July 2018 when FDA warning was released. He was then transitioned to Purina ProPlan Sensitive Skin and Stomach Salmon and Rice.

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: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Fromm's Four Star Grain Free Salmon and Tunalini		

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:

B6

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Report Details - EON-382722			
ICSR:	2064246		
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:	2019-03-19 09:41:10 EDT		
Reported Problem:	Problem Description:	B6 was seemingly healthy and given an echocardiogram to collect "normal" values for training purposes. Echo results were not normal, but revealed he had early stages of Dilated Cardiomyopathy. He was adopted in B6 at age 12 weeks and was started on Fromm Gold Puppy Dry kibble until age 1, when he was transitioned to Fromm Four Star Grain Free Salmon and Tunalini kibble diet. He ate that food until July 2018 when FDA warning was released. He was then transitioned to Purina ProPlan Sensitive Skin and Stomach Salmon and Rice.	
	Date Problem Started:	03/06/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Fromm's Four Star Grain Free Salmon and Tunalini	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	26 Pound	
	Purchase Date:	06/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in bag	
	Product Use Information:	Description:	Feed in a bowl
		Last Exposure Date:	07/15/2018
		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:		No	
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Possibly related	
Other Foods or Products Given to the Animal During This Time Period:		No	
Manufacturer /Distributor Information:			

	Purchase Location Information:	Name:	B6	
		Address:	B6	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Mixed (Dog)		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	40 Pound		
	Age:	3 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	3		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name: B6 Phone: Email: Address: B6 United States	
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name: B6 Phone: Other Phone: Email: Address: B6 United States	
		Practice Name:	B6	
Contact:		Name: B6 Phone: Other Phone: Email: Address: B6 United States		
Type of Veterinarian:		Referred veterinarian		
Date First Seen:		03/06/2018		
Permission to Release Records to FDA:		Yes		

Sender Information:	Name:	[Redacted]	
	Address:	[Redacted]	
		United States	
	Contact:	Phone:	[Redacted]
		Other Phone:	[Redacted]
		Email:	[Redacted]
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:	Attachment:	[Redacted]	echoreport.pdf
	Description:	Echo Report	
	Type:	Echocardiogram	

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification: B6

Sent: 3/19/2019 8:56:56 PM

Subject: Natural Balance LID High Protein Grain-free Lamb or Beef flavors: Lisa Freeman - EON-382772

Attachments: 2064292-report.pdf; 2064292-attachments.zip

A PFR Report has been received and PFR Event [EON-382772] has been created in the EON System.

A "PDF" report by name "2064292-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 "2064292-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382772

ICSR #: 2064292

EON Title: PFR Event created for Natural Balance LID High Protein Grain-free Lamb or Beef flavors; 2064292

AE Date	03/17/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	9 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2064292

Product Group: Pet Food

Product Name: Natural Balance LID High Protein Grain-free Lamb or Beef flavors

Description: DCM and CHF diagnosed 3/17/19 Eating BEG diet Owners have given permission to report and are willing to answer questions Changing to new diet and will recheck in 3 months Taurine and troponin 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: 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 LID High Protein Grain-free Lamb or Beef flavors		

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-382772			
ICSR:	2064292		
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:	2019-03-19 16:49:38 EDT		
Reported Problem:	Problem Description:	DCM and CHF diagnosed 3/17/19 Eating BEG diet Owners have given permission to report and are willing to answer questions Changing to new diet and will recheck in 3 months Taurine and troponin pending	
	Date Problem Started:	03/17/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Chronic dermatologic issues - likely environmental (improved significantly when owners moved to the city) Hypothyroid - on thyroxine Elevated liver enzymes	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Natural Balance LID High Protein Grain-free Lamb or Beef flavors	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Product Use Information:	Description:	This diet (either lamb or beef flavors) has been fed to B6 for last 1 year. Before that, feeding Natural Balance LID fish, chicken, beef, or lamb flavors since 1 year of age. See diet history form for further details Owner does not have current product bag but I have sample of diet
	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:	28.5 Kilogram	
	Age:	9 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:		
	Other Phone:		
	Email:		

		Address:	<div style="border: 1px dashed black; padding: 5px; display: inline-block;"> B6 </div> United States
Sender 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
Additional Documents:		Attachment:	<div style="border: 1px dashed black; padding: 2px; display: inline-block;"> B6 </div> pt_medical_record_preview.pdf
		Description:	Compiled medical records
		Type:	Medical Records

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: B6
Sent: 3/19/2019 1:32:35 PM
Subject: Redford Limited Ingredient Grain-Free Lamb and Sweet Potato; B6
- EON-382721
Attachments: 2064242-report.pdf

A PFR Report has been received and PFR Event [EON-382721] has been created in the EON System.

A "PDF" report by name "2064242-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-382721

ICSR #: 2064242

EON Title: PFR Event created for Redford Limited Ingredient Grain-Free Lamb and Sweet Potato; 2064242

AE Date	03/12/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Weimaraner		
Age	8 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2064242

Product Group: Pet Food

Product Name: Redford Limited Ingredient Grain-Free Lamb and Sweet Potato

Description: Diagnosed upon echocardiogram 3/18/19 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: Better/Improved/Recovering

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Redford Limited Ingredient Grain-Free Lamb and Sweet Potato		

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:

B6

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Report Details - EON-390087

ICSR:	2068031																																															
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:	2019-06-10 15:56:37 EDT																																															
Initial Report Date:	10/09/2018																																															
Parent ICSR:	2055822																																															
Follow-up Report to FDA Request:	Yes																																															
Reported Problem:	<table><tr><td>Problem Description:</td><td colspan="2">Asymptomatic but is housemate of [B6] who was diagnosed with DCM recently (FDA ICSR ID 2055229). Eating same diet until mid-September when switched to Pro Plan Weight Management dry. Note: [B6] does not have clear DCM but has reduced contractility. Will recheck in 6 months. Taurine pending - will submit when available.</td></tr><tr><td>Date Problem Started:</td><td colspan="2">10/02/2018</td></tr><tr><td>Concurrent Medical Problem:</td><td colspan="2">No</td></tr><tr><td>Outcome to Date:</td><td colspan="2">Better/Improved/Recovering</td></tr></table>			Problem Description:	Asymptomatic but is housemate of [B6] who was diagnosed with DCM recently (FDA ICSR ID 2055229). Eating same diet until mid-September when switched to Pro Plan Weight Management dry. Note: [B6] does not have clear DCM but has reduced contractility. Will recheck in 6 months. Taurine pending - will submit when available.		Date Problem Started:	10/02/2018		Concurrent Medical Problem:	No		Outcome to Date:	Better/Improved/Recovering																																		
Problem Description:	Asymptomatic but is housemate of [B6] who was diagnosed with DCM recently (FDA ICSR ID 2055229). Eating same diet until mid-September when switched to Pro Plan Weight Management dry. Note: [B6] does not have clear DCM but has reduced contractility. Will recheck in 6 months. Taurine pending - will submit when available.																																															
Date Problem Started:	10/02/2018																																															
Concurrent Medical Problem:	No																																															
Outcome to Date:	Better/Improved/Recovering																																															
Product Information:	<table><tr><td>Product Name:</td><td colspan="2">Taste of the Wild (various flavors) since Nov 2013</td></tr><tr><td>Product Type:</td><td colspan="2">Pet Food</td></tr><tr><td>Lot Number:</td><td colspan="2"></td></tr><tr><td>Package Type:</td><td colspan="2">BAG</td></tr><tr><td>Product Use Information:</td><td colspan="2"></td></tr><tr><td>Manufacturer /Distributor Information:</td><td colspan="2"></td></tr><tr><td>Purchase Location Information:</td><td colspan="2"></td></tr></table>			Product Name:	Taste of the Wild (various flavors) since Nov 2013		Product Type:	Pet Food		Lot Number:			Package Type:	BAG		Product Use Information:			Manufacturer /Distributor Information:			Purchase Location Information:																										
Product Name:	Taste of the Wild (various flavors) since Nov 2013																																															
Product Type:	Pet Food																																															
Lot Number:																																																
Package Type:	BAG																																															
Product Use Information:																																																
Manufacturer /Distributor Information:																																																
Purchase Location Information:																																																
Animal Information:	<table><tr><td>Name:</td><td colspan="2">[B6]</td></tr><tr><td>Type Of Species:</td><td colspan="2">Dog</td></tr><tr><td>Type Of Breed:</td><td colspan="2">Doberman Pinscher</td></tr><tr><td>Gender:</td><td colspan="2">Female</td></tr><tr><td>Reproductive Status:</td><td colspan="2">Neutered</td></tr><tr><td>Weight:</td><td colspan="2">33.4 Kilogram</td></tr><tr><td>Age:</td><td colspan="2">[B6] ears</td></tr><tr><td>Assessment of Prior Health:</td><td colspan="2">Excellent</td></tr><tr><td>Number of Animals Given the Product:</td><td colspan="2">2</td></tr><tr><td>Number of Animals Reacted:</td><td colspan="2">2</td></tr><tr><td>Owner Information:</td><td colspan="2"><table><tr><td>Owner Information provided:</td><td>Yes</td></tr><tr><td>Contact:</td><td><table><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td></td></tr></table></td></tr><tr><td>Address:</td><td>[B6]</td></tr></table></td></tr></table>			Name:	[B6]		Type Of Species:	Dog		Type Of Breed:	Doberman Pinscher		Gender:	Female		Reproductive Status:	Neutered		Weight:	33.4 Kilogram		Age:	[B6] ears		Assessment of Prior Health:	Excellent		Number of Animals Given the Product:	2		Number of Animals Reacted:	2		Owner Information:	<table><tr><td>Owner Information provided:</td><td>Yes</td></tr><tr><td>Contact:</td><td><table><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td></td></tr></table></td></tr><tr><td>Address:</td><td>[B6]</td></tr></table>		Owner Information provided:	Yes	Contact:	<table><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td></td></tr></table>	Name:	[B6]	Phone:		Email:		Address:	[B6]
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Phone:																																																
Email:																																																
Address:	[B6]																																															

			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:	Diet Hx 4-24-19.pdf	
	Description:	Diet history form	
	Type:	Medical Records	
	Attachment:	echo report 4-24-2019.pdf	
	Description:	Echo report	
	Type:	Echocardiogram	
	Attachment:	B4, B6	
	Description:	Lab work	
	Type:	Laboratory Report	
	Attachment:	Doberman DCM Combo Results Form.pdf	
	Description:	Genetic testing	
	Type:	Laboratory Report	
	Attachment:	troponin 5-30-2019.pdf	
	Description:	Lab work	
	Type:	Laboratory Report	

B4

B6

B6

Species: CANINE
Breed: DOBERMAN_PINSCH
Gender: FEMALE SPAYED
Age: 6Y

Date: 04/24/2019

B6

B4

B6

Account #88933

CARDIOPET proBNP - CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	604 ¹	B6			

Comments:

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 6/10/2019 6:08:32 PM
Subject: Taste of the Wild PREY; [B6] EON-390065
Attachments: 2068021-report.pdf; 2068021-attachments.zip

A PFR Report has been received and PFR Event [EON-390065] has been created in the EON System.

A "PDF" report by name "2068021-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 "2068021-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390065

ICSR #: 2068021

EON Title: PFR Event created for Taste of the Wild PREY; 2068021

AE Date	[B6]	Number Fed/Exposed	1
Best By Date	03/12/2020	Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Mixed (Dog)		
Age	[B6] Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2068021

Product Group: Pet Food

Product Name: Taste of the Wild PREY

Description: On [B6] night, [B6] [B6] couldn't make it back from his nightly walk, had labored breathing, and no appetite. His hind legs were shaking. On [B6] morning [B6] was brought in to the [B6] [B6] where he underwent general sedation for a hip/knee X-Ray. The thought process was that he had injured a hind leg. Under sedation early on, [B6] experienced abnormal heart rate and blood pressure readings as well as gum/ tongue color while being monitored. The vet staff pulled him from sedation, ran a general blood panel (which was unremarkable and otherwise normal - general parameters). The

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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
Taste of the Wild PREY	9072080 PDR0301-19 MSH 17:27	03/12/2020

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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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-390065

ICSR:	2068021										
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:	2019-06-10 14:02:21 EDT										
Reporter is the Animal Owner:	Yes										
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Date Problem Started:	[B6]										
Concurrent Medical Problem:	No										
Outcome to Date:	Died Naturally										
Date of Death:	[B6]										
Product Information:	<table><tr><td>Product Name:</td><td>Taste of the Wild PREY</td></tr><tr><td>Product Type:</td><td>Pet Food</td></tr></table>	Product Name:	Taste of the Wild PREY	Product Type:	Pet Food						
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Product Type:	Pet Food										

	Lot Number:	Lot Number:	9072080 PDR0301-19 MSH 17 27
		Expiration Date:	03/12/2020
	UPC:	074198613687	
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	04/01/2019	
	Number Purchased:	2	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in an air-tight pet food container that was BPA-free	
	Product Use Information:	Description:	1.75 cups fed 2x a day to total a little over 3.75 cups a day. This was taken from the back of the package for a dog in between 60 and 80 lbs.
		First Exposure Date:	04/01/2019
		Last Exposure Date:	B6
		Time Interval between Product Use and Adverse Event:	6 Weeks
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	No
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	No
			Manufacturer /Distributor Information:
Type(s):	Manufacturer		
Address:	United States		
Contact:			
Possess One or More Labels from This Product:	Yes		
	Purchase Location Information:	Name:	B6
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Mixed (Dog)	

	Gender: Male
	Reproductive Status: Neutered
	Weight: 29.8 Kilogram
	Age: B6 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
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: B6
	Permission to Release Records to FDA: Yes
	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Address: B6
	United States
	Type of Veterinarian: Referred veterinarian
Date First Seen: B6	
Permission to Release Records to FDA: Yes	
Sender Information:	Name:
	Address: B6
	Contact: Phone: B6
	Email:
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Phone
	Reported to Other Parties: Manufacturer
	Store/Place of Purchase
Additional Documents:	

Attachment:	B6	Report	B6	pdf
Description:	B6	B6	cardiology recheck and death event. Please note that in the header, B6 discharge status is listed as "Alive", however in the notes, you can see that he had actually died. B6 is not a pure lab, he was a mixed breed.	
Type:	Medical Records			

Attachment:	B6	B6	pdf
Description:	B6	B6	initial diagnosis from B6 on suspected diet-related dilated cardiomyopathy and right ventricular congestive heart failure. B6 is not a pure lab, he was a mixed breed.
Type:	Medical Records		

B6

B6 at 10:33am.

Visit Summary

Admission:
Discharge:**B6**Small Animal Inpatient
Alive**B6**Status: FinalClient #:
Client:
Address:
City, St:**B6**Clinician:
Patient #:
Patient:
Species: K9**B6**Sex: MCBreed: LABRADOR RETRI..Weight: 29.8KG

Pertinent History

B6 presented for an evaluation of lethargy, weakness, fatigue and cardiomegaly. For the past 6 months he has been getting slower on walks, fatiguing easier and less energetic. Has gotten significantly worse in the past week and last night had to be carried home after a few blocks. He has been gagging/coughing occasionally. **B6** went to **B6** today, had muffled heart sounds, was sedated with 100mcg of dexmedetomidine, 4mg butorphanol and radiographs revealed marked cardiomegaly. Was given atipamezole and referred to VSH.

Physical Examination

B6

Clinical Diagnoses

- 1) Suspect diet-associated dilated cardiomyopathy (nutritional cardiomyopathy)
- 2) Severe mitral regurgitation
- 3) Mild to moderate tricuspid regurgitation
- 4) Biventricular failure

Discharge Summary

B6

Visit Summary

B6

Patient:

B6

Page: 2

B6

Clinician Signature

Date

B6

B6 at 4:57pm.

Visit Summary

Admission: **B6** Small Animal Outpatient
Discharge: Alive

B6
Status: Final

Client #:
Client:
Address:
City, St:

B6

Clinician:
Patient #:

B6

Sex: MC

Patient:

Species: K9

Breed: LABRADOR RETRIEVER

Pertinent History

B6 presented for a recheck examination to discuss medication changes based on recent blood work revealing elevated values, including elevated kidney values.

B6 has been anorexic for a week. He is currently being force fed. His breathing rate improved for a few days (40rpm) but was elevated yesterday and today (60rpm). His abdomen appears to be more distended. He was hospitalized at

B6 and was treated with fluids and antibiotics. He is currently receiving pimobendan 7.5mg PO BID, furosemide 60mg PO BID, taurine 1000mg TID, cerenia 160mg PO SID, mirtazapine 15mg PO SID and CoQ10 100mg PO SID. Bob arrested upon presentation.

Medical/Surgical Procedures (Billing)

B6 5068 - Misc. Procedure-Card

Clinical Diagnoses

- 1) Suspect diet-associated dilated cardiomyopathy (nutritional cardiomyopathy).
Severe mitral regurgitation. Mild to moderate tricuspid regurgitation.
Biventricular failure, Death.

Discharge Instructions

B6

Clinician Signature

Date

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: [B6] Cleary, Michael *; HQ Pet Food Report Notification;
[B6]

Sent: 6/10/2019 6:20:41 PM

Subject: Taste of the Wild PREY: [B6] EON-390066

Attachments: 2068022-report.pdf; 2068022-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390066] has been created in the EON System.

A "PDF" report by name "2068022-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 "2068022-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390066

ICSR #: 2068022

EON Title: Related PFR Event created for Taste of the Wild PREY; 2068022

AE Date	[B6]	Number Fed/Exposed	1
Best By Date	03/12/2020	Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Mixed (Dog)		
Age	[B6] Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2068022

Product Group: Pet Food

Product Name: Taste of the Wild PREY

Description: On [B6] night, [B6] [B6] couldn't make it back from his nightly walk, had labored breathing, and no appetite. His hind legs were shaking. On [B6] morning, [B6] was brought in to [B6] [B6] where he underwent general sedation for a hip/knee X-Ray. The thought process was that he had injured a hind leg. Under sedation early on, [B6] experienced abnormal heart rate and blood pressure readings as well as gum/ tongue color while being monitored. The vet staff pulled him from

sedation, ran a general blood panel (which was unremarkable and otherwise normal - general parameters). The vet then decided to do a chest x-ray and found his heart to be 3x the normal size. That same day, I took him to [B6] for a cardiologist follow up as part of their [B6] extension. [B6] was diagnosed with dilated cardiomyopathy and right ventricular congestive heart failure from an echo cardiogram preformed by [B6]. He was prescribed pimobendan and lasix and 1,000 mg of taurine 3x a day. It was the opinion of [B6] that [B6] had diet-related DCM. The following week, [B6] appetite declined severely to the point of syringe feeding. On [B6] we brought him back to [B6] [B6] on the recommendation of the [B6] extension Cardiology department for a kidney panel before his second cardiologist follow up with another cardiologist, [B6] on the same day. Unfortunately, [B6] died of a fatal arrhythmia at the cardiologist's office 8 days after his initial diagnosis of suspected diet-related DCM and right ventricular CHF. The reason [B6] was suspected to have diet related DCM was due to his diet. He was on Taste of the Wild PREY, which is a limited ingredient dry food for the last [B6] years. Before that, he was on Merrick grain-free dog food. After reading information on diet related - DCM, I checked the ingredients on [B6] food and lentils was the second ingredient listed. [B6] was grain-free his whole life and on a grain-free diet high in lentils for [B6] years of his life. His last 2 bags of Taste of the Wild PREY: Bag 1 (consumed up to the time of death): UPC 0-74198-61368-7 Best by 12/Mar/2020 Possible Lot Numbers: 9072080 PDR0301-19 MSH 17:27 Bag 2 (consumed 1.5 months before time of death): UPC 0-74198-61366-3 Best by 08/Mar/2020 Possible Lot Numbers: 9068080 PDB0301-19 JDM 08:09 On a personal note: When I had taken [B6] into his initial cardiologist appointment and the vet came back in with the results, my reaction was "you have to have the wrong dog, he's only [B6] years old!". His response immediately was, "what are you feeding him?" As soon as I said grain-free, he said he had a very belief [B6] case was diet-related because he was a mixed breed. We had reached out to Taste of the Wild to ask them if they knew about this and had heard. Their answer was yes. It's a long shot, but please do contact me to follow up bc I want to know if the FDA has plans to more closely monitor dog food companies in the coming future. I believe that this is necessary. These dog food companies have a huge responsibility to do due-diligence on nutrition profiles. The animal space is highly desirable because it's a channel where savvy marketing pays big dividends and it is completely unregulated by a government agency. I don't want to live in a country where basic items like food are subject to the belief that marketing means more than testing. Please call with any additional questions you have. I'm happy to share [B6] story and provide as much details as I can to help make a difference. I also want to know how many cases have been reported.

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

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

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 PREY	9072080 PDR0301-19 MSH 17:27	03/12/2020

This report is linked to:

Initial EON Event Key: EON-390065

Initial ICSR: 2068021

Sender information

B6

USA

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

B6

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

B6

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Report Details - EON-390066

ICSR:	2068022						
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:	2019-06-10 14:11:22 EDT						
Initial Report Date:	06/10/2019						
Reporter is the Animal Owner:	Yes						
Parent ICSR:	2068021						
Follow-up Report to FDA Request:	Yes						
Reported Problem:	<table><tr><td>Problem Description:</td><td><p>On [B6] night, [B6] [B6] couldn't make it back from his nightly walk, had labored breathing, and no appetite. His hind legs were shaking. On [B6] morning, [B6] was brought in to the [B6] where he underwent general sedation for a hip/knee X-Ray. The thought process was that he had injured a hind leg. Under sedation early on, [B6] experienced abnormal heart rate and blood pressure readings as well as gum/ tongue color while being monitored. The vet staff pulled him from sedation, ran a general blood panel (which was unremarkable and otherwise normal - general parameters). The vet then decided to do a chest x-ray and found his heart to be 3x the normal size. That same day, I took him to [B6] for a cardiologist follow up as part of their [B6] extension. [B6] was diagnosed with dilated cardiomyopathy and right ventricular congestive heart failure from an echo cardiogram preformed by [B6]. He was prescribed pimobendan and lasix and 1,000 mg of taurine 3x a day. It was the opinion of [B6] that [B6] had diet-related DCM. The following week, [B6] appetite declined severely to the point of syringe feeding. On [B6] we brought him back to [B6] on the recommendation of the [B6] [B6] extension Cardiology department for a kidney panel before his second cardiologist follow up with another cardiologist, [B6] on the same day. Unfortunately, [B6] died of a fatal arrhythmia at the cardiologist's office 8 days after his initial diagnosis of suspected diet-related DCM and right ventricular CHF. The reason [B6] was suspected to have diet related DCM was due to his diet. He was on Taste of the Wild PREY, which is a limited ingredient dry food for the last 3.5 years. Before that, he was on Merrick grain-free dog food. After reading information on diet related - DCM, I checked the ingredients on [B6] food and lentils was the second ingredient listed. [B6] was grain-free his whole life and on a grain-free diet high in lentils for 3.5/4.5 years of his life. His last 2 bags of Taste of the Wild PREY: Bag 1 (consumed up to the time of death): UPC 0-74198-61368-7 Best by 12/Mar/2020 Possible Lot Numbers: 9072080 PDR0301-19 MSH 17:27 Bag 2 (consumed 1.5 months before time of death): UPC 0-74198-61366-3 Best by 08/Mar/2020 Possible Lot Numbers: 9068080 PDB0301-19 JDM 08:09 On a personal note: When I had taken [B6] into his initial cardiologist appointment and the vet came back in with the results, my reaction was "you have to have the wrong dog, he's only [B6] years old!". His response immediately was, "what are you feeding him?" As soon as I said grain-free, he said he had a very belief [B6] case was diet-related because he was a mixed breed. We had reached out to Taste of the Wild to ask them if they knew about this and had heard. Their answer was yes. 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I also want to know how many cases have been reported.</p></td></tr><tr><td>Date Problem Started:</td><td>[B6]</td></tr><tr><td>Concurrent Medical Problem:</td><td>No</td></tr></table>	Problem Description:	<p>On [B6] night, [B6] [B6] couldn't make it back from his nightly walk, had labored breathing, and no appetite. His hind legs were shaking. On [B6] morning, [B6] was brought in to the [B6] where he underwent general sedation for a hip/knee X-Ray. The thought process was that he had injured a hind leg. Under sedation early on, [B6] experienced abnormal heart rate and blood pressure readings as well as gum/ tongue color while being monitored. The vet staff pulled him from sedation, ran a general blood panel (which was unremarkable and otherwise normal - general parameters). The vet then decided to do a chest x-ray and found his heart to be 3x the normal size. That same day, I took him to [B6] for a cardiologist follow up as part of their [B6] extension. 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Date Problem Started:	[B6]						
Concurrent Medical Problem:	No						

	Outcome to Date:	Died Naturally		
	Date of Death:	B6		
Product Information:	Product Name:	Taste of the Wild PREY		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	9072080 PDR0301-19 MSH 17/27	
		Expiration Date:	03/12/2020	
	UPC:	074198613687		
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	04/01/2019		
	Number Purchased:	2		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in an air-tight pet food container that was BPA-free		
	Product Use Information:	Description:	1.75 cups fed 2x a day to total a little over 3.75 cups a day. This was taken from the back of the package for a dog in between 60 and 80 lbs.	
		First Exposure Date:	04/01/2019	
		Last Exposure Date:	B6	
		Time Interval between Product Use and Adverse Event:	6 Weeks	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	No	
		Product Use Started Again:	No	
		Perceived Relatedness to Adverse Event:	Definitely related	
Other Foods or Products Given to the Animal During This Time Period:		No		
Manufacturer /Distributor Information:		Name:	Diamond Pet Food Companies - Taste of the Wild	
	Type(s):	Manufacturer		
	Address:	United States		
	Contact:			
	Possess One or More Labels from This Product:	Yes		
Purchase Location Information:	Name:			
	Address:	B6		

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Mixed (Dog)		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	29.8 Kilogram		
	Age:	B6 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:	
		Address:	B6	
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		B6		
Permission to Release Records to FDA:		Yes		
Practice Name:		B6		
Contact:		Name:	B6	
		Phone:		
Address:		B6		
	United States			
Type of Veterinarian:	Referred veterinarian			
Date First Seen:	B6			
Permission to Release Records to FDA:	Yes			
Practice Name:	B6			
Contact:	Name:	B6		
	Phone:			
Address:	B6			
Type of Veterinarian:	Referred 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
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	Manufacturer Store/Place of Purchase
	Additional Documents:	Attachment:
Description:		Taste of the Wile PREY Fed to B6 at the even of his death
Type:		Product Label
Attachment:		TOTW_2.jpg
Description:		Taste of the Wild PREY Fed to B6 ~6-8 weeks leading up to his death on B6 B6
Type:		Product Label
Attachment:		B6 19039110_ Taurine Level (B6 Amino Acid Lab).pdf
Description:		B6 Taurine levels. Echo-cardiogram can be submitted once recieved.
Type:		Medical Records

B6

B6

Account #: 788
Fax:

Rcvd: 15-May-2019 12:28 am

Rptd: 29-May-2019 10:55 am

B6

B6

B6

Final

Age: B6 1 Sex: M Neutered: Y Species: Canine Breed: Labrador Retriever

Tests Ordered: Taurine Level (B6 Amino Acid Lab)

Pending Tests:

Test	Result	Reference Range	Units
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Send Out

Taurine Level (B6 Amino Acid Lab)

Sample type

Plasma

Taurine Level

B6

Plasma normal range: No known risk for Taurine Deficiency

Cat 80 - 120 nmol/ml

Dog 60 - 120 nmol/ml

B6

Whole blood normal range: No risk for Taurine deficiency

Cat 300 - 600 nmol/ml

Dog 200 - 350 nmol/ml

B6

Testing performed at the Amino Acids Laboratory: B6

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**

Sent: 1/23/2019 11:40:21 PM

Subject: Wellness Core Ocean Grain Free Protein-Rich Nutrition; EON-377321 **B6**

Attachments: 2061666-report.pdf; 2061666-attachments.zip

A PFR Report has been received and PFR Event [EON-377321] has been created in the EON System.

A "PDF" report by name "2061666-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 "2061666-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377321

ICSR #: 2061666

EON Title: PFR Event created for Wellness Core Ocean Grain Free Protein-Rich Nutrition; 2061666

AE Date	02/15/2015	Number Fed/Exposed	2
Best By Date	10/24/2019	Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	7 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2061666

Product Group: Pet Food

Product Name: Wellness Core Ocean Grain Free Protein-Rich Nutrition

Description: Began feeding Wellness CORE Ocean Dry Kibble Feb. 2015 as main source of nutrition, fed 1 cup 2x per day. Submitted Whole Blood sample to UC Davis Amino Acid Lab for Taurine Testing 6/26/2018. Lab Result 240 Whole Blood Taurine Results which per Dr. Joshua Stern UC Davis DVM Cardiologist is BELOW the 250 minimum range for a Golden Retriever Dog. Per Dr. Stern's order continue feedling this food and supplement each daily meal with taurine rich foods for 3 months then ReTest. Supplemented kibble with 1/2cup

pan fried Ground Sirloin, 1 Hardboiled Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole Blood Taurine Level October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24/2018 Lab Result Whole Blood Taurine Results 297. Improvement of 57, putting him within the "normal" range Dr. Stern has identified for Golden Retriever Dogs.

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Wellness Core Ocean Grain Free Protein-Rich Nutrition	1228J22	10/24/2019

Sender 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

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Report Details - EON-377321

ICSR:	2061666		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-23 18:29:48 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Began feeding Wellness CORE Ocean Dry Kibble Feb. 2015 as main source of nutrition, fed 1 cup 2x per day. Submitted Whole Blood sample to UC Davis Amino Acid Lab for Taurine Testing 6/26/2018. Lab Result 240 Whole Blood Taurine Results which per Dr. Joshua Stern UC Davis DVM Cardiologist is BELOW the 250 minimum range for a Golden Retriever Dog. Per Dr. Stern's order continue feeding this food and supplement each daily meal with taurine rich foods for 3 months then ReTest. Supplemented kibble with 1/2cup pan fried Ground Sirloin, 1 Hardboiled Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole Blood Taurine Level October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24/2018 Lab Result Whole Blood Taurine Results 297. Improvement of 57, putting him within the "normal" range Dr. Stern has identified for Golden Retriever Dogs.	
	Date Problem Started:	02/15/2015	
	Date of Recovery:	10/24/2018	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Wellness Core Ocean Grain Free Protein-Rich Nutrition	
	Product Type:	Pet Food	
	Lot Number:	Lot Number:	1228J22
		Expiration Date:	10/24/2019
	UPC:	076344884132	
	Package Type:	BAG	
	Package Size:	12 Pound	
	Purchase Date:	01/04/2019	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Bag has a ziplock freshness seal which was opened and resealed after each use.	
	Product Use Information:	Description:	Fed 1 cup kibble soaked in warm water 2x per day to Snickers.
		Last Exposure Date:	01/04/2019
		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:	Yes
		Product Use Started Again:	No
		Perceived	Definitely related

		Relatedness to Adverse Event:	
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Petco
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	73 Pound	
	Age:	7 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	06/26/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact	Yes	

	Sender:	
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other Store/Place of Purchase
Additional Documents:	Attachment:	B6 Oct20182ndTaurineResults_23928.jpg.pdf
	Description:	Taurine Retest Lab Report after 3 months of adding Taurine Rich Foods to existing kibble which was causing the problem.
	Type:	Laboratory Report
	Attachment:	B6 June2620181stTaurineResultsT_19251.pdf
	Description:	First Taurine Results, Per Dr. Stern: "Those taurine levels are ok. I would prefer to see over 250. My recommendation would be either diet change and retest after 3 months or add in taurine rich ingredients and retest in 3 months. "
	Type:	Laboratory Report
	Attachment:	DrStern Lab Taurine RecommendationsAug2018.pdf
	Description:	Aug 2018 Letter from Dr. Joshua Stern DVM Cardiologist explaining the Taurine Deficeincy results specifically to Golden Retriever owners with the correct range that Golden Retriever dogs are to be in.
	Type:	Letter

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/24/2019 12:08:21 AM

Subject: Wellness Core Ocean Grain Free Protein-Rich Nutrition; B6
EON-377324

Attachments: 2061667-report.pdf; 2061667-attachments.zip

A PFR Report has been received and PFR Event [EON-377324] has been created in the EON System.

A "PDF" report by name "2061667-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 "2061667-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377324

ICSR #: 2061667

EON Title: PFR Event created for Wellness Core Ocean Grain Free Protein-Rich Nutrition; 2061667

AE Date	01/02/2017	Number Fed/Exposed	2
Best By Date	10/24/2019	Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2061667

Product Group: Pet Food

Product Name: Wellness Core Ocean Grain Free Protein-Rich Nutrition

Description: Began feeding Wellness CORE Ocean Dry Kibble Jan. 2017 as main source of nutrition, fed 1.5 cup 2x per day. Submitted Whole Blood sample to UC Davis Amino Acid Lab for Taurine Testing 6/26/2018. Lab Result 256 Whole Blood Taurine Results which per Dr. Joshua Stern UC Davis DVM Cardiologist is barely above the 250 minimum range for a Golden Retriever Dog. Per Dr. Stern's order continue feedling this food and supplement each daily meal with taurine rich foods for 3 months then ReTest. Supplemented kibble with 1/2cup

pan fried Ground Sirloin, 1 Hardboiled Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole Blood Taurine Level October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24/2018 Lab Result Whole Blood Taurine Results 348. Improvement of 57, putting him within the "normal" range Dr. Stern has identified for Golden Retriever Dogs.

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Wellness Core Ocean Grain Free Protein-Rich Nutrition	1228J22	10/24/2019

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-377324

ICSR:	2061667		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-23 18:59:19 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	<p>Began feeding Wellness CORE Ocean Dry Kibble Jan. 2017 as main source of nutrition, fed 1.5 cup 2x per day. Submitted Whole Blood sample to UC Davis Amino Acid Lab for Taurine Testing 6/26/2018. Lab Result 256 Whole Blood Taurine Results which per Dr. Joshua Stern UC Davis DVM Cardiologist is barely above the 250 minimum range for a Golden Retriever Dog. Per Dr. Stern's order continue feeding this food and supplement each daily meal with taurine rich foods for 3 months then ReTest. Supplemented kibble with 1/2cup pan fried Ground Sirloin, 1 Hardboiled Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole Blood Taurine Level October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24 /2018 Lab Result Whole Blood Taurine Results 348. Improvement of 57, putting him within the "normal" range Dr. Stern has identified for Golden Retriever Dogs.</p>	
	Date Problem Started:	01/02/2017	
	Date of Recovery:	10/24/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Wellness Core Ocean Grain Free Protein-Rich Nutrition	
	Product Type:	Pet Food	
	Lot Number:	Lot Number:	1228J22
		Expiration Date:	10/24/2019
	UPC:	076344884132	
	Package Type:	BAG	
	Package Size:	12 Pound	
	Purchase Date:	12/04/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Bag has a ziplock freshness seal which was opened and resealed after each use.	
	Product Use Information:	Description:	Fed 1.5 cups kibble soaked in warm water 2x per day to Oly.
		Last Exposure Date:	01/04/2019
		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:	Yes
		Product Use Started Again:	No
		Perceived	Definitely related

		Relatedness to Adverse Event:		
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
		Manufacturer /Distributor Information:	Name:	WellPet
			Type(s):	Manufacturer
			Address:	200 Ames Pond Drive Tewksbury Massachusetts 01876 United States
			Contact:	Phone: 1-800-225-0904 Web Address: http://wellnesspetfood.com/contact-us
			Possess One or More Labels from This Product:	Yes
		Purchase Location Information:	Name:	Petco
			Address:	<div style="border: 1px dashed black; padding: 10px; text-align: center;">B6</div> United States
		Animal Information:	Name:	<div style="border: 1px dashed black; padding: 2px;">B6</div>
Type Of Species:	Dog			
Type Of Breed:	Retriever - Golden			
Gender:	Male			
Reproductive Status:	Neutered			
Weight:	65 Pound			
Age:	3 Years			
Assessment of Prior Health:	Excellent			
Number of Animals Given the Product:	2			
Number of Animals Reacted:	2			
Owner Information:				
Healthcare Professional Information:	Practice Name:		<div style="border: 1px dashed black; padding: 2px;">B6</div>	
	Contact:		Name: Phone: Email:	
	Address:		<div style="border: 1px dashed black; padding: 10px; text-align: center;">B6</div> United States	
	Type of Veterinarian:		Primary/regular veterinarian	
	Date First Seen:	06/26/2018		
	Permission to Release Records to FDA:	Yes		

Sender Information:	Name:	B6																		
	Address:	B6 United States																		
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Phone:	B6	Email:															
	Phone:	B6																		
	Email:																			
	Reporter Wants to Remain Anonymous:	No																		
	Permission To Contact Sender:	Yes																		
Preferred Method Of Contact:	Email																			
Reported to Other Parties:	Store/Place of Purchase Other																			
Additional Documents:	<table border="1"> <tr> <td>Attachment:</td> <td>B6 June20181stTaurineResults_19250.jpg.pdf</td> </tr> <tr> <td>Description:</td> <td>First Taurine Results Lab Report June 2018</td> </tr> <tr> <td>Type:</td> <td>Laboratory Report</td> </tr> <tr> <td>Attachment:</td> <td>B6 Oct20182ndTaurineResults_23928.jpg.pdf</td> </tr> <tr> <td>Description:</td> <td>2nd Lab Results for Taurine from UC Davis Vet Amimno Acid Lab</td> </tr> <tr> <td>Type:</td> <td>Laboratory Report</td> </tr> <tr> <td>Attachment:</td> <td>DrStern Lab Taurine RecommendationsAug2018.pdf</td> </tr> <tr> <td>Description:</td> <td>Per email from Dr. Stern:"Those taurine levels are just ok. I would prefer to see it higher than 256. My recommendation would be either diet change & retest after 3 months or add in taurine rich ingredients & retest in 3 months."</td> </tr> <tr> <td>Type:</td> <td>Letter</td> </tr> </table>		Attachment:	B6 June20181stTaurineResults_19250.jpg.pdf	Description:	First Taurine Results Lab Report June 2018	Type:	Laboratory Report	Attachment:	B6 Oct20182ndTaurineResults_23928.jpg.pdf	Description:	2nd Lab Results for Taurine from UC Davis Vet Amimno Acid Lab	Type:	Laboratory Report	Attachment:	DrStern Lab Taurine RecommendationsAug2018.pdf	Description:	Per email from Dr. Stern:"Those taurine levels are just ok. I would prefer to see it higher than 256. My recommendation would be either diet change & retest after 3 months or add in taurine rich ingredients & retest in 3 months."	Type:	Letter
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Type:	Letter																			

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B4
Sent: 12/4/2018 11:04:49 PM
Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372828
Attachments: 2059621-report.pdf; 2059621-attachments.zip

A PFR Report has been received and PFR Event [EON-372828] has been created in the EON System.

A "PDF" report by name "2059621-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 "2059621-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372828

ICSR #: 2059621

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059621

AE Date	11/20/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2059621

Product Group: Pet Food

Product Name: Earthborn Meadow Feast dry

Description: Eating BEG diet (Earthborn) Echo had subjectively reduced contractility; elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

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: 5

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

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

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Report Details - EON-372828

ICSR:	2059621		
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:	2018-12-04 17:59:30 EST		
Reported Problem:	Problem Description:	Eating BEG diet (Earthborn) Echo had subjectively reduced contractility, elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months	
	Date Problem Started:	11/20/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Earthborn Meadow Feast dry	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Description:	See diet history in records for more details
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Female	
	Reproductive Status:	Intact	
	Pregnancy Status:	Not pregnant	
	Lactation Status:	Not lactating	
	Weight:	30.3 Kilogram	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	5	
	Number of Animals Reacted:	4	
	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:	rpt_medical_record_preview.pdf	
	Description:	Medical records	
	Type:	Medical Records	

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 12/4/2018 11:12:44 PM
Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372831
Attachments: 2059622-report.pdf; 2059622-attachments.zip

A PFR Report has been received and PFR Event [EON-372831] has been created in the EON System.

A "PDF" report by name "2059622-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 "2059622-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372831

ICSR #: 2059622

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059622

AE Date	11/15/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2059622

Product Group: Pet Food

Product Name: Earthborn Meadow Feast dry

Description: Daughter diagnosed with reduced cardiac contractility **B6** and **B6** Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

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: 5

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

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

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Report Details - EON-372831

ICSR:	2059622																																																														
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:	2018-12-04 18:08:14 EST																																																														
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Healthcare Professional Information:	<table><tr><td>Practice Name:</td><td>Tufts Cummings School of Veterinary Medicine</td></tr><tr><td>Contact:</td><td><table><tr><td>Name:</td><td>Lisa Freeman</td></tr></table></td></tr></table>		Practice Name:	Tufts Cummings School of Veterinary Medicine	Contact:	<table><tr><td>Name:</td><td>Lisa Freeman</td></tr></table>	Name:	Lisa Freeman																																																							
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			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:	rpt_medical_record_preview B6 pdf	
	Description:	Medical records	
	Type:	Medical Records	

Amino Acid and Energy Digestibility in Peas (*Pisum sativum*) from White-Flowered Spring Cultivars for Growing Pigs

Ming Z Fan, Willem C Sauer*

Department of Animal Science, University of Alberta, Edmonton, Alberta, Canada, T6G 2P5

and Sam Jaikaran

Alberta Agriculture, Edmonton, Alberta, Canada, T6H 4P2

(Received 15 April 1993; revised version received 25 August 1993; accepted 18 October 1993)

Abstract: Six barrows, average initial weight 35 kg, fitted with a simple T-cannula at the distal ileum, were used to determine the apparent ileal digestibilities of amino acids (AA) and the digestibility of energy in six diets according to a 6 × 6 Latin square design. The pigs were fed six corn starch-based diets formulated to contain 165 g CP per kg from six different white-flowered spring pea cultivars. Chromic oxide was used as the digestibility marker. The pigs were fed twice daily, at 08:00 and 20:00 h. Each experimental period lasted 9 days. Faeces were collected from 08:00 on day 6 to 08:00 h on day 8; ileal digesta from 08:00 on day 7 to 08:00 h on day 9. Of the indispensable (+ semi-) AA, there were differences ($P < 0.05$) in the AA digestibilities of arginine, methionine, phenylalanine and tyrosine between the cultivars. In the same order for these AA, the digestibilities ranged from 81.3 to 89.0%, 67.8 to 75.1%, 68.0 to 74.6% and 66.1 to 74.8%, respectively. Within each cultivar, the digestibilities of cysteine and threonine were relatively low, ranging from 58.5 to 65.9% and from 59.6 to 67.4%, respectively. The digestibility of lysine was relatively high, ranging from 80.3 to 84.0%. The energy digestibilities in the pea cultivars ranged from 87.4 to 90.2% ($P < 0.05$); the digestible energy content from 14.0 to 14.4 MJ kg⁻¹ DM. There was considerable disappearance of energy in the large intestine, ranging from 4.4 to 6.2 MJ kg⁻¹ DM intake from peas. In conclusion, when measured with the ileal analysis method, there were differences ($P < 0.05$) in the digestibilities of some of the indispensable AA between the pea samples. Furthermore, the relatively low digestibilities of methionine and cysteine further accentuate the limitation of the sulphur-containing AA in protein from peas.

Key words: pigs, peas (*pisum sativum*), amino acids, energy, digestibility

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Hodges, April; Norris, Anne; Carey, Lauren; Glover, Mark
Sent: 4/4/2018 2:19:21 PM
Subject: FYI -lentils--deficient in sulfur containing amino acids--methionine, tryptophan, and cysteine

Lentil protein, like other pulse proteins, is a good source of the essential amino acids, particularly leucine, lysine, threonine, and phenylalanine, but is deficient in the sulfur-containing essential amino acids methionine and cysteine

<https://www.sciencedirect.com/science/article/pii/B9780123979353000013>

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

B6 (BB)



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DIETARY CYSTEINE/METHIONINE RATIOS AND TAURINE SUPPLEMENTATION:
EFFECTS ON RAT GROWTH, AMINO ACIDS AND BILE ACIDS

G. Sarwar, Ph.D., R.W. Peace, M.Sc and H.G. Botting
Bureau of Nutritional Sciences, Food Directorate,
Health Protection Branch, Health and Welfare Canada
Tunney's Pasture, Ottawa, Ontario, Canada K1A 0L2

ABSTRACT

Diets containing 15% protein (casein plus arginine, threonine and tryptophan), 20% fat (soybean-coconut oil) and adequate amounts of minerals and vitamins were supplemented with methionine and/or cysteine to provide cysteine/methionine ratios of 0.2, 1.0 and 2.0 simulating those in various dietary proteins, human milk and infant formulas. The dietary cysteine/methionine ratios had significant ($P < 0.05$) effects on 2-wk weight gain and levels of blood serum urea nitrogen (BUN) and taurine-conjugated bile acids in bile of weanling rats, indicating an inferior nutritional quality of the low cysteine/methionine diet (0.2) compared to the medium (1.0) or high (2.0) cysteine/methionine diet. Taurine supplementation increased levels of taurine in liver, serum and urine of rats fed all three cysteine/methionine diets. Taurine supplementation also increased levels of taurine-conjugated bile acids in the bile of rats fed the low cysteine/methionine diet but produced fatty livers in those fed the high cysteine/methionine diet.

KEY WORDS: cysteine/methionine ratio, taurine supplementation, rat growth, protein quality, bile acids, fatty livers

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 3/23/2019 3:42:44 PM
Subject: Cobalt

Hi Jen,

In the Feb, 2019 Vet-LIRN report, it states that cobalt was tested in the diets and was within normal nutrient ranges recommended by AAFCO.

B5

B5

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

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Andrea Fascetti'
Sent: 9/18/2018 11:23:41 AM
Subject: control dog Taurine-urine

Good morning Andrea,

B5, B6

Thank you for the collaborative opportunity!

B6

Take care,
Jen

Jennifer L. A. Jones, DVM

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



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: 12/4/2018 10:01:57 PM
Subject: DCM 12/4/2018 1656
Attachments: Acana Lamb and Apple singles: Lisa Freeman - EON-372606; Blue Buffalo Wilderness Large Breed Grain free dry: Lisa Freeman - EON-372652; Loyall Professional All Life Stages dry: Lisa Freeman - EON-372653; Rachel Ray Nutrish Zero Grain: **B6** - EON-372718

Not as many reports..

B5

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification;
Sent: 12/3/2018 2:36:39 PM
Subject: Acana Lamb and Apple singles: Lisa Freeman - EON-372606
Attachments: 2059540-report.pdf; 2059540-attachments.zip

B6

A PFR Report has been received and PFR Event [EON-372606] has been created in the EON System.

A "PDF" report by name "2059540-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 "2059540-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372606

ICSR #: 2059540

EON Title: PFR Event created for Acana Lamb and Apple singles; 2059540

AE Date	11/08/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Irish Wolfhound		
Age	3 Years		
District Involved	PFR	B6 DO	

Product information

Individual Case Safety Report Number: 2059540

Product Group: Pet Food

Product Name: Acana Lamb and Apple singles

Description: Littermate diagnosed with DCM. Initial taurine level (plasma only) was 42. WB taurine submitted = 304 Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = 2766, troponin mildly elevated at 0.1 (istat) and 0.096 at Texas A&M Will recheck in 3-4 months

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 Lamb and Apple singles		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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From: PFR Event <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 12/3/2018 7:48:38 PM
Subject: Blue Buffalo Wilderness Large Breed Grain free dry: Lisa Freeman - EON-372652
Attachments: 2059566-report.pdf; 2059566-attachments.zip

A PFR Report has been received and PFR Event [EON-372652] has been created in the EON System.

A "PDF" report by name "2059566-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 "2059566-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372652

ICSR #: 2059566

EON Title: PFR Event created for Blue Buffalo Wilderness Large Breed Grain free dry; 2059566

AE Date	09/18/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		
Age	6 Years		
District Involved	PFR	B6 DO	

Product information

Individual Case Safety Report Number: 2059566

Product Group: Pet Food

Product Name: Blue Buffalo Wilderness Large Breed Grain free dry

Description: Evaluated for exercise intolerance; identified ventricular arrhythmia and mildly reduced contractile function. Plasma taurine 174 (WB not evaluated). We will be rechecking dog in a 3-4 months. Was eating BEG diet (Blue Buffalo) at time of diagnosis then switched to Fromm Lg Breed after diagnosis but now transitioning to Pro Plan Weight Management

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Blue Buffalo Wilderness Large Breed Grain free 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:

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/4/2018 3:08:27 PM
Subject: Rachel Ray Nutrish Zero Grain; [B6] EON-372718
Attachments: 2059592-report.pdf; 2059592-attachments.zip

A PFR Report has been received and PFR Event [EON-372718] has been created in the EON System.

A "PDF" report by name "2059592-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 "2059592-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372718

ICSR #: 2059592

EON Title: PFR Event created for Rachel Ray Nutrish Zero Grain; 2059592

AE Date	[B6]	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Other
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2059592

Product Group: Pet Food

Product Name: Rachel Ray Nutrish Zero Grain

Description: I was working from home. [B6] sleeps next to me while I work. The doorbell rang. [B6] jumped up and ran to the window. I got up and looked out the same window to see who it was because we weren't expecting anyone. I didnt know who it was so I did not answer the door. As soon as I said to [B6] it's okay...he instantly fell to the ground and had a heart attack. Died in mid air. He was dead before he hit the ground. Devastated, screaming etc. It was horrible. I called 911, called the emergency vet hospital etc. The family came over to say their good byes. When he was taken to the Vet by our town dog service, the director told us she

believes this is due to feeding him GF food. Apparently GF food is fatal to Golden retrievers. It causes widow makers. There is research done on this - not really advertised like it should be and it needs to be on the labels of GF dry dog food that this is potentially harmful to feed golden retrievers. Can be fatal. In our case it was. A perfectly healthy dog. Dead. Our family will never be the same. He was the best dog in the world and he is gone. BECAUSE of GF Food. If it cannot be taken off the shelf then it needs to be on the labels that it can be harmful to golden retrievers and other breeds. It causes dilated cardiomyopathy. It lowers certain levels in the dog and causes heart attacks.

Submission Type: Initial

Report Type: Both

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Rachel Ray Nutrish Zero Grain		

Sender information

B6

USA

B6

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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 Pet Food Complaint](#)" for additional instructions.

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: 3/22/2019 1:54:08 PM
Subject: DCM Cases 3/22/2019 1000
Attachments: Acana Free Run Poultry dry: Lisa Freeman - EON-374786; Acana Free Run Poultry dry: Lisa Freeman - EON-383005; Freshpet select roasted meals chicken flavor: B6 - EON-383014

One related

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

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 12/27/2018 3:16:35 PM
Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-374786
Attachments: 2060599-report.pdf; 2060599-attachments.zip

A PFR Report has been received and PFR Event [EON-374786] has been created in the EON System.

A "PDF" report by name "2060599-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 "2060599-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374786

ICSR #: 2060599

EON Title: PFR Event created for Acana Free Run Poultry dry; 2060599

AE Date	08/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	10 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060599

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

Description: Housemate was diagnosed with DCM (B6 - previously reported). B6 was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months
WB taurine 328

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Acana Free Run Poultry dry		

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:

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification [B6]
Sent: 3/22/2019 12:28:24 AM
Subject: Freshpet select roasted meals chicken flavor: [B6] - EON-383014
Attachments: 2064400-report.pdf

A PFR Report has been received and PFR Event [EON-383014] has been created in the EON System.

A "PDF" report by name "2064400-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-383014

ICSR #: 2064400

EON Title: PFR Event created for Freshpet select roasted meals chicken flavor; 2064400

AE Date	01/03/2016	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Shih Tzu		
Age	10 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2064400

Product Group: Pet Food

Product Name: Freshpet select roasted meals chicken flavor

Description: My dog was diagnosed with congestive heart failure and cardiomyopathy. He eats freshpet dog food. I don't know if that's why he got it but I've read some dog foods can cause this, especially grain free. This has oats so I don't know if that's considered grain free or not but in case it is helpful I am sharing.

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: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Freshpet select roasted meals chicken flavor		

Sender information

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CARDIOLOGY DIET HISTORY FORM

B5

Document properties

Author: **B6**
Company: **B6**
Template: Normal.dotm
Page count: 1
Paragraph count: 48
Line count: 63
Word count: 395
Character count (spaces excluded): 3536
Character count (spaces included): 4090

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: 3/21/2019 4:17:43 PM
Subject: DCM cases 3/21/2019 1200
Attachments: 2064344-report.pdf; Acana Lamb and Apple singles: Lisa Freeman - EON-372606; Acana Lamb and Apple singles: Lisa Freeman - EON-382951; Acana Puppy and Junior: **B6** EON-382870; American Journey Grain-free Salmon & Sweet Potato Recipe: **B6** EON-382903; American Journey-Salmon and Sweet Potato: **B6** EON-382867; American Journey-Salmon and Sweet Potato: **B6** EON-382867; CANIDAE- ALL LIFE STAGES-CHICKEN MEAL & RICE FORMULA--DRY DOG FOOD: Lisa Freeman - EON-381040; CANIDAE- ALL LIFE STAGES-CHICKEN MEAL & RICE FORMULA--DRY DOG FOOD: Lisa Freeman - EON-382878; CANIDAE- ALL LIFE STAGES-CHICKEN MEAL & RICE FORMULA--DRY DOG FOOD: Lisa Freeman - EON-382884; FROMM Salmon Tunalini: **B6** **B6** EON-382921; Homecooked diet - see diet history in medical record: Lisa Freeman - EON-374789; Homecooked diet - see diet history in medical record: Lisa Freeman - EON-382947; Horizons pulsar grain free diet: **B6** EON-382952; Kirkland Signature Nature's Domain Cat Food: **B6** EON-382911; Nutrisource Large breed puppy Grain free: **B6** **B6** EON-382807; Nutrisource Large breed puppy Grain free: **B6** - EON-382807; Nutro MAX Adult Recipe With Farm Raised Chicken Mini Chunk Dry Dog Food: **B6** EON-382838; Taste of the Wild Grain Free: **B6** **B6** EON-382849

Please note:

American Journey (382867)- histopath findings included.

B5

B5

B5

B5

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 12/3/2018 2:36:39 PM
Subject: Acana Lamb and Apple singles: Lisa Freeman - EON-372606
Attachments: 2059540-report.pdf; 2059540-attachments.zip

A PFR Report has been received and PFR Event [EON-372606] has been created in the EON System.

A "PDF" report by name "2059540-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 "2059540-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372606

ICSR #: 2059540

EON Title: PFR Event created for Acana Lamb and Apple singles; 2059540

AE Date	11/08/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Irish Wolfhound		
Age	3 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2059540

Product Group: Pet Food

Product Name: Acana Lamb and Apple singles

Description: Littermate diagnosed with DCM. Initial taurine level (plasma only) was 42. WB taurine submitted = 304 Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = 2766, troponin mildly elevated at 0.1 (istat) and 0.096 at Texas A&M Will recheck in 3-4 months

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 Lamb and Apple singles		

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

=====

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: [REDACTED] B6; Cleary, Michael *; HQ Pet Food Report Notification;
[REDACTED] B6

Sent: 3/21/2019 4:00:51 PM

Subject: Acana Lamb and Apple singles: Lisa Freeman - EON-382951

Attachments: 2064360-report.pdf; 2064360-attachments.zip

A PFR Report has been received and Related PFR Event [EON-382951] has been created in the EON System.

A "PDF" report by name "2064360-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 "2064360-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382951

ICSR #: 2064360

EON Title: Related PFR Event created for Acana Lamb and Apple singles; 2064360

AE Date	11/08/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Irish Wolfhound		
Age	3 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2064360

Product Group: Pet Food

Product Name: Acana Lamb and Apple singles

Description: Littermate diagnosed with DCM. Initial taurine level (plasma only) was 42. WB taurine submitted = 304 Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = 2766, troponin mildly elevated at 0.1 (istat) and 0.096 at Texas A&M Will recheck in 3-4 months Follow-up - NT-proBNP, troponin, echo and ECG

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Lamb and Apple singles		

This report is linked to:

Initial EON Event Key: EON-372606

Initial ICSR: 2059540

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 3/20/2019 8:28:29 PM
Subject: Acana Puppy and Junior; B6 EON-382870
Attachments: 2064331-report.pdf

A PFR Report has been received and PFR Event [EON-382870] has been created in the EON System.

A "PDF" report by name "2064331-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-382870

ICSR #: 2064331

EON Title: PFR Event created for Acana Puppy and Junior, Horizon Pulsar Pulses & Chicken formula Grain free, Fromm Adult Gold; 2064331

AE Date	03/11/2019	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Shepherd Dog - Belgian Tervueren		
Age	46 Months		
District Involved	PFR-Foreign Firms DO		

Product information

Individual Case Safety Report Number: 2064331

Product Group: Pet Food

Product Name: Acana Puppy and Junior, Horizon Pulsar Pulses & Chicken formula, Grain free, Fromm Adult Gold

Description: Have fed Acana puppy for a few weeks, Horizon Pulsar, a grain free diet, for 3.5 years, Fromm adult gold for 3 months. Veterinarian detected a heart murmur, we elected to have dog under go an echocardiogram. Cardiologist diagnosed "Given her dietary history, it's certainly possible that B6 suffers from a diet-associated dilated cardiomyopathy". She is now on 3 medications, a new grain based diet and restricted activity for 6-12 months. Hopefully this will correct the problem.

Submission Type: Initial

Report Type: Both
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
Acana Puppy and Junior		
Horizon Pulsar Pulses & Chicken formula, Grain free		
Fromm Adult Gold		

Sender 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

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you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]

Sent: 3/21/2019 12:52:52 AM

Subject: American Journey Grain-free Salmon & Sweet Potato Recipe; [B6]
EON-382903

Attachments: 2064342-report.pdf; 2064342-attachments.zip

A PFR Report has been received and PFR Event [EON-382903] has been created in the EON System.

A "PDF" report by name "2064342-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 "2064342-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382903

ICSR #: 2064342

EON Title: PFR Event created for American Journey Grain-free Salmon & Sweet Potato Recipe; 2064342

AE Date	03/10/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		
Age	17 Months		
District Involved	PFR-[B6] DO		

Product information

Individual Case Safety Report Number: 2064342

Product Group: Pet Food

Product Name: American Journey Grain-free Salmon & Sweet Potato Recipe

Description: Labored breathing, coughing, lack of appetite.

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
American Journey Grain-free Salmon & Sweet Potato Recipe	07 30 20, 19002 7833B 0301, 14:21	

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:

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 3/20/2019 8:12:46 PM
Subject: American Journey-Salmon and Sweet Potato; **B6** EON-382867
Attachments: 2064327-report.pdf

A PFR Report has been received and PFR Event [EON-382867] has been created in the EON System.

A "PDF" report by name "2064327-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-382867

ICSR #: 2064327

EON Title: PFR Event created for American Journey Salmon and Sweet Potato; 2064327

AE Date	B6	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Bulldog		
Age	B6 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2064327

Product Group: Pet Food

Product Name: American Journey Salmon and Sweet Potato

Description: She presented for lethargy, presumed by the owner to be due a recent lameness onset. During her exam, we noted that her heart rate was over 200 but her pulses were weak and occurred at 100 per minute. An immediate ECG was ordered but she collapsed before we could get her to the treatment area. We initiated CPR but she had no cardiac electrical activity on our monitor. We continued CPR for 20 minutes but she did not respond. We sent myocardium to **B6** and received the following report: Description Three sections of myocardium are examined. In these sections of myocardium, there are thin strands of fibrous connective tissue interspersed between myocardial fibers. Also interspersed between myocardial fibers are abundant accumulations of adipose tissue. Some of the entrapped myocardial fibers are

atrophic while other myocardial fibers are hypertrophic. Histopathologic Diagnosis Myocardium (three specimens): Multifocal myocardial fibrosis and steatosis with multifocal fiber atrophy Comments The histologic lesions observed in the examined sections of myocardium are compatible with underlying cardiomyopathy. Presumably, arrhythmias associated with cardiomyopathy were the primary underlying cause of the clinical syndrome and death. Authorized by: **B6** DVM, PhD, DACVP Histopathology Section Head & Veterinary Pathologist

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
American Journey Salmon and Sweet Potato		

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:

B6

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From: PFR Event <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 2/27/2019 7:00:50 PM
Subject: CANIDAE- ALL LIFE STAGES-CHICKEN MEAL & RICE FORMULA--DRY
DOG FOOD: Lisa Freeman - EON-381040
Attachments: 2063286-report.pdf; 2063286-attachments.zip

A PFR Report has been received and PFR Event [EON-381040] has been created in the EON System.

A "PDF" report by name "2063286-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 "2063286-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-381040

ICSR #: 2063286

EON Title: PFR Event created for CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD; 2063286

AE Date	02/25/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063286

Product Group: Pet Food

Product Name: CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD

Description: DCM and CHF diagnosed 2/25/19. Eating BEG diet. 2 other dogs in household will be screened. Will change diet on **B6** and reassess in 3 months. Just being discharged today. Taurine and troponin 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: Stable

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD		

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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From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Solomon, Steven M; Forfa, Tracey; Moxley, Shera; Flynn, William T; Murphy, Jeanette; Hartogensis, Martine; Allen, Mary; Edwards, David; Conway, Charlotte; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Benton, Denise; Goddard, Kristina; Dewitt, Susan J; Alvey, Laura - CVM; Stamper, Carmela; Smith-Collier, Chandra E; DeLancey, Siobhan
Sent: 2/15/2019 4:51:30 PM
Subject: Posting on Tuesday, 2/19: DCM Update
Attachments: CVMU_DCM_Feb2019.docx; DCM Plan_Feb2019.docx; DCM_Feb2019_Update.docx; DCM_VetLIRN_Feb2019.docx; WebQA_DCM_Feb2019.docx

Good morning,

CVM's public update on the investigation into diet and canine dilated cardiomyopathy is now scheduled for Tuesday (2/19) morning.

The final, fully cleared documents are attached. The CVM Update, web page, Vet-LIRN update, and updated web QA will post at 10:00 am, [REDACTED] **B5** At 11:00 am, we'll promote the update to email subscribers and through social media.

[REDACTED] **B5** [REDACTED]

Please let me know if you have any questions or concerns. When the links are live on Tuesday, we'll be sure to share.

Thanks,
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: [REDACTED] **B6**
Anne.Norris@fda.hhs.gov



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Carey, Lauren; Rotstein, David; Peloquin, Sarah
Sent: 7/12/2019 1:42:25 PM
Subject: RE: Fish & Taurine

Article on Cobia and also other fish.

[https://reader.elsevier.com/reader/sd/pii/](https://reader.elsevier.com/reader/sd/pii/S0044848607005601?token=F145C6C9CDFD137474AA20B39DA5F05536438CC14F3EE1D768C1E32A09F56)

[/S0044848607005601?token=F145C6C9CDFD137474AA20B39DA5F05536438CC14F3EE1D768C1E32A09F56](https://reader.elsevier.com/reader/sd/pii/S0044848607005601?token=F145C6C9CDFD137474AA20B39DA5F05536438CC14F3EE1D768C1E32A09F56)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4754659/pdf/srep21231.pdf>

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



From: Jones, Jennifer L
Sent: Thursday, July 11, 2019 6:16 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Fish & Taurine

Excellent! Thank you :)

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



From: Carey, Lauren
Sent: Wednesday, July 10, 2019 2:53 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Fish & Taurine

Yup, pretty interesting. It's a Dr. Fascetti article so I think it must have made the rounds, but just in case, especially since we were

B5

From: Rotstein, David
Sent: Wednesday, July 10, 2019 2:52 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Fish & Taurine

Sarah and Jen may have seen it---very interesting---and states in the very first sentence about the development on DCM on the rice-based diet.

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

7519 Standish Place

B6



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From: Carey, Lauren

Sent: Wednesday, July 10, 2019 2:48 PM

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

Subject: RE: Fish & Taurine

Good thoughts
seen this one?

B5

Have we

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4971673/>

From: Rotstein, David

Sent: Wednesday, July 10, 2019 2:44 PM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Subject: RE: Fish & Taurine

B5

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

B6



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From: Carey, Lauren

Sent: Wednesday, July 10, 2019 2:42 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>;
Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: Fish & Taurine

B5

Thanks,
Lauren

Lauren Carey, DVM

Veterinary Medical Officer / Division of Veterinary Product Safety HFV-242

**Center for Veterinary Medicine
Office of Surveillance and Compliance
U.S. Food and Drug Administration**

Tel: 240-402-5738

Lauren.Carey@fda.hhs.gov



From: [REDACTED] **B6**
To: Darcy Adin
CC: Lisa Freeman; jstern@ucdavis.edu; rfries@illinois.edu [REDACTED] **B6** Jones, Jennifer L
Sent: 4/18/2018 9:34:02 PM
Subject: Re: Diet DCM Call

Hi Darcy, I can do 11 on Friday. I made plans at 3, but if others need to do it later, I can change them.

[REDACTED] **B6** Sent from my iPhone

> On Apr 18, 2018, at 7:09 AM, Darcy Adin <dbadin@ncsu.edu> wrote:

>

> Hi All,

>

> We had originally proposed

[REDACTED] **B4, B5**

[REDACTED] **B4, B5**

> I'm going to pick 11am EST arbitrarily - please let me know if you can talk then or if a different time is better. I'm available throughout the day.

>

> Thanks Everyone!

> Darcy

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Darcy Adin
CC: Jones, Jennifer L; Joshua A Stern; Fries, Ryan C; [REDACTED] B6; Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 4/30/2018 10:02:18 PM
Subject: RE: DCM cases - proposed diet history

Hi Darcy

You're more than welcome to use it although John has already asked for a few tweaks and I'd love to hear from this group if there are any other edits that you think would be useful so that it could be widely used.

Thanks

Lisa

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

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, April 30, 2018 10:13 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] B6; Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: Re: DCM cases - proposed diet history

That is really great Lisa! We have one as well but this is much better / more detailed. Is this OK to share with our group?

Thanks!

Darcy

On Fri, Apr 27, 2018 at 7:26 PM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi everyone

I'm attaching a proposed diet history form; [REDACTED] B5

B5

Once I get some input from you, I can make into a fillable form so we can send out electronically.

B5

Thanks

Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor

Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

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

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

To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] B6

[REDACTED] B6

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

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

Importance: High

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

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



From: Jones, Jennifer L

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

To: 'Darcy Adin' <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] B6

[REDACTED] B6

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

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

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

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

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

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Thursday, April 19, 2018 11:00 AM

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

B6

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

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

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

B6

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

B6

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med

Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

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

Sincerely,
Darcy Adin

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

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

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

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

To: "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey, Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

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--

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

--

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

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L
CC: Ceric, Olgica; Reimschuessel, Renate; Nemser, Sarah
Sent: 5/3/2018 4:33:53 PM
Subject: RE: 800.267-EON-345858-DCM Cluster

Agreed!

From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Date: May 3, 2018 at 12:26:29 PM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-EON-345858-DCM Cluster

Hi Jen,

I think testing some non-grain free samples would be an interesting comparison.

Thanks,
Lauren

From: Jones, Jennifer L
Sent: Tuesday, May 01, 2018 9:06 AM
To: Rotstein, David <David.Rotstein@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>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: 800.267-EON-345858-DCM Cluster

B5

I wonder about either

B5

B5

Thoughts?

Dave previously sent an email about lentils being deficient in Cystine and Methionine. I found the same information about peas (attached). For Growing labrador dogs, if cystine is limited (~ 0.2%), a Cys:Met cutoff may lie somewhere between 0.32 : 1 and 0.38 : 1. **Above that ratio, the dogs in the study here did poorly** (<https://academic.oup.com/jn/article-abstract/112/11/2033/4554028?redirectedFrom=fulltext>).

In chickens (Sarwar article), a Cys/Met ratio of 0.2 : 1 in low protein diets causes lower 2 wk weight gain, food intake, BUN, and taurine-conjugated bile acids in weanling rats

B5

B5

In pigs, there is absolute methionine and cystine values but also the met : met+cys ratio is important. For pigs the ratio is between 30-70% but the Qiao says 54.15%. I wonder

B5

B5

B5

Also-This is an older study in beagles,

B5

(<https://academic.oup.com/jn/article-abstract/111/12/2117/4771254?redirectedFrom=fulltext>.

B5

B5

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: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Jones, Jennifer L; Rotstein, David; Carey, Lauren; Pohl, Aurelie
Sent: 8/15/2019 4:31:06 PM
Subject: Brief update on cardiomyocyte idea (and metabolomics)
Attachments: Harikrishnan 2019 microbiome and heart failure.pdf; Nsbshomo and tang 2015.pdf; Yoshida et al. 2018 gut flora.pdf

Hi all – just a brief update for you and then more info and meetings ahead where we all can be involved!
Marilyn Martinez from ONADE approached me about 2 weeks ago

B5

B5

Interesting things to consider:

B5

B5

Thanks!

Lee Anne
Lee Anne M. Palmer, VMD, MPH
Acting Director, Division of Veterinary Product Safety

Center for Veterinary Medicine
Office of Surveillance and Compliance
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov



Review Articles

Intersections Between Microbiome and Heart Failure: Revisiting the Gut Hypothesis

YUJI NAGATOMO, MD, PhD,¹ AND W. H. WILSON TANG, MD^{1,2}

Cleveland, Ohio

ABSTRACT

Microbes play an important role in human health and disease. In the setting of heart failure (HF), substantial hemodynamic changes, such as hypoperfusion and congestion in the intestines, can alter gut morphology, permeability, function, and possibly the growth and composition of gut microbiota. These changes can disrupt the barrier function of the intestines and exacerbate systemic inflammation via microbial or endotoxin translocation into systemic circulation. Furthermore, cardiorenal alterations via metabolites derived from gut microbiota can potentially mediate or modulate HF pathophysiology. Recently, trimethylamine *N*-oxide (TMAO) has emerged as a key mediator that provides a mechanistic link between gut microbiota and multiple cardiovascular diseases, including HF. Potential intervention strategies which may target this microbiota-driven pathology include dietary modification, prebiotics/probiotics, and selective binders of microbial enzymes or molecules, but further investigations into their safety and efficacy are warranted. (*J Cardiac Fail* 2015;21:973–980)

Key Words: Microbiome, TMAO, heart failure.

B4

B4

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B4

B4

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6
Sent: 9/14/2018 2:16:03 PM
Subject: RE: FDA study
Attachments: 800.267-Sample Testing Procedures-v11.doc

Thank you, [REDACTED] B6 This is helpful feedback. I've again, updated the procedures to reflect your comments.

Have you submitted a report to the Safety Reporting portal? If so, please let me know the ICSR # (confirmation number). After we get the report, I'll send the box to collect the samples.

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



From: [REDACTED] B6 <[REDACTED]@cvcavets.com>
Sent: Wednesday, September 12, 2018 4:46 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FDA study

Hi Jennifer,

I have collected all the samples from the first patient in the study and they are in the freezer. I have attached the submission form for the study. I understand you will now be sending us the container to send you the samples in.

I also wanted to let you know that the directions for the

[REDACTED] B4, B5

[REDACTED] B4, B5

[REDACTED] B6

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: [B6]
CC: Andrea Fascetti
Sent: 8/20/2019 6:06:11 PM
Subject: RE: Question about results

Great, thank you for the clarification. This helps tremendously.

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



From: [B6]
Sent: Tuesday, August 20, 2019 1:53 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: Question about results

Good Morning Dr. Jones,

ND and NLD are the same meaning below detection limits (sorry for the inconsistency) . From our [B6] results using [B5] our BLD results normally fall into a range from [B5] [B5] Statisticians may be able to give some meaningful suggestions about how to deal with this problem.

Kind regards,

[B6]

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, August 20, 2019 4:44 AM
To: [B6]
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Question about results

Good morning Josh and Andrea,
I had two quick general questions about the [B5]

[B5]

Thank you in advance,
Jen

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
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e-mail: jennifer.jones@fda.hhs.gov

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



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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: [REDACTED] B6
CC: Andrea Fascetti
Sent: 5/29/2019 4:22:06 PM
Subject: RE: Heads up: Vet-LIRN shipped 800.267-CO samples

Great! Thank you.

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



From: [REDACTED] B5
Sent: Wednesday, May 29, 2019 12:11 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: Heads up: Vet-LIRN shipped 800.267-CO samples

Dear Dr. Jones and Jake,

I have added the WB taurine in. Please find the updated results in attachment. The # 10 WB & PL taurine results seem off. We will check them as soon as we can.

Thanks,

[REDACTED] B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Wednesday, May 29, 2019 4:49 AM
To: Jones, Jennifer L; [REDACTED] B6
Subject: RE: Heads up: Vet-LIRN shipped 800.267-CO samples

Hi,
I asked [REDACTED] B6 and replied with some results. He will add WB results.

Jake

From: Jones, Jennifer L
Sent: Wednesday, May 29, 2019 6:54 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>; [REDACTED] B6
Subject: RE: Heads up: Vet-LIRN shipped 800.267-CO samples

Good morning [REDACTED] B6
I wanted to check-in on the samples and see if you had any results.
Thanks so much and hope you had a nice vacation,
Jen

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



From: Guag, Jake
Sent: Thursday, May 16, 2019 10:15 AM
To: [REDACTED] B6
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Heads up: Vet-LIRN shipped 800.267-CO samples

Hi [REDACTED] B6

Both boxes are arrived in your location yesterday. Could you please check package and sample condition and provide the sample inventory forms?

Thanks
Jake

From: [REDACTED] B6
Sent: Tuesday, May 14, 2019 2:38 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Heads up: Vet-LIRN shipped 800.267-CO samples

Hi Jake,

Thanks for the update. Will let you know when they arrive.

Kind regards,

[REDACTED] B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, May 14, 2019 6:57 AM
To: [REDACTED] B6
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN shipped 800.267-CO samples

Hi [REDACTED] B6

We shipped 800.267-CO samples on dry ice to you this morning. Box #1 has urine samples and Box #2 has whole blood and plasma samples.

Both boxes will be your location tomorrow (May 15, 2019), and their tracking numbers are 1ZA4420T0198935852 (Box#1) and 1ZA4420T0195716460 (Box#2) with UPS.

Inside box, you will find an inventory form. Please check and provide us (Fax or Scan)

Note:

Please charge the urine sample testing under AA contract, and submit invoice for whole bold and plasma sample testing.

For each CO case, we shipped 1 tube blood and plasma tube and 2 tubes for urine samples except CO-08 and CO-10 (only 1 tube available)

Thank you,
Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708

Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

Taurine deficiency in dogs with dilated cardiomyopathy: 12 cases (1997–2001)

Andrea J. Fascetti, VMD, PhD, DACVN, DACVIM; John R. Reed, DVM, MS, DACVIM;
Quinton R. Rogers, PhD, DACVN; Robert C. Backus, DVM, PhD

Objective—To determine signalment, history, clinical signs, blood and plasma taurine concentrations, electrocardiographic and echocardiographic findings, treatment, and outcome of dogs with low blood or plasma taurine concentrations and dilated cardiomyopathy (DCM).

Design—Retrospective study.

Animals—12 client-owned dogs with low blood or plasma taurine concentrations and DCM.

Procedure—Medical records were reviewed, and clinical data were obtained.

Results—All 12 dogs were being fed a commercial dry diet containing lamb meal, rice, or both as primary ingredients. Cardiac function and plasma taurine concentration improved with treatment and taurine supplementation. Seven of the 12 dogs that were still alive at the time of the study were receiving no cardiac medications except taurine.

Conclusions and Clinical Relevance—Results suggest that consumption of certain commercial diets may be associated with low blood or plasma taurine concentrations and DCM in dogs. Taurine supplementation may result in prolonged survival times in these dogs, which is not typical for dogs with DCM. Samples should be submitted for measurement of blood and plasma taurine concentrations in dogs with DCM, and taurine supplementation is recommended while results of these analyses are pending. (*J Am Vet Med Assoc* 2003;223:1137–1141)

B4

B4

B4

B4

B4

B4

From: Andrea Fascetti <ajfascetti@ucdavis.edu>
To: Jones, Jennifer L
Sent: 7/9/2018 3:42:06 PM
Subject: Paper and link to Pet Food Industry Magazine
Attachments: torres paper.pdf

Hi Jen - Thank you again for taking my call. I have attached the paper by Dr. Torres on cyst(e)ine and its stability (or lack thereof) in plasma.

It also occurred to me that you may be already subscribed to Pet Food Industry Magazine, but if not you may wish to consider. It is free to receive. They do have some good articles by folks such as Dave Dzanis and Greg Aldrich on pet food production. In fact the issue I just got has an article on legumes. I have attached the latest version (which just landed in my in box) below.

Take care - Andrea

Begin forwarded message:

Petfood Industry - July 2018
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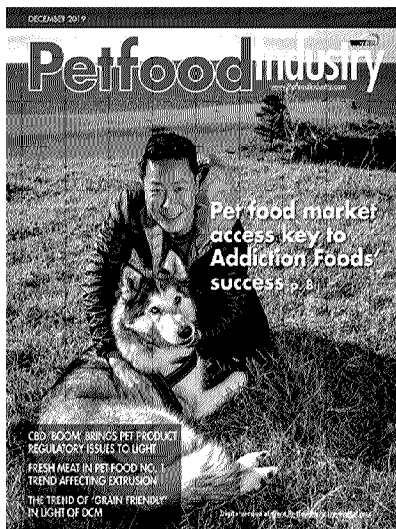
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Sincerely,

Debbie Phillips-
Donaldson
Editor-in-chief, Petfood
Industry
dphillips@wattglobal.com

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Andrea Fascetti'
Sent: 7/9/2018 3:37:27 PM
Subject: Link to Article I mentioned

Hi Andrea,
Thanks again for the call. Here's a link to the free article I mentioned.
<https://academic.oup.com/jn/article/131/2/276/4687012>

Take care,
Jen

Jennifer L. A. Jones, DVM

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



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From: Andrea Fascetti <ajfascetti@ucdavis.edu>
To: Jones, Jennifer L
Sent: 7/9/2018 3:46:48 PM
Subject: Re: Link to Article I mentioned

Thanks! I should have guessed George Fahey was involved. He is a nutrition rock star! He has officially retired but is still active last I heard. He is a great resource and has done a ton of research on fiber/digestibility /bioavailability of feed ingredients in canine and feline diets. B6 who has continued some of his work but seems to have more of an emphasis on the microbiome these days.

Best regards -

Andrea

On Jul 9, 2018, at 8:37 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Andrea,
Thanks again for the call. Here's a link to the free article I mentioned.
<https://academic.oup.com/jn/article/131/2/276/4687012>

Take care,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>
<image001.png> <image004.png>

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: 2/25/2019 11:19:34 AM
Subject: DCM 1 of 2 - Freeman Reports ONLY- 2/25/2019 0615
Attachments: Acana: Lisa Freeman - EON-380708; Earthborn Coastal Catch dry: Lisa Freeman - EON-380720; Fromm Large Breed Adult dry: Lisa Freeman - EON-380709; Poulin Pro Form Lamb and Rice Adult Maintenance Dry: Lisa Freeman - EON-380706; Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-380707; Solid Gold Mighty Mini Beef: Lisa Freeman - EON-380716; Taste of the Wild Sierra Mountain Dry: Lisa Freeman - EON-380714

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: Cleary, Michael *; HQ Pet Food Report Notification;
Sent: 2/24/2019 10:08:57 PM
Subject: Acana: Lisa Freeman - EON-380708
Attachments: 2063115-report.pdf; 2063115-attachments.zip

B6

A PFR Report has been received and PFR Event [EON-380708] has been created in the EON System.

A "PDF" report by name "2063115-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 "2063115-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380708

ICSR #: 2063115

EON Title: PFR Event created for Acana Natural Balance Petcurean (see diet history for additional details); 2063115

AE Date	B6	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Terrier - Bull - American Pit		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063115

Product Group: Pet Food

Product Name: Acana, Natural Balance, Petcurean (see diet history for additional details)

Description: DCM and CHF diagnosed **B6** Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.

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, Natural Balance, Petcurean (see diet history for additional details)		

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.

Client:

Address:

B6

All Medical Records

Patient:

B6

Breed: Pit Bull

DOB:

B6

Species: Canine

Sex: Female
(Spayed)

Home Phone:

B6

Work Phone: () -

Cell Phone: () -

Referring Information

B6

Client:

B6

Patient:

B6

Initial Complaint:

Emergency

SOAP Text

B6

9:00AM -

B6

Subjective

NEW VISIT (ER)

Doctor:

B6

Student:

B6

V'20

Presenting complaint: CHF

Referral visit? integrative animal health in bolton

Diagnostics completed prior to visit: rads

Chest x-rays (at rDVM) - in ER email

HISTORY:

Signalment: 5yo FS Pitbull

Current history:

Coughing 2-3 weeks ago - after physical exercise gotten worse after any exercise, hacking some fluid a little productive, labored breathing, low energy. still eating/drinking, normal bathroom, no v/d. lost weight, looking skinny.

Prior medical history: allergies

Current medications: none

Diet: dry. 2 cups a day (o unsure exactly which diet - rotates through 4 different types of food)

Vaccination status/flea & tick preventative use: UTD, no heartworm preventative or flea/tick

Client: **B6**
Patient: **B6**

Travel history: none

EXAM:

B6

ASSESSMENT:

A1: Congestive heart failure r/o secondary to DCM vs other

PLAN:

Diagnostics:

B6

- Chest x-rays (at rDVM) - in ER email
 - Diffuse interstitial pattern bilaterally, pulmonary vessels not easily visible. Severe cardiomegaly with left mainstem bronchi compression and trachea is dorsally deviated.

Treatments/monitoring:

B6

- Diet: HA or ZD only

Client communication:

B6

Deposit & estimate status: **B6**

Client: B6
Patient: B6

Resuscitation code (if admitting to ICU): yellow

SOAP approved (DVM to sign): B6 DVM

SOAP Text B6 9:49AM - B6

DUPLICATE. IGNORE.

SOAP Text B6 10:25AM - B6

B6

Signalment: 5yo FS Pitbull presenting for biventricular heart failure due to DCM, respiratory distress. Day 1 of hospitalization

Presenting history:

Coughing 2-3 weeks ago - after physical exercise gotten worse after any exercise, hacking some fluid a little productive, labored breathing, low energy. still eating/drinking, normal bathroom, no v/d. lost weight, looking skinny to the owner.

Prior medical history: allergies

Current medications: none

Diet: dry. 2 cups a day (o unsure exactly which diet - rotates through 4 different types of food)- brought in samples to fill out forms for the diet study she is enrolled in.

Vaccination status/flea & tick preventative use: UTD, no heartworm preventative or flea/tick

Travel history: none

EXAM:

B6

ASSESSMENT:

A1: Congestive heart failue r/o secondary to DCM vs other

Client: **B6**
Patient: **B6**

Diagnostics performed **B6**

B6

- Chest x-rays (at rDVM) - in ER email

- Diffuse interstitial pattern bilaterally, pulmonary vessels not easily visible. Severe cardiomegaly with left mainstem bronchi compression and trachea is dorsally deviated.

Diagnostics performed **B6**

B6

PLAN:

Treatments/monitoring:

B6

- Diet: HA or ZD only

B6

-recheck Echo for diet study

-recheck chemistry

-continue in diet study

Deposit & estimate status **B6**

Resuscitation code (if admitting to ICU): yellow

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

SOAP Text **B6** 11:55AM - **B6**

Signalment: 5yo FS Pitbull presenting for biventricular heart failure due to DCM, respiratory distress. Day 1 of hospitalization

Presenting history:

Coughing 2-3 weeks ago - after physical exercise gotten worse after any exercise, hacking some fluid a little productive, labored breathing, low energy. still eating/drinking, normal bathroom, no v/d. lost weight, looking skinny to the owner.

Prior medical history: allergies

Current medications: none

Diet: dry. 2 cups a day (o unsure exactly which diet - rotates through 4 different types of food)- brought in samples to fill out forms for the diet study she is enrolled in.

Vaccination status/flea & tick preventative use: UTD, no heartworm preventative or flea/tick

Travel history: none

Overnight update:

Very bright, RR 24-36, eating well and passing urine frequently.

Subjective

Client: **B6**
Patient: **B6**

EXAM, GENERAL

B6

ASSESSMENT:

A1: Dilated Cardiomyopathy

Diagnostics performed **B6**

B6

- Chest x-rays (at rDVM) - in ER email
 - Diffuse interstitial pattern bilaterally, pulmonary vessels not easily visible. Severe cardiomegaly with left mainstem bronchi compression and trachea is dorsally deviated.

Diagnostics performed **B6**

B6

Plan:

- NOVA
- TGH
- Recheckk with cardio in one week.

SOAP completed by: **B6** BVSc

Initial Complaint:

Recheck - **B6** - DCM Study

Client: [B6]
Patient: [B6]

SOAP Text [B6] 1:53PM [B6]

Disposition/Recommendations

Client:

B6

Patient:

B6

Client: B6
Patient: B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client: B6
Veterinarian:
Patient ID: B6
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Pit Bull
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU		B6	9:28:25 AM	Accession ID:	B6
Test	Results	Reference Range	Units		
SO2%	B6	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			

Client: **B6**
 Patient: **B6**

FiO2	B6	Room air)	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** 9:36:03 AM Accession ID: **B6**

Test	Results	Reference Range	Units
Blood Glucose (Glucometer) - FHSA	B6	0 - 0	mg/dl

Nova Full Panel-ICU **B6** 9:56:38 AM Accession ID: **B6**

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU **B6** 10:12:18 AM 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
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

Nova Full Panel-ICU **B6** 9:19:25 AM Accession ID: **B6**

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%

Client: B6
Patient: B6

HB (POC)	B6	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
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
FiO2		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

9:27:23 AM

Accession ID:

B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl



stringsoft

10/46

B6

B6

Printed Sunday, February 24, 2019

Vitals Results

B6	9:09:11 AM	Weight (kg)	B6
	9:09:38 AM	Notes	
	9:10:28 AM	Lasix treatment note	
	9:45:06 AM	Lasix treatment note	
	10:45:50 AM	Lasix treatment note	

Client: B6
Patient: B6

Vitals Results

11:21:04 AM	FiO2 (%)
11:21:11 AM	Respiratory Rate
11:21:41 AM	Nursing note
12:19:43 PM	Nursing note
12:37:05 PM	Quantify IV Fluids (CRI) in mls
12:37:06 PM	Catheter Assessment
12:37:44 PM	FiO2 (%)
12:38:25 PM	Respiratory Rate
12:39:49 PM	Heart Rate (/min)
1:47:10 PM	Eliminations
1:48:12 PM	FiO2 (%)
2:01:58 PM	FiO2 (%)
2:02:58 PM	Heart Rate (/min)
2:06:40 PM	Respiratory Rate
2:07:31 PM	Quantify IV Fluids (CRI) in mls
2:07:32 PM	Catheter Assessment
2:11:44 PM	Lasix treatment note
3:19:35 PM	Nursing note
3:20:12 PM	Respiratory Rate
3:20:33 PM	FiO2 (%)
3:20:55 PM	Quantify IV Fluids (CRI) in mls
3:45:02 PM	Quantify IV Fluids (CRI) in mls
3:45:03 PM	Catheter Assessment
4:07:19 PM	FiO2 (%)
4:07:46 PM	Respiratory Rate
4:09:20 PM	Eliminations
4:18:29 PM	Heart Rate (/min)
4:18:40 PM	Quantify IV Fluids (CRI) in mls
4:18:41 PM	Catheter Assessment
5:12:04 PM	Respiratory Rate
5:12:14 PM	FiO2 (%)
5:13:48 PM	Eliminations
5:17:48 PM	Amount eaten
5:19:29 PM	Heart Rate (/min)
5:19:47 PM	FiO2 (%)
5:26:16 PM	Lasix treatment note
5:47:32 PM	Respiratory Rate

B6

B6

Client: **B6**
Patient: **B6**

Vitals Results

5:47:46 PM	Quantify IV Fluids (CRI) in mls
5:47:47 PM	Catheter Assessment
6:01:17 PM	Eliminations
6:54:17 PM	FiO2 (%)
6:54:24 PM	Respiratory Rate
7:11:55 PM	Heart Rate (/min)
7:12:08 PM	Temperature (F)
7:44:34 PM	FiO2 (%)
7:44:43 PM	Quantify IV Fluids (CRI) in mls
7:44:44 PM	Catheter Assessment
7:45:08 PM	Respiratory Rate
9:03:32 PM	FiO2 (%)
9:03:41 PM	Respiratory Rate
9:17:37 PM	Weight (kg)
9:18:17 PM	Heart Rate (/min)
9:19:05 PM	Quantify IV Fluids (CRI) in mls
9:19:06 PM	Catheter Assessment
9:19:42 PM	Eliminations
9:21:04 PM	Lasix treatment note
9:45:41 PM	Respiratory Rate
9:45:54 PM	FiO2 (%)
10:49:36 PM	Respiratory Rate
10:50:01 PM	FiO2 (%)
11:31:31 PM	Quantify IV Fluids (CRI) in mls
11:31:32 PM	Catheter Assessment
11:32:09 PM	Heart Rate (/min)
11:46:46 PM	Respiratory Rate
11:47:01 PM	FiO2 (%)
12:46:34 AM	FiO2 (%)
12:46:44 AM	Respiratory Rate
1:07:50 AM	Eliminations
1:38:01 AM	Quantify IV Fluids (CRI) in mls
1:38:02 AM	Catheter Assessment
1:39:26 AM	Heart Rate (/min)
1:56:06 AM	FiO2 (%)
1:56:16 AM	Respiratory Rate
3:06:11 AM	FiO2 (%)
3:06:25 AM	Respiratory Rate
3:12:19 AM	Lasix treatment note
3:12:37 AM	Quantify IV Fluids (CRI) in mls
3:12:38 AM	Catheter Assessment

B6

B6

Client: B6
Patient: B6

Vitals Results

B6	4:06:40 AM	Respiratory Rate	B6
	4:07:00 AM	FiO2 (%)	
	4:07:08 AM	Heart Rate (/min)	
	4:49:25 AM	FiO2 (%)	
	4:49:37 AM	Respiratory Rate	
	4:52:42 AM	Eliminations	
	4:59:34 AM	Amount eaten	
	5:24:06 AM	Nursing note	
	5:24:55 AM	Heart Rate (/min)	
	5:45:41 AM	Respiratory Rate	
	5:45:53 AM	FiO2 (%)	
	6:44:05 AM	FiO2 (%)	
	6:44:44 AM	Respiratory Rate	
	7:57:10 AM	Respiratory Rate	
	7:57:26 AM	FiO2 (%)	
	7:59:14 AM	Nursing note	
	8:02:34 AM	Heart Rate (/min)	
	8:05:21 AM	Temperature (F)	
	8:08:24 AM	Lasix treatment note	
	8:14:38 AM	Weight (kg)	
	8:16:10 AM	Eliminations	
	9:02:29 AM	FiO2 (%)	
	9:03:17 AM	Respiratory Rate	
	10:02:20 AM	FiO2 (%)	
	10:04:29 AM	Heart Rate (/min)	
	10:08:31 AM	Respiratory Rate	
	10:59:22 AM	FiO2 (%)	
	10:59:52 AM	Respiratory Rate	
	11:47:25 AM	FiO2 (%)	
	11:47:53 AM	Respiratory Rate	
	11:53:10 AM	Heart Rate (/min)	
	11:53:48 AM	Eliminations	
	12:59:52 PM	FiO2 (%)	
	1:00:37 PM	Respiratory Rate	
	2:17:38 PM	Respiratory Rate	
	2:17:51 PM	Heart Rate (/min)	
	2:22:20 PM	Lasix treatment note	
	2:59:31 PM	Respiratory Rate	
	3:30:08 PM	Heart Rate (/min)	
	3:52:22 PM	Respiratory Rate	
	4:58:59 PM	Respiratory Rate	

Client: B6
Patient: B6

Vitals Results

B6	5:16:42 PM	Amount eaten
	5:17:09 PM	Eliminations
	5:28:18 PM	Heart Rate (/min)
	6:03:04 PM	Respiratory Rate
	6:54:20 PM	Respiratory Rate
	6:56:33 PM	Weight (kg)
	7:20:10 PM	Temperature (F)
	7:20:22 PM	Heart Rate (/min)
	7:56:01 PM	Respiratory Rate
	8:17:54 PM	Eliminations
	9:00:37 PM	Respiratory Rate
	9:15:46 PM	Heart Rate (/min)
	9:41:52 PM	Respiratory Rate
	9:43:34 PM	Lasix treatment note
	10:40:52 PM	Respiratory Rate
	11:31:23 PM	Heart Rate (/min)
	11:31:28 PM	Respiratory Rate
	12:28:12 AM	Respiratory Rate
	1:05:10 AM	Eliminations
	1:12:38 AM	Heart Rate (/min)
	1:12:45 AM	Respiratory Rate
	2:47:00 AM	Respiratory Rate
	3:16:57 AM	Heart Rate (/min)
	3:37:24 AM	Respiratory Rate
	4:23:24 AM	Respiratory Rate
	5:36:11 AM	Amount eaten
	5:36:20 AM	Heart Rate (/min)
	5:36:27 AM	Respiratory Rate
	5:40:28 AM	Lasix treatment note
	5:59:29 AM	Eliminations
	6:21:11 AM	Eliminations
	6:51:01 AM	Respiratory Rate
	7:42:21 AM	Weight (kg)
	8:08:18 AM	Temperature (F)
	8:08:28 AM	Respiratory Rate
	8:08:42 AM	Heart Rate (/min)
	9:06:23 AM	Eliminations
	9:07:04 AM	Respiratory Rate

B6

Client: **B6**
Patient:

Vitals Results

B6	9:20:15 AM	Catheter Assessment	B6
	10:02:30 AM	Heart Rate (/min)	
	10:02:36 AM	Respiratory Rate	
	10:02:52 AM	Eliminations	
	11:09:18 AM	Respiratory Rate	
	12:17:30 PM	Respiratory Rate	
	12:17:40 PM	Heart Rate (/min)	
	12:17:48 PM	Eliminations	
	1:05:31 PM	Respiratory Rate	
	1:36:34 PM	Catheter Assessment	
	1:36:42 PM	Respiratory Rate	
	1:36:58 PM	Heart Rate (/min)	
	1:25:45 PM	Weight (kg)	
	1:53:45 PM	Lasix treatment note	

Patient History

B6	09:09 AM	Vitals	B6
	09:09 AM	Vitals	
	09:09 AM	Purchase	
	09:10 AM	Purchase	
	09:10 AM	Purchase	
	09:10 AM	Vitals	
	09:28 AM	Purchase	
	09:36 AM	Labwork	
	09:45 AM	Vitals	
	09:55 AM	Treatment	
	09:56 AM	Labwork	
	09:57 AM	Treatment	
	10:04 AM	Prescription	
	10:08 AM	Prescription	
	10:45 AM	Vitals	
	10:55 AM	Treatment	
	11:21 AM	Treatment	
	11:21 AM	Vitals	
	11:21 AM	Treatment	
	11:21 AM	Vitals	
	11:21 AM	Vitals	
	11:23 AM	Purchase	
	11:23 AM	Purchase	

Client: **B6**
Patient: **B6**

Patient History

B6	11:42 AM	UserForm	B6
	11:54 AM	Treatment	
	11:56 AM	Purchase	
	11:56 AM	Purchase	
	12:19 PM	Vitals	
	12:37 PM	Treatment	
	12:37 PM	Vitals	
	12:37 PM	Vitals	
	12:37 PM	Vitals	
	12:37 PM	Treatment	
	12:37 PM	Vitals	
	12:38 PM	Treatment	
	12:38 PM	Vitals	
	12:39 PM	Treatment	
	12:39 PM	Vitals	
	01:47 PM	Treatment	
	01:47 PM	Vitals	
	01:48 PM	Treatment	
	01:48 PM	Vitals	
	02:01 PM	Treatment	
	02:01 PM	Vitals	
	02:02 PM	Treatment	
	02:02 PM	Vitals	
	02:06 PM	Treatment	
	02:06 PM	Treatment	
	02:06 PM	Vitals	
	02:06 PM	Treatment	
	02:07 PM	Treatment	
	02:07 PM	Vitals	
	02:07 PM	Vitals	
	02:11 PM	Vitals	
	02:11 PM	Treatment	
	03:19 PM	Vitals	
	03:20 PM	Treatment	
	03:20 PM	Vitals	
	03:20 PM	Treatment	
	03:20 PM	Vitals	

Client:
Patient:

B6

Patient History

B6	03:20 PM	Vitals
	03:22 PM	Treatment
	03:23 PM	Treatment
	03:45 PM	Treatment
	03:45 PM	Vitals
	03:45 PM	Vitals
	04:07 PM	Treatment
	04:07 PM	Vitals
	04:07 PM	Treatment
	04:07 PM	Vitals
	04:09 PM	Vitals
	04:18 PM	Treatment
	04:18 PM	Vitals
	04:18 PM	Treatment
	04:18 PM	Vitals
	04:18 PM	Vitals
	04:38 PM	Purchase
	04:39 PM	Purchase
	05:12 PM	Treatment
	05:12 PM	Vitals
	05:12 PM	Treatment
	05:12 PM	Vitals
	05:12 PM	Treatment
	05:13 PM	Treatment
	05:13 PM	Vitals
	05:17 PM	Treatment
	05:17 PM	Treatment
	05:17 PM	Vitals
	05:18 PM	Treatment
	05:19 PM	Treatment
	05:19 PM	Vitals
	05:19 PM	Treatment
	05:19 PM	Vitals
	05:26 PM	Vitals
	05:27 PM	Treatment
	05:47 PM	Treatment
	05:47 PM	Vitals
	05:47 PM	Treatment
	05:47 PM	Vitals

B6

Client:
Patient:

B6

Patient History

05:47 PM	Vitals
06:01 PM	Vitals
06:54 PM	Treatment
06:54 PM	Vitals
06:54 PM	Treatment
06:54 PM	Vitals
07:11 PM	Treatment
07:11 PM	Vitals
07:12 PM	Treatment
07:12 PM	Vitals
07:44 PM	Treatment
07:44 PM	Vitals
07:44 PM	Treatment
07:44 PM	Vitals
07:44 PM	Vitals
07:45 PM	Treatment
07:45 PM	Vitals
09:03 PM	Treatment
09:03 PM	Vitals
09:03 PM	Treatment
09:03 PM	Vitals
09:04 PM	Treatment
09:17 PM	Treatment
09:17 PM	Vitals
09:18 PM	Treatment
09:18 PM	Vitals
09:19 PM	Treatment
09:19 PM	Vitals
09:19 PM	Vitals
09:19 PM	Treatment
09:19 PM	Vitals
09:21 PM	Vitals
09:21 PM	Treatment
09:45 PM	Treatment
09:45 PM	Vitals
09:45 PM	Treatment
09:45 PM	Vitals
10:49 PM	Treatment
10:49 PM	Vitals
10:50 PM	Treatment
10:50 PM	Vitals

B6

B6

Client:
Patient:

B6

Patient History

11:07 PM	Purchase
11:31 PM	Treatment
11:31 PM	Vitals
11:31 PM	Vitals
11:32 PM	Treatment
11:32 PM	Vitals
11:46 PM	Treatment
11:46 PM	Vitals
11:47 PM	Treatment
11:47 PM	Vitals
12:46 AM	Treatment
12:46 AM	Vitals
12:46 AM	Treatment
12:46 AM	Vitals
01:04 AM	Treatment
01:07 AM	Treatment
01:07 AM	Vitals
01:08 AM	Treatment
01:38 AM	Treatment
01:38 AM	Vitals
01:38 AM	Vitals
01:39 AM	Treatment
01:39 AM	Vitals
01:56 AM	Treatment
01:56 AM	Vitals
01:56 AM	Treatment
01:56 AM	Vitals
03:06 AM	Treatment
03:06 AM	Vitals
03:06 AM	Treatment
03:06 AM	Vitals
03:12 AM	Vitals
03:12 AM	Treatment
03:12 AM	Treatment
03:12 AM	Vitals
03:12 AM	Vitals
04:06 AM	Treatment
04:06 AM	Vitals
04:07 AM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

04:07 AM	Vitals
04:07 AM	Treatment
04:07 AM	Vitals
04:49 AM	Treatment
04:49 AM	Vitals
04:49 AM	Treatment
04:49 AM	Vitals
04:52 AM	Treatment
04:52 AM	Vitals
04:53 AM	Treatment
04:59 AM	Treatment
04:59 AM	Vitals
05:00 AM	Treatment
05:24 AM	Vitals
05:24 AM	Treatment
05:24 AM	Vitals
05:45 AM	Treatment
05:45 AM	Vitals
05:45 AM	Treatment
05:45 AM	Vitals
06:44 AM	Treatment
06:44 AM	Vitals
06:44 AM	Treatment
06:44 AM	Vitals
07:57 AM	Treatment
07:57 AM	Vitals
07:57 AM	Treatment
07:57 AM	Vitals
07:59 AM	Vitals
08:02 AM	Treatment
08:02 AM	Vitals
08:05 AM	Treatment
08:05 AM	Vitals
08:08 AM	Vitals
08:08 AM	Treatment
08:14 AM	Treatment
08:14 AM	Vitals
08:16 AM	Vitals
09:02 AM	Treatment
09:02 AM	Vitals
09:03 AM	Treatment
09:03 AM	Vitals
09:10 AM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

09:10 AM	Treatment
09:14 AM	Treatment
10:02 AM	Treatment
10:02 AM	Vitals
10:04 AM	Treatment
10:04 AM	Vitals
10:08 AM	Treatment
10:08 AM	Vitals
10:12 AM	Purchase
10:13 AM	Treatment
10:59 AM	Treatment
10:59 AM	Vitals
10:59 AM	Treatment
10:59 AM	Vitals
11:05 AM	Purchase
11:05 AM	Purchase
11:30 AM	Purchase
11:45 AM	Deleted Reason
11:47 AM	Treatment
11:47 AM	Vitals
11:47 AM	Treatment
11:47 AM	Vitals
11:53 AM	Treatment
11:53 AM	Vitals
11:53 AM	Vitals
12:59 PM	Treatment
12:59 PM	Vitals
01:00 PM	Treatment
01:00 PM	Vitals
01:01 PM	Treatment
02:13 PM	Treatment
02:17 PM	Treatment
02:17 PM	Vitals
02:17 PM	Treatment
02:17 PM	Vitals
02:22 PM	Vitals
02:22 PM	Treatment
02:59 PM	Treatment
02:59 PM	Vitals
03:30 PM	Treatment
03:30 PM	Vitals

B6

B6

12

Client:
Patient:

B6

Patient History

03:52 PM	Treatment
03:52 PM	Vitals
04:58 PM	Treatment
04:58 PM	Vitals
05:02 PM	Treatment
05:03 PM	UserForm
05:16 PM	Treatment
05:16 PM	Vitals
05:17 PM	Treatment
05:17 PM	Treatment
05:17 PM	Treatment
05:17 PM	Vitals
05:28 PM	Treatment
05:28 PM	Vitals
06:03 PM	Treatment
06:03 PM	Vitals
06:54 PM	Treatment
06:54 PM	Vitals
06:56 PM	Treatment
06:56 PM	Vitals
07:20 PM	Treatment
07:20 PM	Vitals
07:20 PM	Treatment
07:20 PM	Vitals
07:56 PM	Treatment
07:56 PM	Vitals
08:17 PM	Treatment
08:17 PM	Vitals
09:00 PM	Treatment
09:00 PM	Vitals
09:00 PM	Treatment
09:15 PM	Treatment
09:15 PM	Vitals
09:41 PM	Treatment
09:41 PM	Vitals
09:43 PM	Vitals
09:43 PM	Treatment
10:40 PM	Treatment
10:40 PM	Vitals
11:07 PM	Purchase
11:31 PM	Treatment
11:31 PM	Vitals
11:31 PM	Treatment
11:31 PM	Vitals
12:28 AM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

B6

12:28 AM	Vitals
01:05 AM	Treatment
01:05 AM	Vitals
01:05 AM	Treatment
01:06 AM	Treatment
01:09 AM	Treatment
01:12 AM	Treatment
01:12 AM	Vitals
01:12 AM	Treatment
01:12 AM	Vitals
02:47 AM	Treatment
02:47 AM	Vitals
03:16 AM	Treatment
03:16 AM	Vitals
03:37 AM	Treatment
03:37 AM	Vitals
04:23 AM	Treatment
04:23 AM	Vitals
05:33 AM	Treatment
05:33 AM	Treatment
05:36 AM	Treatment
05:36 AM	Vitals
05:36 AM	Treatment
05:36 AM	Vitals
05:36 AM	Treatment
05:36 AM	Vitals
05:40 AM	Vitals
05:40 AM	Treatment
05:59 AM	Treatment
05:59 AM	Vitals
06:21 AM	Vitals
06:51 AM	Treatment
06:51 AM	Vitals
07:42 AM	Treatment
07:42 AM	Vitals
08:08 AM	Treatment
08:08 AM	Vitals
08:08 AM	Treatment
08:08 AM	Vitals
08:08 AM	Treatment
08:08 AM	Vitals
09:06 AM	Treatment
09:06 AM	Vitals
09:07 AM	Treatment
09:07 AM	Vitals
09:16 AM	Treatment
09:19 AM	Purchase

B6

Client:
Patient:

B6

Patient History

09:20 AM	Treatment
09:20 AM	Treatment
09:20 AM	Vitals
09:27 AM	Labwork
10:02 AM	Treatment
10:02 AM	Vitals
10:02 AM	Treatment
10:02 AM	Vitals
10:02 AM	Vitals
11:05 AM	Purchase
11:05 AM	Purchase
11:09 AM	Treatment
11:09 AM	Vitals
11:29 AM	Appointment
12:17 PM	Treatment
12:17 PM	Vitals
12:17 PM	Treatment
12:17 PM	Vitals
12:17 PM	Treatment
12:17 PM	Vitals
01:05 PM	Treatment
01:05 PM	Vitals
01:07 PM	Treatment
01:27 PM	Deleted Reason
01:27 PM	Purchase
01:32 PM	Prescription
01:36 PM	Prescription
01:36 PM	Treatment
01:36 PM	Vitals
01:36 PM	Treatment
01:36 PM	Vitals
01:36 PM	Treatment
01:36 PM	Vitals
02:35 PM	Email
12:59 PM	UserForm
01:22 PM	Treatment
01:23 PM	UserForm
01:25 PM	Vitals
01:37 PM	Purchase
01:38 PM	Purchase
01:53 PM	Vitals
02:20 PM	Prescription

B6

B6

Client: **B6**
Patient:

Patient History

B6	02:22 PM	Purchase
	03:19 PM	Appointment
	03:21 PM	Email

B6

Best Available Copy

Best Available Copy

Best Available Copy

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

Discharge Instructions

Patient**Name:**

B6

Signalment: B6 Years Old Brown/White Female (Spayed) Pit Bull**Owner****Name:****Address:**

B6

Patient ID: 439571**Emergency Clinician:** B6 DVM (Intern - SAM), B6 BVSc (Resident - Emergency and Critical Care)**Consulting Clinician:****ER Supervisor:**

B6

Admit Date: B6 8:55:09 AM**Check Out Date:** B6**Diagnosis:****1. Congestive Heart Failure: dilated cardiomyopathy**

Case Summary: B6 presented to the ER in significant respiratory distress. She was diagnosed with heart failure and required hospitalisation in an oxygen kennel alongside intravenous medications (furosemide, pimobendan, and nitroprusside) to control her breathing. Echocardiography (heart scan) showed that she had a dilated heart, a condition called dilated cardiomyopathy. B6 has responded well to treatment and soon started breathing well outside of oxygen. She has done well today and can now go home. B6 must receive all her medications in order to manage her heart condition. It is also very important that she is fed the prescription hypoallergenic food ONLY.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is minimal if heart failure is controlled.
- An increase in breathing rate or effort will usually mean that you should give an extra dose of furosemide (Lasix). If difficulty breathing is not improved by within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

B6

Diet suggestions:

B6 should continue to be fed Purina HA dry. She seemed to like that food while in hospital.

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable – a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (<http://vet.tufts.edu/heartsmart/diet/>).

Your dog's usual diet may also have more sodium than recommended – we want your dog to continue to eat their normal diet for the first 7 to 14 days so we can make sure they are tolerating medications well. After that time, we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). You can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise 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/Follow-up:

A recheck exam has been scheduled for

Friday, February 22, 2019 at 1:00pm with B6

B6

Patient ID: B6
Elsa Canine
B6 Years Old Female (Spayed) Pit Bull
Brown/White BW: Weight (kg) 19.00

Cardiology Consultation
ENROLLED IN DCM STUDY

Date: B6
Weight: Weight (kg) 19.00
Requesting Clinician: B6 (ern - SAM)

Attending Cardiologist:

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?

- ☒ Yes - in ER email
☐ Yes - in PACS
☐ No

Patient location: ER

Presenting complaint and important concurrent diseases: Dyspnea

STOP - remainder of form to be filled out by Cardiology

Physical Examination

B6

Muscle condition:

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

Cardiovascular Physical Exam

Murmur Grade:

- ☐ None ☐ IV/VI
☐ I/VI ☐ V/VI

- ☒ II/VI
- ☐ III/VI

- ☐ VI/VI

Murmur location/description: left apical systolic (animal panting, difficult auscultation)

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 vs.
- ☒ Fair at most
- ☐ Good
- ☐ Strong
- ☐ Bounding
- ☐ Pulse deficits
- ☐ Pulsus paradoxus
- ☐ Other (describe):

Arrhythmia:

- ☒ None
- ☐ Sinus arrhythmia
- ☐ Premature beats
- ☐ Bradycardia
- ☐ Tachycardia

Gallop:

- ☐ Yes
- ☒ No
- ☐ Intermittent
- ☐ Pronounced
- ☐ Other:

Pulmonary assessments:

- ☐ Eupneic
- ☐ Mild dyspnea
- ☒ Marked dyspnea
- ☐ Normal BV sounds
- ☒ Pulmonary Crackles
- ☐ Wheezes
- ☐ Upper airway stridor
- ☐ Other auscultatory findings:

Abdominal exam:

- ☐ Normal
- ☐ Abdominal distension
- ☐ Hepatomegaly
- ☐ Mild ascites

Echocardiogram Findings:

General/2-D findings: **brief exam as patient got more dyspneic during exam**

LV walls are normal in thickness and LV contractile function is markedly decreased with severe LA enlargement. MV is thickened. RH is markedly dilated, TV is thickened and anterior leaflet looks longer than the posterior one. TV annulus is not apical displaced. Trace pericardial effusion. PA is bigger than the aorta. Tried to get an RVOT view, could not as P got worse. Could not see nor evidence of PDA, PS, neither heard a continuous murmur.

Doppler findings:

3+ TR, PG 71mmHg, without RA pressure;
2+ MR, jet centrally directed.

Mitral inflow: not assessed

- ☐ Summated
- ☐ Pseudonormal
- ☐ Normal
- ☐ Restrictive

☐ Delayed relaxation

Blood Pressure (mmHg): recommended

Radiographic findings:

Diffuse interstitial pattern bilaterally, pulmonary vessels not easily visible. Severe cardiomegaly with left mainstem bronchi compression and trachea is dorsally deviated.

Assessment and recommendations:

B6

Treatment plan:

B6

Final Diagnosis: DCM with LCHF; PHTN

Heart Failure Classification Score:

ISACHC Classification:

☐ Ia

☐ Ib

☐ II

☒ IIIa

☐ IIIb

ACVIM CHF Classification:

☐ A

☐ B1

☐ B2

☒ C

☐ D

M-Mode

IVSd	B6	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
Time		ms
HR		BPM
CO(Teich)		l/min
CI(Teich)		l/min/m
Ao Diam		cm
LA Diam		cm
LA/Ao		
EPSS		cm

M-Mode Normalized

IVSdN	B6	{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} !

2D

SA LA	B6	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
Sphericity Index
LVld LAX
LVAd LAX
LVEDV A-L LAX
LVEDV MOD LAX
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
RVIDD
RVIDS

B6

cm

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

Doppler

MR Vmax
MR maxPG
MV E Vel
MV DecT
MV Dec Slope
MV A Vel
MV E/A Ratio
E'
E/E'
A'
S'
IVRT
AV Vmax
AV maxPG
PV Vmax
PV maxPG
TR Vmax
TR maxPG

B6

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

m/s

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

Discharge Instructions

Patient

Name: B6

Species: Canine

Brown/White Female (Spayed) Pit Bull

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: 439571

Attending Cardiologist:

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Admit Date: B6 12:37:33 PM

Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure

Diagnostic test results and findings:

- o Labwork findings: The labwork results are pending. We will call you with these results.
- o ECG: The ECG did not show any arrhythmias on examination today.

Case summary:

Thank you for bringing B6 in for evaluation by the Tufts cardiology department for her recently diagnosed heart disease.

On exam today, B6 was bright and alert. You report that she is doing well at home and her respiratory rate has been between 18-24 when she is sleeping. ECG did not show any arrhythmias. B6 was breathing slightly harder after her exam so she was given one dose of furosemide. We are going to keep her on her current medication regimen and add an ACE inhibitor (enalapril) to reduce the workload on her heart.

Monitoring at home:

- o We would like you to continue monitoring B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- o In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 30-34 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- o An increase in breathing rate or effort will usually mean that you should give an extra dose of B6 if difficulty breathing is not improved by within 30-60 minutes after giving extra B6 then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.

- o There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- o We also want you to watch for 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.
- o If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

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:

A recheck has been scheduled for

Monday, May 13, 2019 at 1:00PM with B6

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

<http://vet.tufts.edu/heartsmart/>

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 (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case	B6	Owner	B6	Discharge Instructions
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Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6 Canine

B6 Years Old Female (Spayed) Pit Bull
Brown/White

Cardiology Appointment Report -Patient enrolled in the DCM study-

Date: 2/22/2019

Attending Cardiologist:

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Presenting Complaint:

DCM

General Medical History:

Presented to ER for dyspnea B6 On exam, grade II/VI murmur. Echo showed decreased contractility, marked RH dilation, thickened MV and TV, 2+ MR.
O reports doing well at home since discharge

Diet and Supplements:

Prescription purina cardiac diet, eating well
coconut oil to give medication

Cardiovascular History:

Prior CHF diagnosis? N

Prior heart murmur? Y

Prior ATE? N

Prior arrhythmia? N

Monitoring respiratory rate and effort at home? Yes, once a day, around 18-24

Cough? Coughed a few times last night, otherwise no cough, some sneezing

Shortness of breath or difficulty breathing? No

Syncope or collapse? No

Sudden onset lameness? No

Exercise intolerance? No

Current Medications Pertinent to CV System:

B6

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 apical systolic

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 with excitement
- ☐ Marked dyspnea
- ☒ Normal BV sounds
- ☐ Pulmonary crackles
- ☐ Wheezes
- ☐ Upper airway stridor

Abdominal exam:

- ☒ Normal
- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Mild ascites
- ☐ Marked ascites

Problems:

DCM - CHF

Differential Diagnoses:

Diet-induced DCM vs. primary DCM

Diagnostic plan:

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

ECG findings:

Heart rate: 128bpm

P wave: 0.06s - suggestive of LA enlargement

PR interval: 0.13s

QRS: 0.08s - suggestive of ventricular enlargement

R wave: 4.5mV - suggestive of LV enlargement

R-R interval: 0.48s

QT interval: 0.20s

cQT: 0.24s

ST segment: depressed -0.2mV

T wave: negative (-0.4mV)

MEA: +90 degrees

Interpretation: sinus rhythm with suggestion of LA and LV enlargement. No ventricular or atrial premature beats observed.

Assessment and recommendations:

Patient improved since discharge, normal appetite, good energy level and respiratory rate is ~18-20bpm. ACE inhibitor was started today (10mg SID for 3-4 days) and then increase to 10mg in the morning and 5mg in the evening, unless patient does not tolerate this dose or bloodwork performed today reveals any kidney change that may need dose adjustments. Patient will be on hydrolyzed diet (HA) until she's through with current bag and then will try the ProPlan Sensitive Skin and Stomach. If she develops diarrhea on this diet, client is instructed to go back to HA. Recheck scheduled for 3 months, or sooner in

case patient develops clinical signs consistent with worsening of the disease.

Final Diagnosis:

DCM - r/o primary vs. diet-induced.

Heart Failure Classification Score:

ISACHC Classification:

- | | |
|----------------------------------------|-------------------------------|
| <input type="checkbox"/> Ia | <input type="checkbox"/> IIIa |
| <input type="checkbox"/> Ib | <input type="checkbox"/> IIIb |
| <input checked="" type="checkbox"/> II | |

ACVIM Classification:

- | | |
|-----------------------------|---------------------------------------|
| <input type="checkbox"/> A | <input checked="" type="checkbox"/> C |
| <input type="checkbox"/> B1 | <input type="checkbox"/> D |
| <input type="checkbox"/> B2 | |

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>
Referring Vet Direct Line 508-887-4988

Notice of Patient Admit

Date: B6 8:55:09 AM
Referring Doctor: B6
Client Name: B6
Patient Name: B6

Case No: B6

Dear B6

Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.

The attending doctor is: B6

The reason for admission to the FHSA is: DCM, PHT, CHF

If you have any questions regarding this particular case, please call 508-887-4988 to reach the ECC Service. Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

Female (Spayed)

Canine Pit Bull Brown/White

B6

B6

Dear **B6**

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

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM (Resident - Cardiology)

Cummings
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AT TUFTS UNIVERSITY

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Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

B6

Female (Spayed)

Canine Pit Bull Brown/White

B6

B6

Dear B6

Thank you for referring B6 with their pet B6

B6 presented to the Tufts ER on B6 in significant respiratory distress. She was diagnosed with congestive heart failure secondary to dilated cardiomyopathy (DCM). B6 was stabilised with oxygen therapy, B6

B6 was enrolled into a research project with our Cardiology Service investigating an association between DCM and dogs fed grain free diets. She has done well and was discharged on B6

B6

B6 has a recheck appointment scheduled with B6, Resident in Cardiology, on 2/22/19.

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 BVSc (Resident - Emergency & Critical Care)

From: PFR Event <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 2/25/2019 12:17:08 AM
Subject: Earthborn Coastal Catch dry: Lisa Freeman - EON-380720
Attachments: 2063120-report.pdf; 2063120-attachments.zip

A PFR Report has been received and PFR Event [EON-380720] has been created in the EON System.

A "PDF" report by name "2063120-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 "2063120-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380720

ICSR #: 2063120

EON Title: PFR Event created for Earthborn Coastal Catch dry; 2063120

AE Date	02/01/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063120

Product Group: Pet Food

Product Name: Earthborn Coastal Catch dry

Description: Annual RDVM visit identified murmur. Echo done by mobile ultrasonographer showed DCM. We evaluated as part of study 2/1/19 - has DCM Eating BEG diet Changed to Pro Plan Weight management dry and we will recheck in 3 months

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
Earthborn Coastal Catch 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.

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/24/2019 10:36:57 PM
Subject: Fromm Large Breed Adult dry: Lisa Freeman - EON-380709
Attachments: 2063117-report.pdf; 2063117-attachments.zip

A PFR Report has been received and PFR Event [EON-380709] has been created in the EON System.

A "PDF" report by name "2063117-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 "2063117-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380709

ICSR #: 2063117

EON Title: PFR Event created for Fromm Large Breed Adult dry; 2063117

AE Date	01/29/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Poodle - Standard		
Age	16 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063117

Product Group: Pet Food

Product Name: Fromm Large Breed Adult dry

Description: Murmur and arrhythmia ausculted by RDVM. Echoed by another cardiologist who referred to us for study. Eating Fromm Lg Breed Adult (not grain free) so unclear if diet related. Screened other 2 standard poodles in household eating same diet and their hearts were fine. Owners have changed diet for all 3 dogs to Iams MiniChunks and we will recheck in 3 months

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: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Fromm Large Breed Adult dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6	
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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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.

Client:

B6

Address:

All Medical Records

Patient:

B6

Breed: Poodle

DOB:

B6

Species: Canine

Sex: Male
(Neutered)

Home Phone:

B6

Work Phone:

Cell Phone: () -

Referring Information

B6

Client:

B6

Patient:

B6

Initial Complaint:

Scanned Record

Initial Complaint:

Cardiology New - per Dr. Freeman

SOAP Text

B6

9:52AM - Rush, John

Initial Complaint:

B6

Blood draw and ECG for DCM study

Client: B6
Patient:

Disposition/Recommendations

Client:

Patient:

B6

Client: **B6**
Patient:

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client: **B6**
Veterinarian:
Patient ID: **B6**
Visit ID:

Patient:	B6 r
Species:	Canine
Breed:	Poodle
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Accession ID:			
Test	Results	Reference Range	Units



4/24

B6

B6

Printed Sunday, February 24, 2019

Vitals Results

B6	1:49:26 PM	Weight (kg)	24.0000
-----------	------------	-------------	---------

Patient History

B6	12:06 PM	Appointment
	08:30 AM	UserForm
	08:30 AM	UserForm
	08:38 AM	UserForm
	09:06 AM	Purchase
	01:49 PM	Vitals
	05:45 PM	UserForm
	04:01 PM	Appointment

B6

Client: **B6**
Patient:

Patient History

B6	11:34 AM	Appointment
	09:24 AM	Purchase
	09:25 AM	Purchase
	09:25 AM	Purchase
	10:31 AM	UserForm
	05:20 PM	Appointment
	05:47 PM	Email
	04:30 PM	Purchase
B6		

B6

B6

Male (Neutered)

Canine Poodle Beige

Patient ID: **B6**

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tufts University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 16% applied to the average daily balance outstanding, with a minimum fee of \$50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above-agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name: B6 Date: B6

Owner's address: B6

B6

B6

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

The owner of the animal B6 has granted me authority to obtain medical treatment and to bind this owner to pay the veterinary medical services provided at Cummings School pursuant to the terms and conditions described above

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City

State

Zip

Discharge Instructions

Patient**Name:** B6**Species:** Canine**Breed:** Male (Neutered) Poodle**Birthdate:** B6**Owner****Name:** B6**Address:** B6**Patient ID:** B6**Attending Cardiologist:**☒ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC**B6****Cardiologist's Office Address:****B6****Cardiologist Technician:****B6****Also Veterinary Nutritionist Dr. Lisa Freeman****Student:** B6 V19**Admit Date:** B6 10:27:28 AM**Discharge Date:** B6

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure, ventricular arrhythmias (ventricular tachycardia, ventricular bigeminy), short runs of supraventricular arrhythmias

Case Summary:

Thank you for bringing B6 to Tufts Cardiology Service for evaluation of his dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. If you notice that B6 breathing rate is faster than normal at home we will want to have chest x-rays taken. B6 also have some arrhythmias that are likely secondary to his heart disease. We will be starting him on some medications to try to limit the arrhythmias that he is experiencing. We would like to adjust B6 diet and we provided some dietary recommendations below.

Diagnostic test results and findings:

- o **Echocardiogram findings:** The walls of the chambers of his heart are thinner than normal and he has reduced contractile function. The left ventricle and left atrium are dilated.
- o **ECG findings:** The ECG showed arrhythmias that are mostly ventricular in origin but there are also some from the upper heart chamber as well.
- o **Labwork findings:** We will call you when we have the results of his bloodwork. Most of it should come back

tomorrow, but some of it will take a week or so to return.

Monitoring at home:

- o We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- o In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- o An increase in breathing rate or effort will usually mean that you should give an extra dose of furosemide (Lasix). If difficulty breathing is not improved by within 30-60 minutes give another dose, and if after giving 2 doses of furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- o There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- o We also want you to watch for 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.
- o If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

B6

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable- a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (<https://vet.tufts.edu/heartsmart/diet/>)

Your dog's usual diet may also have more sodium than recommended – we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50/50, etc.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

- o The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- o We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- o The FDA issued a statement regarding this issue (<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/uom613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>).
- o Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula
Iams Chunks

Canned Food Options:

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise Recommendations:

We recommend limited activity. Leash walking only is ideal, and short walks to start. 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:

Thank you for enrolling B6 in our clinical study. Ideally B6 would get an ECG (or an Alivecor reading sent to us) in around two weeks once he has had some time on the anti-arrhythmic medication. It would also be great if you can obtain an Alivecor reading if B6 has an episode of collapse or abnormal behavior.

A recheck of liver values, kidney values, and electrolytes is recommended in 2-3 weeks and then about 1 month after that, so we can keep an eye on the liver values, kidney values, and potassium. This can be done at your primary care veterinarian.

B6 is supposed to have an appointment here at Tufts in about 3 months. We will perform an echo, ECG and bloodwork at this time.

Thank you for entrusting us with B6 care! It was a pleasure to meet you all today and he was a very good boy. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
<http://vet.tufts.edu/heartsmart/>

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 (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case: B6

Owner: B6

Discharge Instructions

B6

B6

Male (Neutered)

Canine Poodle Beige

Patient ID: B6

Outside Prescription Log

1. Date: B6 left message on voicemail at 5:45pm
Clinician: John Rush

B6

Pharmacy sent to: B6 / inside B6

Completed by: B6

Origin of request: Owner and her very B6

2. Date: B6 left message at 8:56am
Clinician: Rush

B6

Pharmacy sent to: B6 / inside B6

Completed by: B6

Origin of request: owner price shopping

3. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

4. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

5. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

6. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:

Origin of request:

7. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

8. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

9. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

10. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: **B6**

B6

Canine

B6 Years Old Male (Neutered) Poodle
Beige

Cardiology Appointment Report Enrolled in DCM Study

Date: **B6**

Attending Cardiologist:

☒ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC (PRIMARY)

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Presenting Complaint:

DCM diagnosed 1/29/19 by **B6** **B6** but asymptomatic). Eating BEG diet x 3 years

B6

Concurrent Diseases: Arthritis

General Medical History: Liver enzyme elevation

Diet and Supplements: Fromm Large Breed Adult dry

Cardiovascular History:

Prior CHF diagnosis? no

Prior heart murmur? yes

Prior ATE? no

Prior arrhythmia? yes

Monitoring respiratory rate and effort at home? no

Cough? maybe

Shortness of breath or difficulty breathing? no

Syncope or collapse? no

Sudden onset lameness? chronic lameness and weakness back legs

Exercise intolerance? limited by above

Current Medications Pertinent to CV System:

B6

B6

Cardiac Physical Examination:

General PE: Thin, weak, posterior weakness

MM Color and CRT: OK

BCS (1-9): 4

BW (kg): 24.0

Heart rate: 150

Respiratory rate: eupneic vs mildly dyspneic - 28

Temp (if possible):

Muscle condition:

☐ Normal

☐ Mild muscle loss

☒ Moderate cachexia

☐ Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

☐ None

☐ I/V

☒ II/V

☐ III/V

☐ IV/V

☐ V/V

☐ VI/V

Murmur location/description: left apical

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 to

☒ 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: minimal exam

☒ Normal

☐ Hepatomegaly

☐ Mild ascites

☐ Marked ascites

☐ Abdominal distension

Problems:

Prior DCM, arrhythmia, +/- cough/gag from laryngeal disease vs other

Diagnostic plan:

- ☒ Echocardiogram
- ☒ Chemistry profile
- ☐ ECG
- ☐ Renal profile
- ☐ Blood pressure

- ☐ Dialysis profile
- ☐ Thoracic radiographs
- ☒ NT-proBNP
- ☒ Troponin I
- ☐ Other tests: DCM study testing

B6

Assessment and recommendations:

DCM with VPCs and APCs and some runs of SVT and ventricular tachycardia. Suspect the cough/gag is related to more chronic laryngeal disease, but the dog is breathing with slightly more effort than normal at rest. DCM may be related to diet or may be unrelated. Recommend continuing **B6** (but maybe at 6.25 since maybe arrhythmias more frequent now than before **B6** vs day-to-day variation?), give furosemide if dyspnea develops, ideally start low dose **B6** if tolerated (potassium is a bit high on recent bloodwork so will have to watch this serially too). The dog has enough arrhythmia that I would likely start an antiarrhythmic today **B6** might be the choice, but the dog has increased liver enzymes - if we start this then follow LFs closely. I am not sure if sotalol would be tolerated **B6** is TID and might not get supraventricular ectopy, but this might be an option if amiodarone is not well tolerated. Diet change +/- taurine is recommended. Recheck ECG and kidney values, potassium, and liver enzymes in about 2 weeks. Discussed **B6** option with owners.

Final Diagnosis:

DCM with cardiac arrhythmias

Heart Failure Classification Score:

ISACHC Classification:

- ☐ Ia
- ☒ Ib close to II
- ☐ II
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☒ B2 close to C
- ☐ C
- ☐ D

M-Mode

IVSd	B6	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
TAPSEI		cm

M-Mode Normalized

IVSdN	B6	{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	B6	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

LVAd LAX
LVEDV A-L LAX
LVEDV MOD LAX
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
R-R
HR
CO A-L LAX
CO MOD LAX

B6

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

Doppler
MR Vmax
MR maxPG
MV E Vel
MV DecT
MV Dec Slope
MV A Vel
MV E/A Ratio
E'
E/E'
A'
S'
AV Vmax
AV maxPG
PV Vmax
PV maxPG
TR Vmax
TR maxPG

B6

m/s
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mmHg

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

Discharge Instructions

Cardiology Technician

Patient**Name:** B6**Species:** Canine**Beige Male (Neutered) Poodle****Birthdate:** B6**Owner****Name:** B6**Address:** B6**Patient ID:** B6**Attending Cardiologist:**☒ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Date: B6

We saw B6 today for an ECG and a chemistry panel. We are happy to hear he is doing well at home, although he has been a bit more clingy at night in the last week. Dr Rush saw a bit more arrhythmia today on his ECG than he would like to see. His bloodwork looked ok, although his liver values are still moderately elevated. He would like to add in a low dose of a beta blocker called B6

Medications:

B6

B6

Recheck Visits: A recheck visit is scheduled for

May 30th at 10:00am

Thank you for bringing B6 in to see us today, he is such a sweet boy!

Kind Regards,

B6

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

<http://vet.tufts.edu/heartsmart/>

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 (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case: B6

Owner: B6

Discharge Instructions

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

Male (Neutered)

Canine Poodle Beige

B6

B6

Dear **B6**

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

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

Male (Neutered)

Canine Poodle Beige

B6

B6

Dear B6

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Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

Male (Neutered)

Canine, Poodle, Beige

B6

B6

Dear **B6**

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

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

Male (Neutered)

Canine Poodle Beige

B6

B6

Dear **B6**

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

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification **B6**
Sent: 2/24/2019 9:32:37 PM
Subject: Poulin Pro Form Lamb and Rice Adult Maintenance Dry: Lisa Freeman - EON-380706
Attachments: 2063113-report.pdf; 2063113-attachments.zip

A PFR Report has been received and PFR Event [EON-380706] has been created in the EON System.

A "PDF" report by name "2063113-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 "2063113-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380706

ICSR #: 2063113

EON Title: PFR Event created for Poulin Pro Form Lamb and Rice Adult Maintenance Dry; 2063113

AE Date	12/22/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Irish Wolfhound		
Age	6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063113

Product Group: Pet Food

Product Name: Poulin Pro Form Lamb and Rice Adult Maintenance Dry

Description: Had pneumonia in September 2018; re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnI elevated. Owner already changed diet in January to Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.

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
Poulin Pro Form Lamb and Rice Adult Maintenance 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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you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

Client:

B6

Address:

All Medical Records

Patient:

B6

Breed:

Doberman

DOB:

B6

Species: Canine

Sex: Male

(Neutered)

Home Phone:

B6

Work Phone: () -

Cell Phone:

B6

Referring Information

B6

Client:

B6

Patient:

B6

Initial Complaint:

Scanned Record

Initial Complaint:

New **B6** - CHF

SOAP Text

B6

5:37PM

B6

Initial Complaint:

Chem 21

B6

SOAP Text

B6

3:04PM

B6

Disposition/Recommendations

Client:

Patient:

B6

Client: **B6**
Patient:

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client: **B6**
Veterinarian:
Patient ID: **B6**
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Doberman
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Accession ID:			
Test	Results	Reference Range	Units



3/3

B6

B6

Printed Sunday, February 24, 2019

Vitals Results

B6	4:07:45 PM	Weight (kg)
	4:43:10 PM	Nursing note
	3:12:02 PM	Weight (kg)

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification;
Sent: 2/24/2019 11:56:39 PM
Subject: Solid Gold Mighty Mini Beef: Lisa Freeman - EON-380716
Attachments: 2063119-report.pdf; 2063119-attachments.zip

B6

A PFR Report has been received and PFR Event [EON-380716] has been created in the EON System.

A "PDF" report by name "2063119-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 "2063119-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380716

ICSR #: 2063119

EON Title: PFR Event created for Solid Gold Mighty Mini Beef Sweet Potato and Apple grain free dry;
2063119

AE Date	01/02/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Chihuahua		
Age	9 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063119

Product Group: Pet Food

Product Name: Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry

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

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
Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free 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-380716

ICSR:	2063119		
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:	2019-02-24 18:45:24 EST		
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	
	Date Problem Started:	01/02/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	PDA - occluded 2016; overweight	
	Outcome to Date:	Stable	
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: 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:	T_26346.pdf	
	Description:	Taurine - will send rest of records by email (too large)	
	Type:	Laboratory Report	

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 2/24/2019 11:24:38 PM
Subject: Taste of the Wild Sierra Mountain Dry: Lisa Freeman - EON-380714
Attachments: 2063118-report.pdf; 2063118-attachments.zip

A PFR Report has been received and PFR Event [EON-380714] has been created in the EON System.

A "PDF" report by name "2063118-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 "2063118-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380714

ICSR #: 2063118

EON Title: PFR Event created for Taste of the Wild Sierra Mountain Dry; 2063118

AE Date	01/14/2019	Number Fed/Exposed	7
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063118

Product Group: Pet Food

Product Name: Taste of the Wild Sierra Mountain Dry

Description: BEG diet being fed to **B6** dogs. We evaluated her other dog **B6** who had a murmur and elevated BNP, with reduced contractility and elevated troponin found on exam (see previous report - 2061171). Owner worried about this dog's breathing so we screened her and found reduced contractility, elevated troponin, but normal BNP. Changing diet on both dogs to Pro Plan Sensitive Skin/Stomach Salmon and will recheck in 3 months Other dogs we have not screened: **B6** Labrador 5 years old **B6** Golden 3 1/2 years old **B6** Golden 3 years old **B6** Golden 3 years 5 months **B6** Golden 3 years 9 months

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: 7

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Sierra Mountain 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-380714							
ICSR:	2063118						
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:	2019-02-24 18:16:40 EST						
Reported Problem:	<p>Problem Description: BEG diet being fed to B6 dogs. We evaluated her other dog B6, who had a murmur and elevated BNP, with reduced contractility and elevated troponin found on exam (see previous report - 2061171). Owner worried about this dog's breathing so we screened her and found reduced contractility, elevated troponin, but normal BNP. Changing diet on both dogs to Pro Plan Sensitive Skin/Stomach Salmon and will recheck in 3 months Other dogs we have not screened: B6 Labrador 5 years old B6 Golden 3 1/2 years old B6 Golden 3 years old B6 Golden 3 years 5 months B6 Golden 3 years 9 months</p> <p>Date Problem Started: 01/14/2019</p> <p>Concurrent Medical Problem: No</p> <p>Outcome to Date: Stable</p>						
Product Information:	<p>Product Name: Taste of the Wild Sierra Mountain Dry</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Package Type: BAG</p> <p>Product Use Information: Description: Please see diet history for additional information</p> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p>						
Animal Information:	<p>Name: B6</p> <p>Type Of Species: Dog</p> <p>Type Of Breed: Retriever - Golden</p> <p>Gender: Female</p> <p>Reproductive Status: Neutered</p> <p>Weight: 25.8 Kilogram</p> <p>Age: 5 Years</p> <p>Assessment of Prior Health: Excellent</p> <p>Number of Animals Given the Product: 7</p> <p>Number of Animals Reacted: 2</p> <p>Owner Information:</p> <table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact:</td> <td> <p>Name: B6</p> <p>Phone: B6</p> <p>Email: B6</p> </td> </tr> <tr> <td>Address:</td> <td> <p>B6</p> <p>United States</p> </td> </tr> </table> <p>Healthcare Professional Practice Name: Tufts Cummings School of Veterinary Medicine</p>	Owner Information provided:	Yes	Contact:	<p>Name: B6</p> <p>Phone: B6</p> <p>Email: B6</p>	Address:	<p>B6</p> <p>United States</p>
Owner Information provided:	Yes						
Contact:	<p>Name: B6</p> <p>Phone: B6</p> <p>Email: B6</p>						
Address:	<p>B6</p> <p>United States</p>						

	Information:	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:	rpt_medical_record_preview.pdf		
	Description:	Medical records		
	Type:	Medical Records		

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6

Sent: 3/20/2019 9:20:46 PM

Subject: CANIDAE- ALL LIFE STAGES-CHICKEN MEAL & RICE FORMULA--DRY
DOG FOOD: Lisa Freeman - EON-382878

Attachments: 2064335-report.pdf; 2064335-attachments.zip

A PFR Report has been received and Related PFR Event [EON-382878] has been created in the EON System.

A "PDF" report by name "2064335-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 "2064335-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382878

ICSR #: 2064335

EON Title: Related PFR Event created for CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD; 2064335

AE Date	02/25/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2064335

Product Group: Pet Food

Product Name: CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD

Description: DCM and CHF diagnosed 2/25/19. Eating BEG diet. 2 other dogs in household will be screened. Will change diet on B6 and reassess in 3 months. Just being discharged today. Taurine and troponin pending

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD		

This report is linked to:

Initial EON Event Key: EON-381040

Initial ICSR: 2063286

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

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Report Details - EON-382878

ICSR:	2064335																																																											
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:	2019-03-20 17:15:18 EDT																																																											
Initial Report Date:	02/27/2019																																																											
Parent ICSR:	2063286																																																											
Follow-up Report to FDA Request:	Yes																																																											
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	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:	Reported to Other Parties:	None		
	Attachment:	Taurine level 2-25-19.pdf		
	Description:	UCDavis Taurine Panel		
	Type:	Laboratory Report		
	Attachment:	Chemistry 3-8-19.pdf		
	Description:	Chemistry panel		
	Type:	Laboratory Report		
	Attachment:	Diet history 3-8-19.pdf		
	Description:	Diet history 3-8-19		
	Type:	Record		
	Attachment:	Troponin level 3-6-19.pdf		
	Description:	Texas A and M Troponin		
	Type:	Laboratory Report		
	Attachment:	Diet history 2-26-19.pdf		
	Description:	Diet history 2-26-19		
	Type:	Record		


Tufts Cummings School Of Veterinary Medicine

 200 Westboro Road
 North Grafton, MA 01536

DUPLICATE

Name/DOB:	B6	(5/15/2015)	Sex: M	Provider:	B6
Patient ID:	B6		Age: 3	Order Location:	V320559: Investigation into
Phone number:			Species: Canine	Sample ID:	1903080084
Collection Date:	3/8/2019 1:35 PM		Breed: Doberman Pinscher		
Approval date:	3/8/2019 3:27 PM				

Research Chemistry Profile - Small Animal (Cobas)

TFRANK			Ref. Range/Males
Glucose			67-135 mg/dL
Urea			8-30 mg/dL
Creatinine			0.6-2.0 mg/dL
Phosphorus			2.6-7.2 mg/dL
Calcium 2			9.4-11.3 mg/dL
Magnesium 2+	L		1.8-3.0 mEq/L
Total Protein			5.5-7.8 g/dL
Albumin			2.8-4.0 g/dL
Globulins			2.3-4.2 g/dL
A/G Ratio			0.7-1.6
Sodium			140-150 mEq/L
Chloride	L		106-116 mEq/L
Potassium			3.7-5.4 mEq/L
tCO2(Bicarb)			14-28 mEq/L
AGAP	H		8.0-19.0
NA/K			29-40
Total Bilirubin			0.10-0.30 mg/dL
Alkaline Phosphatase			12-127 U/L
GGT			0-10 U/L
ALT			14-86 U/L
AST			9-54 U/L
Creatine Kinase			22-422 U/L
Cholesterol	H		82-355 mg/dL
Triglycerides			30-338 mg/dl
Amylase			409-1250 U/L
Osmolality (calculated)	L		291-315 mmol/L

 Sample ID: 1903080084/1
 REPRINT: Orig. printing on 3/8/2019 (Final)

Reviewed by: _____

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6

Sent: 3/20/2019 9:44:47 PM

Subject: CANIDAE- ALL LIFE STAGES-CHICKEN MEAL & RICE FORMULA--DRY
DOG FOOD: Lisa Freeman - EON-382884

Attachments: 2064340-report.pdf; 2064340-attachments.zip

A PFR Report has been received and Related PFR Event [EON-382884] has been created in the EON System.

A "PDF" report by name "2064340-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 "2064340-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382884

ICSR #: 2064340

EON Title: Related PFR Event created for CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD; 2064340

AE Date	02/25/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2064340

Product Group: Pet Food

Product Name: CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD

Description: DCM and CHF diagnosed 2/25/19. Eating BEG diet. 2 other dogs in household will be screened. Will change diet on B6 and reassess in 3 months. Just being discharged today. Taurine and troponin pending

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD		

This report is linked to:
Initial EON Event Key: EON-381040
Initial ICSR: 2063286

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
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	Contact:	Phone:	5088874523	
		Email:	lisa.freeman@tufts.edu	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Additional Documents:	Reported to Other Parties:	None		
	Attachment:	Cardio reports 3-8-19.pdf		
	Description:	Cardiology Appointment Report 3-8-19		
	Type:	Medical Records		
	Attachment:	ECG 3-8-19.pdf		
	Description:	ECG 3-8-19		
	Type:	Medical Records		
	Attachment:	BNP 2-25-19.pdf		
	Description:	B6 NT-proBNP 2-25-19		
	Type:	Laboratory Report		

B6

Discharge Instructions

Patient

Name: B6
Species: Canine
Black Male Doberman Pinscher
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: 438113

Attending Cardiologist:

☒ John E. Bush DVM, MS, DACVIM (Cardiology), DACVECC

B6

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

Admit Date: 3/8/2019 1:03:15 PM

Discharge Date: 3/8/2019

Diagnoses:

Dilated Cardiomyopathy with Congestive Heart Failure

Case Summary:

Thank you for bringing B6 to the Tufts Cardiology Service for a recheck of his heart disease. We are happy to hear B6 appetite has recently improved at home, although he unfortunately does not enjoy his new diet.

Today we performed an electrocardiogram (ECG) to monitor his heart rate and rhythm. He has a normal rhythm and there was no evidence of an arrhythmia (abnormal rhythm). We also looked quickly at his chest and heart with the ultrasound and there was no evidence of free fluid in his chest, which is excellent!

As discussed, B6 taurine levels were normal, which means he does not require his taurine supplementation. If he is taking his supplementation readily, you may continue the supplementation if desired.

We also took a blood sample to monitor his kidney and liver values. We will call you with these results when they return, either later today or tomorrow, and recommend any needed changes to his medications. We hope that B6 continues to improve at home!

Monitoring at Home:

We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort,

noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing rate or effort will usually mean that you should give an extra dose of B6. If difficulty breathing is not improved within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that B6 be evaluated by an emergency clinic. There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).

Diet Suggestions:

We sent you home with Royal Canin Early Cardiac today. Please slowly mix this food in with his old food to transition his diet. We hope that he likes this food, but please contact us if you would like to try another diet (below are other possibilities).

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)

Royal Canin Boxer

Purina Pro Plan Adult Weight Management

Purina Pro Plan Bright Mind Adult Small Breed Formula

Canned Food Options:

Hill's Science Diet Adult Beef and Barley Entree

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew

Royal Canin Mature 8+

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise Recommendations:

As B6 heart failure has improved, you may start taking him on longer leash walks. 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.

B6

Recheck Visits:

B6 will need a recheck in 3 months for an echocardiogram and bloodwork. We may also reassess his heart rhythm with an ECG at this appointment and a recheck echocardiogram.

Thank you for entrusting us with B6's care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Sincerely,

Dr. B6

Please visit our HeartSmart website for more information

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 (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case

B6

Owner

B6

Discharge Instructions

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: 438113

Dexter Canine

B6 Years Old Male Doberman Pinscher
Black

Cardiology Appointment Report

Date: 3/8/2019

Attending Cardiologist:

☒ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

(primary)

Cardiology Technician:

B6

Student: **B6**

Presenting Complaint: Recheck DCM with CHF

Concurrent Diseases: Chronic skin issues

General Medical History:

Hospitalized from **B6** for coughing and increased RR/RE - diagnosed with DCM and CHF. Doing well since last here. Owner tried to switch his food and adding in new food, but he won't eat the new food, spits out those pieces. Since getting home his appetite wasn't that great, but over the last 1-2 days his appetite has finally gotten back to normal. RR at rest is usually around 25 brpm. When sleeping and awake he is shaking more than he used to. His urine stream is much slower since he has been home. Urinating frequently (2-3 times overnight). Activity is normal, has always been "lazy" and hasn't changed.

Diet and Supplements:

New food - Purina Sensitive Skin and Stomach

Previous diet - Canidae

Cardiovascular History:

Prior CHF diagnosis? Y

Prior heart murmur? N

Prior ATE? N

Prior arrhythmia?

Monitoring respiratory rate and effort at home? Y

Cough? N

Shortness of breath or difficulty breathing? N

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? N

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

General PE: cutaneous sores on feet
from chronic licking

MM Color and CRT: pink, CRT <2 sec

BCS (1-9): 6/9

BW (kg): 54.4 kg

Heart rate: 120 bpm

Respiratory rate: 16 bpm to panting

Temp (if possible):

Muscle condition:

☒ Normal

☐ Mild muscle loss

☐ Moderate cachexia

☐ Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- | | |
|--------------------------------------------|--------------------------------|
| <input type="checkbox"/> None | <input type="checkbox"/> IV/VI |
| <input type="checkbox"/> I/VI | <input type="checkbox"/> V/VI |
| <input type="checkbox"/> II/VI | <input type="checkbox"/> VI/VI |
| <input checked="" type="checkbox"/> III/VI | |

Murmur location/description: Right apical, systolic

Jugular vein:

- | | |
|------------------------------------------------------------|----------------------------------------------|
| <input checked="" type="checkbox"/> Bottom 1/3 of the neck | <input type="checkbox"/> 1/2 way up the neck |
| <input type="checkbox"/> Middle 1/3 of the neck | <input type="checkbox"/> Top 2/3 of the neck |

Arterial pulses:

- | | |
|------------------------------------------|-------------------------------------------|
| <input type="checkbox"/> Weak | <input type="checkbox"/> Bounding |
| <input checked="" type="checkbox"/> Fair | <input type="checkbox"/> Pulse deficits |
| <input type="checkbox"/> Good | <input type="checkbox"/> Pulsus paradoxus |
| <input type="checkbox"/> Strong | <input type="checkbox"/> Other: |

Arrhythmia:

- | | |
|-------------------------------------------|--------------------------------------|
| <input checked="" type="checkbox"/> None | <input type="checkbox"/> Bradycardia |
| <input type="checkbox"/> Sinus arrhythmia | <input type="checkbox"/> Tachycardia |
| <input type="checkbox"/> Premature beats | |

Gallop:

- | | |
|----------------------------------------|-------------------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> Pronounced |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Other: |
| <input type="checkbox"/> Intermittent | |

Pulmonary assessments:

- | | |
|------------------------------------------------------|-----------------------------------------------|
| <input checked="" type="checkbox"/> Eupneic | <input type="checkbox"/> Pulmonary crackles |
| <input type="checkbox"/> Mild dyspnea | <input type="checkbox"/> Wheezes |
| <input type="checkbox"/> Marked dyspnea | <input type="checkbox"/> Upper airway stridor |
| <input checked="" type="checkbox"/> Normal BV sounds | |

Abdominal exam:

- | | |
|-----------------------------------------------|-----------------------------------------|
| <input checked="" type="checkbox"/> Normal | <input type="checkbox"/> Mild ascites |
| <input type="checkbox"/> Hepatomegaly | <input type="checkbox"/> Marked ascites |
| <input type="checkbox"/> Abdominal distension | |

Problems:

DCM with CHF

History of Atrial fibrillation

Grade III/VI Right sided systolic heart murmur

Differential diagnoses:

Murmur - r/o tricuspid regurgitation (secondary to DCM vs valvular disease) vs pulmonic stenosis

Diagnostic plan:

- | | |
|---------------------------------------------------|-----------------------------------------------|
| <input type="checkbox"/> Echocardiogram | <input type="checkbox"/> Dialysis profile |
| <input type="checkbox"/> Chemistry profile | <input type="checkbox"/> Thoracic radiographs |
| <input checked="" type="checkbox"/> ECG | <input type="checkbox"/> NT-proBNP |
| <input checked="" 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: ***Fluid check***

No evidence of pleural effusion.

ECG findings:

Normal sinus rhythm with no evidence of atrial fibrillation today.

Assessment and recommendations:

The patient has been doing well at home since the last appointment and the owner estimates that he is 85% back to his normal self. They tried switching him to the Purina sensitive skin and stomach but he didn't like the food and is back to his previous food. His RR and RE have been within normal limits and the owner do not have any issues giving the medications. Today B6 looked very good! There was no pleural effusion and he remains in sinus rhythm. We submitted some bloodwork to reassess his kidney and liver values today and decide if we need to adjust any of his current cardiac medications. We also send him home with a bag of Royal Canin Early Cardiac diet. Recheck echocardiogram is recommended in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease.

Final Diagnosis:

- DCM with history of active CHF

Heart Failure Classification Score:

ISACHC Classification:

- | | |
|----------------------------------------|-------------------------------|
| <input type="checkbox"/> Ia | <input type="checkbox"/> IIIa |
| <input type="checkbox"/> Ib | <input type="checkbox"/> IIIb |
| <input checked="" type="checkbox"/> II | |

ACVIM Classification:

- | | |
|-----------------------------|---------------------------------------|
| <input type="checkbox"/> A | <input checked="" type="checkbox"/> C |
| <input type="checkbox"/> B1 | <input type="checkbox"/> D |
| <input type="checkbox"/> B2 | |

Client: **B6**
Patient: **B6**

ECG from Cardio

B6

3/8/2019 2:51:01 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

3/8/2019 2:51:01 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

B6

NP - 2/25/2019

B6

Reference Laboratories

Client: NATAUPSKY

B6

Client:

B6

Patient:

Species: CANINE

Breed: DOBERMAN_PINSCH

Gender: MALE

Age: 3Y

Date: 02/25/2019

Requisition:

Accession:

Ordered by:

B6

B6

IDEXX VetConnect 1-888-433-9967

TUFTS UNIVERSITY

200 WESTBORO RD

NORTH GRAFTON, Massachusetts 01536

508-839-5395

Account #88933

CARDIOPET proBNP - CANINE

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

B6

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

From: PFR Event <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 3/21/2019 12:20:27 PM
Subject: FROMM Salmon Tunalini: [B6] - EON-382921
Attachments: 2064347-report.pdf

A PFR Report has been received and PFR Event [EON-382921] has been created in the EON System.

A "PDF" report by name "2064347-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-382921

ICSR #: 2064347

EON Title: PFR Event created for FROMM Salmon Tunalini; 2064347

AE Date	03/04/2019	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Sheepdog - Shetland		
Age	6 Years		
District Involved	PFR-[B6] DO		

Product information

Individual Case Safety Report Number: 2064347

Product Group: Pet Food

Product Name: FROMM Salmon Tunalini

Description: HISTORY [B6] a 6 Yrs. 7 Mos., Spayed Female, Sheepdog, Shetland, was presented on 3/4/2019 for cardiac evaluation. The owner reports that [B6] was diagnosed with a small paramembranous VSD in 2013- no cardiac chamber enlargement was noted at that time. The owner adopted her from the breeder 2 years ago and has not had an echocardiogram rechecked. No coughing, no syncope, and no other clinical signs are noted. The owner reports that [B6] is in need of anesthesia and dental cleaning. No unusual coughing, sneezing, vomiting or diarrhea. No polyuria/polydypsia. Appetite and activity level normal. [B6] is fed Fromm salmon diet. She is current on vaccines and heartworm prevention. She has a history of DJD in her hip and a prior left coxofemoral joint injury that [B6] had previously evaluated and recommended medical

management. Current Medications

B6

Previous

Diagnostics: 1/23/2013 - Echocardiogram: Small indistinctly margined approximately 2.7 mm defect in the upper portion of the interventricular septum, just below the mitral & tricuspid valves. Small jet of turbulent blood flow from left ventricle to right ventricle at site of defect. Velocity of turbulent jet measured 4.82 m/s, corresponding to a pressure gradient of 93.1 mm Hg. FS at that time was wnl at 31%. No cardiac chamber enlargement was noted. A grade 3/6 heart murmur was also noted on exam. Physical Exam HR: 130; RR: 24 Weight: 19.5 lb/8.86 kg Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur, no arrhythmias, lungs clear, pulses good. Skin normal. Musculoskeletal system normal. Normal peripheral lymph nodes Diagnostics ECG: normal sinus rhythm on lead II ECG during echocardiogram Doppler Blood Pressure: 144 mm Hg; # 3 cuff LF Echocardiogram: IVSd: 0.68 cm LVIDd: 3.02 cm LVPWd: 0.69 cm IVSs: 0.80 cm LVDs: 2.56 cm LVPWs: 0.78 cm %FS: 15 % EPSS: 0.76 cm Ao: 1.5 cm LAD: 1.6 cm LA/Ao: 1.08 AV Vmax: 0.92 m/s PV Vmax: 0.77 m/s MV Evel: 0.56 m/s MV Avel: 0.46 m/s MV E/A ratio: 1.21 E': 0.06 m/s Comments: A small defect measuring 2 mm was noted within the paramembranous interventricular septum with a small band of tissue visualized spanning the defect. No flow was noted crossing the defect with color flow Doppler. 2D/M-MODE: Left ventricle: Chamber size: mildly increased end-diastolic dimensions; moderately increased end-systolic dimensions - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: moderately to severely decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: normal Right ventricle: Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal Tricuspid valve leaflets: normal Aortic valve leaflets: normal Pulmonic valve leaflets: normal Aortic root: normal Aortic root motion: normal Main pulmonary artery: normal No evidence of pericardial or pleural effusion. CFD/PWD/CWD: Mitral regurgitation: none - Mitral inflows: normal - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: none - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy - r/o diet-associated vs. idiopathic History of small paramembranous VSD- no flow noted across this defect on exam today Treatment/Medications We discussed performing a bubble study today, which the owner elected not to pursue at this time. We would like to recheck **B6** in 3 months to recheck her echocardiogram. I would recommend transitioning **B6** off of her current diet to either Royal Canin, Science Diet or Purina. Please start the following: Supplements (see handout for brand recommendations) Taurine 500 mg tablets: give 1 tablet by mouth every 12 hours. L-carnitine 500 mg tablets: give 1 tablet by mouth every 8 hours with food.

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: Unknown

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
FROMM Salmon Tunalini		

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-382921

ICSR:	2064347		
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:	2019-03-21 08:13:45 EDT		
Reported Problem:	Problem Description:	<p>HISTORY: [B6] a 6 Yrs. 7 Mos., Spayed Female, Sheepdog, Shetland, was presented on 3/4/2019 for cardiac evaluation. The owner reports that [B6] was diagnosed with a small paramembranous VSD in 2013- no cardiac chamber enlargement was noted at that time. The owner adopted her from the breeder 2 years ago and has not had an echocardiogram rechecked. No coughing, no syncope, and no other clinical signs are noted. The owner reports that [B6] is in need of anesthesia and dental cleaning. No unusual coughing, sneezing, vomiting or diarrhea. No polyuria/polydypsia. Appetite and activity level normal. [B6] is fed Fromm salmon diet. She is current on vaccines and heartworm prevention. She has a history of DJD in her hip and a prior left coxofemoral joint injury that Dr. [B6] had previously evaluated and recommended medical management.</p> <p>Current Medications: [B6]</p> <p>Previous Diagnostics: 1/23/2013 - Echocardiogram: Small indistinctly margined approximately 2.7 mm defect in the upper portion of the interventricular septum, just below the mitral & tricuspid valves. Small jet of turbulent blood flow from left ventricle to right ventricle at site of defect. Velocity of turbulent jet measured 4.82 m/s, corresponding to a pressure gradient of 93.1 mm Hg. FS at that time was wnl at 31%. No cardiac chamber enlargement was noted. A grade 3/6 heart murmur was also noted on exam. Physical Exam HR: 130; RR: 24 Weight: 19.5 lb/8.86 kg Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur, no arrhythmias, lungs clear, pulses good. Skin normal. Musculoskeletal system normal. Normal peripheral lymph nodes</p> <p>Diagnostics ECG: normal sinus rhythm on lead II ECG during echocardiogram Doppler Blood Pressure: 144 mm Hg; # 3 cuff LF Echocardiogram: IVSd: 0.68 cm LVId: 3.02 cm LVPWd: 0.69 cm IVSs: 0.80 cm LVDs: 2.56 cm LVPWs: 0.78 cm %FS: 15 % EPSS: 0.76 cm Ao: 1.5 cm LAD: 1.6 cm LA /Ao: 1.08 AV Vmax: 0.92 m/s PV Vmax: 0.77 m/s MV Evel: 0.56 m/s MV Avel: 0.46 m/s MV E/A ratio: 1.21 E': 0.06 m/s Comments: A small defect measuring 2 mm was noted within the paramembranous interventricular septum with a small band of tissue visualized spanning the defect. No flow was noted crossing the defect with color flow Doppler. 2D/M-MODE: Left ventricle: Chamber size: mildly increased end-diastolic dimensions; moderately increased end-systolic dimensions - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: moderately to severely decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: normal Right ventricle: Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal Tricuspid valve leaflets: normal Aortic valve leaflets: normal Pulmonic valve leaflets: normal Aortic root: normal Aortic root motion: normal Main pulmonary artery: normal No evidence of pericardial or pleural effusion. CFD/PWD/CWD: Mitral regurgitation: none - Mitral inflows: normal - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: none - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none</p> <p>Diagnosis: Dilated cardiomyopathy - r/o diet-associated vs. idiopathic History of small paramembranous VSD- no flow noted across this defect on exam today Treatment /Medications We discussed performing a bubble study today, which the owner elected not to pursue at this time. We would like to recheck [B6] in 3 months to recheck her echocardiogram. I would recommend transitioning [B6] off of her current diet to either Royal Canin, Science Diet or Purina. Please start the following: Supplements (see handout for brand recommendations) Taurine 500 mg tablets: give 1 tablet by mouth every 12 hours. L-carnitine 500 mg tablets: give 1 tablet by mouth every 8 hours with food.</p>	
	Date Problem Started:	03/04/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Pet had previously been diagnosed with a Ventricular Septal Defect in 2013 at about 5 months of age.	
	Outcome to Date:	Unknown	

Product Information:	Product Name:	FROMM Salmon Tunalini			
	Product Type:	Pet Food			
	Lot Number:				
	Product Use Information:				
	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:	8.86 Kilogram			
	Age:	6 Years			
	Number of Animals Reacted:	1			
	Owner Information:	Owner Information provided:	No		
	Healthcare Professional Information:	Practice Name:	B6		
		Contact:	Name:	B6	
			Phone:		
		Type of Veterinarian:	Primary/regular veterinarian		
		Practice Name:	B6		
Contact:		Name:	B6		
		Phone:			
Type of Veterinarian:		Primary/regular veterinarian			
Sender Information:	Name:	B6			
	Address:	B6			
		United States			
	Contact:	Phone:			
		Email:	B6		
	Reporter Wants to Remain Anonymous:	No			
	Permission To Contact Sender:	Yes			
Preferred Method Of Contact:	Email				
Additional Documents:					

From: PFR Event <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 12/27/2018 3:56:41 PM
Subject: Homecooked diet - see diet history in medical record: Lisa Freeman - EON-374789
Attachments: 2060600-report.pdf; 2060600-attachments.zip

A PFR Report has been received and PFR Event [EON-374789] has been created in the EON System.

A "PDF" report by name "2060600-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 "2060600-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374789

ICSR #: 2060600

EON Title: PFR Event created for Homecooked diet - see diet history in medical record; 2060600

AE Date	11/15/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	[REDACTED] B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060600

Product Group: Other

Product Name: Homecooked diet - see diet history in medical record

Description: Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts 12/5/18 and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet. WB taurine [REDACTED] B6 (plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months

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
Homecooked diet - see diet history in medical record		

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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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6

Sent: 3/21/2019 3:41:24 PM

Subject: Homecooked diet - see diet history in medical record: Lisa Freeman - EON-382947

Attachments: 2064359-report.pdf; 2064359-attachments.zip

A PFR Report has been received and Related PFR Event [EON-382947] has been created in the EON System.

A "PDF" report by name "2064359-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 "2064359-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382947

ICSR #: 2064359

EON Title: Related PFR Event created for Homecooked diet - see diet history in medical record; 2064359

AE Date	11/15/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2064359

Product Group: Other

Product Name: Homecooked diet - see diet history in medical record

Description: Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts 12/5/18 and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet. WB taurine B6 plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Homecooked diet - see diet history in medical record		

This report is linked to:

Initial EON Event Key: EON-374789

Initial ICSR: 2060600

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

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From: PFR Event <pfreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 3/21/2019 4:08:56 PM
Subject: Horizons pulsar grain free diet; **B6** EON-382952
Attachments: 2064363-report.pdf; 2064363-attachments.zip

A PFR Report has been received and PFR Event [EON-382952] has been created in the EON System.

A "PDF" report by name "2064363-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 "2064363-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382952

ICSR #: 2064363

EON Title: PFR Event created for Horizons pulsar grain free diet; 2064363

AE Date	03/08/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Mixed (Dog)		
Age	4 Years		
District Involved	PFR-Baltimore DO		

Product information

Individual Case Safety Report Number: 2064363

Product Group: Pet Food

Product Name: Horizons pulsar grain free diet

Description: **B6** is presented as a consultation through CVCA Cardiology on 3/18/19 for evaluation of a coughing and marked cardiomegaly with concern for DCM. Arthur initially presented to the pDVM on 3/11 for a few day hx of coughing and was started on cough tabs. His symptoms progressed w/coughing noted mostly at night, decreased energy level and appetite, and he presented to the Emergency Vet Service in **B6**. CXR showed severe heart enlargement and possible early CHF. He was given a dose of Lasix (with significant improvement in C and appetite per O) and started on Enalapril 15 mg BID with recommendation for referral. He

has been on a grain free diet for the last ~4 years (since he was a puppy) and so DCM was discussed and a diet change recommended. The O's switched **B6** to Purina **B6** and he has had no adverse effects. They also submitted a taurine level (unsure if whole blood vs. plasma) to UC Davis. UTD on HW and F/T preventatives; has also been on salmon oils. PE: HR 180 bpm; grade III/VI holosystolic plateau quality heart murmur - PMI equal over MV and TV; regular tachycardia with s/s femoral pulses; mildly increased RE, RR 40-50 bpm, harsh lung sounds in all fields but no discreet crackles or wheezes. Echo diagnosis: Advanced dilated cardiomyopathy - suspect secondary to nutritional deficiency Moderate to severe mitral valve regurgitation Severely dilated left atrial dimensions Severely dilated left ventricular dimensions with severely decreased heart muscle function Moderate to severe right heart enlargement Left-sided congestive heart failure

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: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Horizons pulsar grain free diet		

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:

B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 3/20/2019 12:48:26 PM
Subject: Nutrisource Large breed puppy Grain free: [B6] EON-382807
Attachments: 2064306-report.pdf; 2064306-attachments.zip

A PFR Report has been received and PFR Event [EON-382807] has been created in the EON System.

A "PDF" report by name "2064306-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 "2064306-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382807

ICSR #: 2064306

EON Title: PFR Event created for Nutrisource Large breed puppy Grain free, Nutro Large breed puppy Farm raised chicken, Taste of the Wild Pacific Stream Puppy; 2064306

AE Date	03/19/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Not Applicable
Breed	Retriever - Golden		
Age	7 Months		
District Involved	PFR- [B6] DO		

Product information

Individual Case Safety Report Number: 2064306

Product Group: Pet Food

Product Name: Nutrisource Large breed puppy Grain free, Nutro Large breed puppy Farm raised chicken, Taste of the Wild Pacific Stream Puppy

Description: On March 18, 2019 my dog had an ECG in pre-op for his neutering surgery. This was done because he has a heart murmur. There was an abnormality found and we were sent to a cardiologist. On March 19, 2019 my dog was diagnosed with early stages of nutritionally mediated DCM at a board certified veterinary cardiologist. The breeder had my dog on Nutrisource food after weening until we got him at 9 weeks. We then

put him on Nutro large breed puppy chicken formula. He was on this food until January where we switched him to Taste of the Wild Pacific Stream Puppy.

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: Not Applicable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Nutro Large breed puppy Farm raised chicken		
Taste of the Wild Pacific Stream Puppy		
Nutrisource Large breed puppy Grain free		

Sender 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

=====

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 3/20/2019 4:36:36 PM
Subject: Nutro MAX Adult Recipe With Farm Raised Chicken Mini Chunk Dry Dog Food: [REDACTED] B6 EON-382838
Attachments: 2064311-report.pdf; 2064311-attachments.zip

A PFR Report has been received and PFR Event [EON-382838] has been created in the EON System.

A "PDF" report by name "2064311-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 "2064311-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382838

ICSR #: 2064311

EON Title: PFR Event created for Nutro MAX Adult Recipe With Farm Raised Chicken Mini Chunk Dry Dog Food (1) 25 lbs; Rich in Nutrients and Full of Flavor, NUTRO MAX Senior Recipe With Farm Raised Chicken Dry Dog Food Whole Grain.; 2064311

AE Date	05/21/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Portuguese Water Dog		
Age	11 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2064311

Product Group: Pet Food

Product Name: Nutro MAX Adult Recipe With Farm Raised Chicken Mini Chunk Dry Dog Food, (1) 25 lbs; Rich in Nutrients and Full of Flavor, NUTRO MAX Senior Recipe With Farm Raised Chicken Dry Dog Food, Whole Grains for Nutritious Fiber, (1) 25-lb. bag; Rich in Nutrients and Full of Flavor, NUTRO MAX Large Breed Adult Recipe With Farm Raised Chicken Dry Dog Food, (1) 25-lb. bag; Rich in Nutrients and Full of

Flavor for Large Breed Dogs, Nutro MAX Adult Grain Free With Salmon Dry Dog Food, 25 lbs., Zignature TROUT & SALMON MEAL FORMULA, Zignature WHITEFISH FORMULA

Description: B6 started coughin in the last week of May, progressively lethargic since that time. Seen by primary vet. Suspected Kennel Cough (misdiagnosis). B6 l given with no improvement after one week started on B6 100mg 2x daily. No improvement seen. Syncope episode occurred about 2 weeks after, mouth to mouth resuscitation performed. Recovered after a few moments. No improvement seen with antibiotics, worried owners rushed B6 specialty center of B6 around June 13, knowing cardiologist B6 would be there that day. He had an appointment scheduled a few weeks from that day but we realized we could not wait. Gums were pale on arrival. Was in critical condition. He had to stay overnight in oxygen tank with high dosage of lasix and received echocardiogram. Prognosis was poor. We decided to try medical management vs. euthanization. He was prescribed various medications for his problem. Problems: Atrial and ventricular premature contractions, coughing and collapse, lethargy, stage C mitral and tricuspid valvular insufficiency with severe left side congestive heart failure and severe pulmonary hypertension. He lasted 2 months and passed away in late August. Respiratory rate was high during that time period, sometimes trouble getting comfortable. He had been fed NUTRO max (various kinds) 2017 and 2018. I don't have records of prior to then because i started buying it online through Chewy and Amazon in 2017. But my mom said that he and my older dog had always been on Nutro. Foods provided before diagnosis: Nutro Max Large Breed Adult Recipe with Farm-Raised Chicken Nutro MAX Adult Recipe With Farm Raised Chicken Mini Chunk Dry Dog Food, (1) 25 lbs; Rich in Nutrients and Full of Flavor NUTRO MAX Senior Recipe With Farm Raised Chicken Dry Dog Food, Whole Grains for Nutritious Fiber, (1) 25-lb. bag; Rich in Nutrients and Full of Flavor NUTRO MAX Large Breed Adult Recipe With Farm Raised Chicken Dry Dog Food, (1) 25-lb. bag; Rich in Nutrients and Full of Flavor for Large Breed Dogs Nutro MAX Adult Grain Free With Salmon Dry Dog Food, 25 lbs. After his diagnosis I was concerned about the food and a friend recommended Zignature, so i switched him for the last few months, he was on Zignature at time of death: Zignature - Whitefish (August) Zignature - Wild Trout (July) I am discovering there is a link to heart problems and dry kibble, since echocardiogram was performed, decided to submit case to FDA to help other dogs/owners. 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
Zignature TROUT & SALMON MEAL FORMULA		
Nutro MAX Adult Grain Free With Salmon Dry Dog Food, 25 lbs.		
NUTRO MAX Senior Recipe With Farm Raised Chicken Dry Dog Food, Whole Grains for Nutritious Fiber, (1) 25-lb. bag; Rich in Nutrients and Full of Flavor		
Zignature WHITEFISH FORMULA		

Sender information

B6

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

B6

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nutro

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4 orders matching "nutro"



Order details Ordered on April 26, 2018 (1 item)

Nutro MAX Adult Recipe With Farm Raised Chicken Mini Chunk Dry Dog Food, (1) 25 lbs; Rich in Nutrients and Full of Flavor

Sold by: Fat Happy Pets



Order details Ordered on March 5, 2018 (1 item)

NUTRO MAX Senior Recipe With Farm Raised Chicken Dry Dog Food, Whole Grains for Nutritious Fiber, (1) 25-lb. bag; Rich in Nutrients and Full of Flavor

Nutro

Sold by: Amazon.com Services, Inc.



Order details Ordered on January 21, 2018 (1 item)

NUTRO MAX Large Breed Adult Recipe With Farm Raised Chicken Dry Dog Food, (1) 25-lb. bag; Rich in Nutrients and Full of Flavor for Large Breed Dogs

Nutro

Sold by: Amazon.com Services, Inc.



Order details Ordered on October 18, 2017 (1 item)

Nutro MAX Adult Grain Free With Salmon Dry Dog Food, 25 lbs.

Nutro

Sold by: Amazon.com LLC

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Schick Intuition
Revitalizing Moisture Razor
Blade Refills for Women, 6
Count

844

\$16.59



Bonsai Jack Succulent and
Cactus Soil Gritty Mix #111
- (2 Quarts) – Fast Draining
– Zero Root Rot –...

199

\$12.49



Cover Dot Acne Care (48
Dots) Exposed Skin
Blemish Treatment with
Hydrocolloid | Clear,...

564

\$15.75



Tinkle Eyebrow Razor Pack
of 6

2,103

\$4.60



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Page 1 of 2



Greenies Dog Pill Pockets Tablets

283



Merrick Power Bites Real Rabbit Dog Treats

64



Merrick Grain Free Gluten Free Power Bites Dog Treats, 6 oz



Greenies Pill Pocket Soft Dog Treats - Peanut Butter

1,911



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Prime Now FREE 2-hour Delivery on Everyday Items	Amazon Photos Unlimited Photo Storage Free With Prime	Prime Video Direct Video Distribution Made Easy	Shopbop Designer Fashion Brands	Amazon Warehouse Great Deals on Quality Used Products	Whole Foods Market America's Healthiest Grocery Store	Woot! Deals and Shenanigans
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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 3/20/2019 6:28:36 PM
Subject: Taste of the Wild Grain Free; [REDACTED] B6 EON-382849
Attachments: 2064322-report.pdf

A PFR Report has been received and PFR Event [EON-382849] has been created in the EON System.

A "PDF" report by name "2064322-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-382849

ICSR #: 2064322

EON Title: PFR Event created for Taste of the Wild Grain Free; 2064322

AE Date	03/20/2019	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Pointing Dog - German Short-haired		
Age	5 Years		
District Involved	PFR-[REDACTED] B4 DO		

Product information

Individual Case Safety Report Number: 2064322

Product Group: Pet Food

Product Name: Taste of the Wild Grain Free

Description: [REDACTED] B4 was diagnosed with a new heart murmur on 12/4/18 when she was seen for routine vaccines. At that time she was being fed Taste of the Wild Grain free Salmon diet. [REDACTED] B4 regular veterinarian recommended switching diets and she was switched to Purina Proplan Sport. She was seen today and 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 Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild 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:

B6

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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: 4/15/2019 10:48:01 AM
Subject: DCM cases 4/15/2019 0645
Attachments: Nature's Domain - Salmon and Sweet Potato-Nature's Domain - Turkey ad Sweet Potato-Nature's Domain - Beef and Sweet Potato-Nature's Domain - Canned Grain free Dog Food: [B6] - EON-385037; Solid Gold Mighty Mini Beef: Lisa Freeman - EON-380716; Solid Gold Mighty Mini Beef: Lisa Freeman - EON-384905

Related EON-348905 (not sure if following the original)

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 <ppreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**

Sent: 4/14/2019 11:20:28 PM

Subject: Nature's Domain - Salmon and Sweet Potato-Nature's Domain - Turkey ad Sweet Potato-Nature's Domain - Beef and Sweet Potato-Nature's Domain - Canned Grain free Dog Food; **B6** - EON-385037

Attachments: 2065806-report.pdf

A PFR Report has been received and PFR Event [EON-385037] has been created in the EON System.

A "PDF" report by name "2065806-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-385037

ICSR #: 2065806

EON Title: PFR Event created for Nature's Domain - Salmon and Sweet Potato Nature's Domain - Turkey ad Sweet Potato Nature's Domain - Beef and Sweet Potato Nature's Domain - Canned Grain free Dog Food; 2065806

AE Date	03/11/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	10 Years		
District Involved	PFR; B6 DO		

Product information

Individual Case Safety Report Number: 2065806

Product Group: Pet Food

Product Name: Nature's Domain - Salmon and Sweet Potato Nature's Domain - Turkey ad Sweet Potato Nature's Domain - Beef and Sweet Potato Nature's Domain - Canned Grain free Dog Food

Description: A heart function blood test was run on **B6** and **B6** as part of their senior examination.

B6 numbers came back at around **B6** (top of normal range **B6**). While not formally diagnosed, DCM is suspected **B6** numbers came back at **B6**. An ultrasound was run on **B6** and she has been diagnosed

with DCM; sever dilation of left ventricle with mild thickening of the mitral valve **B6** is deemed to be at moderate risk for CHF. Both dogs are being given Taurine supplements and traditional dog food **B6** is currently taking a beta blocker and Vetmedin. Both dogs were fed Nature's Domain (Costco or Kirkland brand of Grain Free Dog Food). They each rotated through the Salmon and Sweet Potato, Turkey and Sweet Potato, and Beef and Sweet Potato formulas throughout their lives. The grain free food was recommended for a third Labrador Retriever with severe allergies. This third dog was never diagnosed with DCM and was euthanized in **B6** at 15+ years due to severe arthritis.

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: 3

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Nature's Domain - Salmon and Sweet Potato Nature's Domain - Turkey ad Sweet Potato Nature's Domain - Beef and Sweet Potato Nature's Domain - Canned Grain free 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

B6

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6

Sent: 4/12/2019 6:44:58 PM

Subject: Solid Gold Mighty Mini Beef: Lisa Freeman - EON-384905

Attachments: 2065743-report.pdf; 2065743-attachments.zip

A PFR Report has been received and Related PFR Event [EON-384905] has been created in the EON System.

A "PDF" report by name "2065743-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 "2065743-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-384905

ICSR #: 2065743

EON Title: Related PFR Event created for Solid Gold Mighty Mini Beef Sweet Potato and Apple grain free dry; 2065743

AE Date	B6	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Chihuahua		
Age	9 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2065743

Product Group: Pet Food

Product Name: Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry

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.

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry		

This report is linked to:

Initial EON Event Key: EON-380716

Initial ICSR: 2063119

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

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B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 7/24/2018 11:24:13 PM
Subject: Taste of the Wild Pine Forrest; [B6] - EON-360238
Attachments: 2052688-report.pdf; 2052688-attachments.zip

A PFR Report has been received and PFR Event [EON-360238] has been created in the EON System.

A "PDF" report by name "2052688-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 "2052688-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-360238

ICSR #: 2052688

EON Title: PFR Event created for Taste of the Wild Pine Forrest Venison and Legumes; 2052688

AE Date	05/08/2017	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-[B6] DO		

Product information

Individual Case Safety Report Number: 2052688

Product Group: Pet Food

Product Name: Taste of the Wild Pine Forrest, Venison and Legumes

Description: Just before [B6] second birthday, her energy level dropped and she developed a dry cough in the mornings. On the advice of a friend, I had her blood tested for taurine because she was on a grain-free food high in legumes. The result was [B6] ml by the plasma test (normal level is 60-120 ml). I then took her to cardiologist Dr. Joshua Stern at UCD VMTH. Dr. Stern did an echocardiogram and also found the Mitral Valve Dysplasia, but did not see SAS. He found Mild to Moderate DCM. His report reads: "Moderately dilated left ventricular chamber and LV systolic dysfunction - ddx: taurine responsive DCM vs idiopathic DCM. Lv chamber has

significantly increased in the recheck interim ([REDACTED] B6 [REDACTED] previous July 2016)." He prescribed increasing the taurine and l-carnitine supplements and return for repeat echo in 3-4 months.

Submission Type: Initial

Report Type: Both

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
Taste of the Wild Pine Forrest, Venison and Legumes		

Sender information

[REDACTED] B6 [REDACTED]

USA

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

[REDACTED] B6 [REDACTED]

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

[REDACTED] B6 [REDACTED]

[REDACTED] B6 [REDACTED]

=====

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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: Norris, Anne; Hartogensis, Martine; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica; Nemser, Sarah
Sent: 6/27/2018 5:26:20 PM
Subject: DCM Product [REDACTED] B5
Attachments: [REDACTED] B5

Based on Bill's recommendation, I [REDACTED] B5 we've been notified about, including those from Tufts, CVCA, NCSU, and OH (i.e. not necessarily received through the Safety reporting portal). [REDACTED] B5

[REDACTED] B5

For the Bottom Line, see the PPT. The ppt notes will walk you through my analysis. Please let me know if you have questions.

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>



B5

I did not:

B5

B5

B5

Document properties

Author: Jones, Jennifer L
Template: Normal.dotm
Page count: 2
Paragraph count: 132
Line count: 179
Word count: 662
Character count (spaces excluded): 3098
Character count (spaces included): 3654

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/1/2019 9:32:34 PM
Subject: 4Health grain=free beef and potato; [B6] EON-375111
Attachments: 2060740-report.pdf; 2060740-attachments.zip

A PFR Report has been received and PFR Event [EON-375111] has been created in the EON System.

A "PDF" report by name "2060740-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 "2060740-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375111

ICSR #: 2060740

EON Title: PFR Event created for 4Health grain=free beef and potato; 2060740

AE Date	12/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	4.5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060740

Product Group: Pet Food

Product Name: 4Health grain=free beef and potato

Description: Weight loss x 3-4 weeks Coughing and dyspnea developed - too to ER in [B6] where they did T-FAST and suspected DCM. Started on [B6] before we saw him Eating BEG diet. Taurine pending. Switched to new food. Will also try to evaluate other dog in their home eating the same diet (15 years old) Owners happy to provide additional info and have saved some of the food they've been feeding (4Health)

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
4Health grain=free beef and potato		

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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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/15/2019 9:05:17 PM
Subject: 4Health whitefish and potato dry: Lisa Freeman - EON-376448
Attachments: 2061217-report.pdf; 2061217-attachments.zip

A PFR Report has been received and PFR Event [EON-376448] has been created in the EON System.

A "PDF" report by name "2061217-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 "2061217-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376448

ICSR #: 2061217

EON Title: PFR Event created for 4Health whitefish and potato dry, 4Health salmon and potato adult dog food; 2061217

AE Date	01/03/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Pit Bull		
Age	7.5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061217

Product Group: Pet Food

Product Name: 4Health whitefish and potato dry, 4Health salmon and potato adult dog food

Description: Eating BEG diet Syncopal episodes - identified arrhythmia recently Owner changing diet and will recheck in 3 months Elevated BNF B6 taurine and troponin pending 2 other dogs in household eating same diet - they have not been screened yet

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: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4Health salmon and potato adult dog food		
4Health whitefish and potato dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

B6

USA

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

B6

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

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 12/27/2018 3:16:35 PM
Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-374786
Attachments: 2060599-report.pdf; 2060599-attachments.zip

A PFR Report has been received and PFR Event [EON-374786] has been created in the EON System.

A "PDF" report by name "2060599-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 "2060599-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374786

ICSR #: 2060599

EON Title: PFR Event created for Acana Free Run Poultry dry; 2060599

AE Date	08/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	10 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060599

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

Description: Housemate was diagnosed with DCM (**B6** - previously reported). **B6** was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine **B6**

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Acana Free Run Poultry 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:

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/14/2019 9:56:41 PM
Subject: Annamaet chicken and rice dry + Honest kitchen beef; B6 - EON-376360
Attachments: 2061170-report.pdf; 2061170-attachments.zip

A PFR Report has been received and PFR Event [EON-376360] has been created in the EON System.

A "PDF" report by name "2061170-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 "2061170-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376360

ICSR #: 2061170

EON Title: PFR Event created for Annamaet chicken and rice dry + Honest kitchen beef chicken or turkey; 2061170

AE Date	12/21/2017	Number Fed/Exposed	3
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Doberman Pinscher		
Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061170

Product Group: Pet Food

Product Name: Annamaet chicken and rice dry + Honest kitchen beef, chicken, or turkey

Description: 2 other dogs in household affected previously Eating various BEG diets Early DCM with infrequent ventricular ectopy Have been following - owner agreed to change diet at December 2018 appointment so will follow Taurine normal

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: 3
Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Annamaet chicken and rice dry + Honest kitchen beef, chicken, or turkey		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/2/2019 5:32:22 PM
Subject: 4Health beef and potato and 4health untamed lamb and Lentil; EON-375168 [B6]
Attachments: 2060761-report.pdf

A PFR Report has been received and PFR Event [EON-375168] has been created in the EON System.

A "PDF" report by name "2060761-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375168

ICSR #: 2060761

EON Title: PFR Event created for 4Health beef and potato and 4health untamed lamb and Lentil; 2060761

AE Date	03/01/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Griffon - French Wire-haired Pointing		
Age	5 Years		
District Involved	PFR-Minneapolis DO		

Product information

Individual Case Safety Report Number: 2060761

Product Group: Pet Food

Product Name: 4Health beef and potato and 4health untamed lamb and Lentil

Description: Female spayed dog in excellent health developed DCM and died from it. ([B6] months old) [B6] (2 year Old Spayed female) is now showing early signs of enlarged heart and elevated proBNP. Normal range is 0-900 and her level is [B6]. We have an appointment with cardiologist at the [B6] on Feb 7th, 2019.

Submission Type: Initial

Report Type: Both

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
4Health beef and potato and 4health untamed lamb and Lentil		

Sender information

B6

USA

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6

Sent: 12/26/2018 11:40:53 PM

Subject: 4health optimal nutrition for optimal health weight management formula for dogs: B6 - EON-374758

Attachments: 2060587-report.pdf; 2060587-attachments.zip

A PFR Report has been received and Related PFR Event [EON-374758] has been created in the EON System.

A "PDF" report by name "2060587-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 "2060587-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374758

ICSR #: 2060587

EON Title: Related PFR Event created for 4health optimal nutrition for optimal health weight management formula for dogs, Purina ProPlan Savor Adult Shredded Blend Chicken and Rice Formula (this is one the new diet that patient was transi...; 2060587

AE Date	09/20/2018	Number Fed/Exposed	
Best By Date	05/31/2020	Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Hound - Afghan		
Age	6 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2060587

Product Group: Pet Food

Product Name: 4health optimal nutrition for optimal health weight management formula for dogs, Purina ProPlan Savor Adult Shredded Blend Chicken and Rice Formula (this is one the new diet that patient was transitioned to after initial cardiac disease diagnosis), Purina One Smartblend Chicken and Rice Formula (this

diet gets mixed into Puirina ProPlan Savor food and has been transitioned to since the patient was initially diagnosed with cardiac disease).

Description: Onset of cough 9/20/18, progressed to biventricular congestive heart failure and atrial fibrillation. 12/26/18- six week follow-up: significant improvement with now normal energy, normal respirations; finicky appetite persists but is reportedly not unusual for the patient

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Purina ProPlan Savor Adult Shredded Blend Chicken and Rice Formula (this is one the new diet that patient was transitioned to after initial cardiac disease diagnosis)	82871085 1039L09	04/30/2020
4health optimal nutrition for optimal health weight management formula for dogs	WHH0504-18 HMS	05/31/2019
Purina One Smartblend Chicken and Rice Formula (this diet gets mixed into Puirina ProPlan Savor food and has been transitioned to since the patient was initially diagnosed with cardiac disease).	83071085 1237L02	05/31/2020

This report is linked to:

Initial EON Event Key: EON-370883

Initial ICSR: 2058754

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

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B6

Referring Hospital:

B6

Examination Date:

B6

TIME: Patient:

B6

5 year, male, English Lab

Re: Client:

B6

B6

Chief Complaint/Clinical History:

B6 was referred for a suspected tracheal mass. The owner reports that his appetite has been off for the past week. He is still eating but eating slowly and only wants people food. No vomiting/diarrhea
Last night the owner noted increased respiratory noise to his breathing and his cheeks were puffing out. He has been coughing some the past 24hours only. He ate 1 cup of food this morning
He is on a limited ingredient, grain free diet(blue buffalo lamb/potato) for the past 2-3 years.

B6

meds: none

B6

Laboratory:

Treatment:

I called owner and advised that **B6** is in CHF and likely has DCM. Discussed treatment for CHF. Owner wants to proceed. Gave owner estimate for 48hrs

B6

B6

B6

Diagnosis:

Fulminating Congestive heart failure.
Suspect DCM

Thank you very much for the referral, if you have any questions regarding B6 or any other case, please do not hesitate to call me.

B6

DVM

B6

DVM,

B6

B6

B6

B6

Patient: B6 B6 years and B6 months old M Canine Golden Retriever

Client: B6

Account #: 300G

Referring Hospital: B6

Referring Doctor: B6

Referring Hospital:

Referring Doctor: Dr.

Date: Jan 03, 2019

Cardiology Consultation

Current History: B6 is a 3-year-old male Golden Retriever that presents today for a 2 month follow-up echocardiogram after the identification of a dilated cardiomyopathy phenotype and a marginal taurine level. The owner has been supplementing taurine since the last echocardiogram and carnitine for the past 6 weeks (see below). B6 was not symptomatic at the last evaluation and has remained active and energetic. The owner does not report any other noncardiac problems. He has tolerated the supplements without apparent side effects. No other new medical problems were reported.

Past medical history:

- Immature cataract, OS
- Historical dermatitis

Current Medications:

- Taurine 1g twice a day
- Carnitine 2g a.m./p.m., 1.5g "midnight snack"
- Cosequin joint supplement

Cardiopulmonary Exam: B6 is alert and friendly as usual. He is mildly overweight (38.3 kg, BCS 6/9) and has gained 1 kg since the last evaluation. Cardiac auscultation was unremarkable with no arrhythmias, gallop sounds, or murmurs. Oral mucous membrane color and refill time are within normal limits. Pulmonary auscultation was unremarkable. Arterial pulse quality was excellent and there were no pulse deficits or jugular pulsations.

General Physical Exam Abnormalities: The patient has a fractured right maxillary third incisor. An incipient cataract is present OS

Diagnostic Procedures

Electrocardiogram: A bipolar monitoring ECG recorded during the echocardiogram demonstrates a normal sinus rhythm with heart rates between 87-120 bpm. No ectopy was observed during the study.

Echocardiogram: Left ventricular internal chamber dimensions are mildly increased for a dog of this size but have remained static since the last examination. Right and left ventricular myocardial thicknesses are within normal limits, and echogenicity of the ventricular myocardium is subjectively normal as well. Left ventricular sphericity has decreased (sphericity index 1.22) although it is still mildly abnormal. Estimates of left ventricular systolic function have improved since the last exam and are now for the most part within normal

B6

B6

limits (FS 26%, EF 54-55%, EPSS 8 mm). Both atria are normal in size (LA 3.7 cm, LA/Ao 1.37). Valvular anatomy was unremarkable and color flow Doppler did not document any pathologic valvular insufficiencies, although physiologic tricuspid regurgitation was present (2.2 m/s). Ejection velocities and great vessel anatomy were normal (Ao 1.6 m/s, PA 1.1 m/s). The mitral inflow profile is normal as well (E wave 0.8 m/s, A-wave 0.5 m/s). Left ventricular IVRT is at the upper limit of normal at 95 ms. Pulsed tissue Doppler evaluation of the mitral annulus was normal (Ea 0.17 m/s). No masses or vegetations were observed.

Diagnosis/Problem List:

- Historical dilated cardiomyopathy phenotype - resolving
- Probable taurine deficiency - appropriately supplemented
- Overweight
- Fractured right maxillary I3
- Immature cataract OS

Summary/Prognosis: **B6** echocardiogram has improved since the last examination with normal or near-normal estimates of LV systolic function and subjectively diminished sphericity. Atrial dimensions are still normal, and no secondary functional valvular insufficiencies were identified. The improvement in systolic function is presumably related to supplementation with taurine and carnitine. Based on today's evaluation no additional diagnostics were recommended, and **B6** does not currently require any other therapy. His left ventricular internal dimensions are still slightly increased, but this may be a reflection of a physiologic change in a very active dog, since his LV dimensions have been mildly increased since his initial evaluation in 2017. He will continue to be monitored, but hopefully identification of a relative taurine deficiency early in the disease process will prevent progression to any overt clinical symptoms.

Treatment Plan:

- Continue supplements as above

Follow-up Recommendations: Recheck echocardiography in 3-4 months

B6

B6, DVM

Diplomate ACVIM (Cardiology)

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]

Sent: 1/2/2019 8:12:39 PM

Subject: Pure Vita Venison & Red Lentils Grain Free Entree [B6] - EON-375203

Attachments: 2060773-report.pdf; 2060773-attachments.zip

A PFR Report has been received and PFR Event [EON-375203] has been created in the EON System.

A "PDF" report by name "2060773-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 "2060773-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375203

ICSR #: 2060773

EON Title: PFR Event created for Pure Vita Venison & Red Lentils Grain Free Entree, Whole Life Pet Just One Ingredient Pure Beef Liver Treat; 2060773

AE Date	10/05/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	8 Years		
District Involved	PFR- [B6] DO		

Product information

Individual Case Safety Report Number: 2060773

Product Group: Pet Food

Product Name: Pure Vita Venison & Red Lentils Grain Free Entree, Whole Life Pet Just One Ingredient Pure Beef Liver Treat

Description: Low whole blood taurine noted 10/05/18 (135 nmol/mL). Mild decrease in systolic function noted on echocardiogram 10/06/18. Generally asymptomatic but seems heat intolerant and tires easily on walks (not a new finding).

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
Whole Life Pet Just One Ingredient Pure Beef Liver Treat		
Pure Vita Venison & Red Lentils Grain Free Entree		

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:

B6

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From: PFR Event <ppreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]

Sent: 1/3/2019 8:56:20 PM

Subject: Solid Gold Wee Bit formula-Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food: [B6] - EON-375339

Attachments: 2060822-report.pdf

A PFR Report has been received and PFR Event [EON-375339] has been created in the EON System.

A "PDF" report by name "2060822-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375339

ICSR #: 2060822

EON Title: PFR Event created for Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food; 2060822

AE Date	[B6]	Number Fed/Exposed	3
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Not Applicable
Breed	Terrier - Yorkshire		
Age	6 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2060822

Product Group: Pet Food

Product Name: Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food

Description: There are 3 of my dogs that have been diagnosed with Enlarged heart. None of theses dogs are related. [B6] died of diagnosed enlarged heart (via xray) at age 14 in [B6] [B6] was diagnosed (xray) with an enlarged heart on 4/12/18 measured 10.7 heart score. [B6] is now on 3 heart meds twice a day. Indefinitely [B6] was recently diagnosed on 12/31/18 with an enlarged heart measured 11.5 heart score. [B6] is now on 3 heart meds twice a day. Indefinitely.

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Not Applicable

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry 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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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/26/2019 1:54:30 AM
Subject: Taste of the Wild - EON-377564
Attachments: 2061774-report.pdf

A PFR Report has been received and PFR Event [EON-377564] has been created in the EON System.

A "PDF" report by name "2061774-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377564

ICSR #: 2061774

EON Title: PFR Event created for Taste of the Wild, 4 health; 2061774

AE Date	12/04/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Bulldog - American		
Age	3 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061774

Product Group: Pet Food

Product Name: Taste of the Wild, 4 health

Description: We have been feeding [B6] grain free food his whole life. Around christmas he developed a cough. Since he had stayed at the vet for surgery, they treated him for kennell cough. I brought him to the vet today for a follow up as the cough had progressed. He HATES the vet so on order to get an xray, they wanted to sedate him. As soon as they did they had to use counter medicine to get him out of it Nd admitted iter oxygen. He was on oxygen for an hour as they were [B6] to emergency veterinarian 1 hour away. They weren't sure he would make it to the other vet. He was diagnosed Congestive heart failure, secondary to dialated cardiomyopathy (DCM) . His heart is so enlarged, its pumping blood into his lungs. He is now being with heart medication, medication to dry out his lungs, and high doses of the vitamins(taurine) that he was starved of with

the grain free food. The veterinarian is certain it was caused by lack of these nutrients with the grain free diet.

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: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4 health		
Taste of the Wild		

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: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 1/23/2019 7:40:22 PM
Subject: Taste of the Wild (Pacific Stream formula); [REDACTED] B6 - EON-377278
Attachments: 2061637-report.pdf; 2061637-attachments.zip

A PFR Report has been received and PFR Event [EON-377278] has been created in the EON System.

A "PDF" report by name "2061637-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 "2061637-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377278

ICSR #: 2061637

EON Title: PFR Event created for Taste of the Wild (Pacific Stream formula); 2061637

AE Date	08/22/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Recovered Completely
Breed	Retriever - Golden		
Age	6 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2061637

Product Group: Pet Food

Product Name: Taste of the Wild (Pacific Stream formula)

Description: [REDACTED] B6 had been fed two brands of grain-free kibble since I purchased him at 8 weeks of age. In August 2018, I became aware of a possible link between this type of food and a taurine deficiency which could lead to heart disease. A blood test was performed at [REDACTED] B6 at that time, and his whole blood taurine result of 222 was below the recommended level for a Golden Retriever. An echocardiogram a few weeks later confirmed DCM, moderate dilation of the left ventricle. His diet was changed to a grain inclusive kibble. He was also given daily heart medications and a taurine supplement. Four months later, another echocardiogram showed his heart to

be completely normal.

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Recovered Completely

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 (Pacific Stream formula)		

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 <ppreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 1/22/2019 11:08:32 PM
Subject: Taste of the Wild High Prairie grain-free with roasted bison and roasted venison; [REDACTED] B6 - EON-377174
Attachments: 2061583-report.pdf

A PFR Report has been received and PFR Event [EON-377174] has been created in the EON System.

A "PDF" report by name "2061583-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377174

ICSR #: 2061583

EON Title: PFR Event created for Taste of the Wild High Prairie grain-free with roasted bison and roasted venison; 2061583

AE Date	[REDACTED] B6	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mixed (Dog)		
Age	11 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2061583

Product Group: Pet Food

Product Name: Taste of the Wild High Prairie grain-free with roasted bison and roasted venison

Description: Anorexia, lethargy and abdominal distention noted 6 days before presentation to the ER. He was diagnosed with chronic degenerative valve disease, Dilated cardiomyopathy, myocardial dysfunction, congestive heart failure, both left- and right-sided, atrial fibrillation,

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 Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie grain-free with roasted bison and roasted venison		

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:

B6

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B6

B6

CARDIOLOGY

B6

DVM, DACVIM-Cardiology
DVM, DACVIM-Cardiology

Date: Thursday, **B6**

Patient: **B6** - Shepherd, Australian, Spayed Female, **B6**

Owner: **B6**

Referring Veterinarian:

B6

Phone: **B6**

Fax: **B6**

Chief Concern: **B6** is here for further evaluation of a heart murmur noted at her exam with **B6** in December. At home, she's showing no clinical signs suggestive of cardiac disease. She will have an intermittent hacking cough, but is breathing comfortably.

Weight: 24.9 kilograms

Current Medications: None

Diagnosis: Degenerative valvular disease - mild (no left atrial enlargement)
Ventricular premature complexes - mild (infrequent, single beats)
Moderate hypertension - possibly excitement-related, recommend recheck

Procedures: **Physical exam:**
BAR, nervous. MM pink, moist, CRT < 2s. III-IV/VI left apical systolic murmur auscultated. Pulses strong and synchronous. No arrhythmias noted during physical exam. Lung sounds normal, eupneic. HR = **B6** bpm, RR = **B6** bpm

Echocardiogram:

B6

Comments:

The left atrium is normal in size. The left ventricle is normal in size and LV systolic function is normal. The mitral valve is mildly thickened and prolapses. The tricuspid valve is mildly thickened. All other valves are subjectively normal in appearance. The right atrium and right ventricle are both subjectively normal in size and function. No masses or effusions are noted. The main and branch pulmonary arteries are subjectively normal in size. ECG shows sinus rhythm/sinus tachycardia when anxious - intermittent, sometimes very infrequent single ventricular premature complexes are noted (no couplets, triplets, or runs of ventricular tachycardia observed).

B6

Comments:

Mild mitral regurgitation is noted. Mild tricuspid valve regurgitation is noted. Based on the TR

velocity, there is no evidence of significant pulmonary hypertension. No other valvular regurgitations are noted. Normal, laminar flow is noted across the aortic and pulmonic valves during systole.

Assessment:

Based on today's evaluation, the murmur that is heard is due to degenerative valvular disease and a resultant leak across the mitral valve. The mitral valve is located on the left side of the heart and lies in between the atrium (top chamber) and ventricle (bottom chamber). As dogs age, the degenerative process causes a progressive thickening of the valve and the leaflets that make up the valve do not completely close. When the ventricle pumps, a small amount of blood is leaking backwards across the mitral valve and this is what we hear as a murmur. Currently, the leak across the valve is small and is causing no heart enlargement. The remainder of the heart is very normal and the muscle of the heart is functioning normally. Due to the lack of heart enlargement and an otherwise normal heart, no treatment is indicated at this time as significant clinical signs of heart disease are not likely to be present. Structural heart disease is not present to result in the ventricular premature complexes. They could be due to stress (most likely), hypertension, or non-cardiac disease. Recheck ecg in 1-2 months with blood pressure.

Additionally, there is minimal (if any) risk of anesthesia, so any procedures (surgery or dental cleaning) that must be performed in the near future have no cardiac contraindications.

Blood pressure: #4 cuff left front limb, Doppler; 175mmHg. She was nervous during her blood pressure and this could be the cause of moderate hypertension. Prior to any therapy, I recommend rechecking this in 1-2 months.

Client Instructions:



CAUSE OF MURMUR:

Degenerative valve disease (DVD) is the most common acquired heart disease in dogs. It is especially common in older, small breed dogs. DVD is typically a slowly progressive condition and not all dogs will develop clinical signs associated with degenerative valve disease. Any valve in the heart can be affected by DVD, but the most common valve involved is the mitral valve. This is the valve that sits between the left ventricle and the left atrium. As it becomes degenerative and starts to fail, it can allow blood to leak back into the left atrium (top chamber on left). If severe enough, this 'backing up' of blood can affect the pulmonary circulation as well, resulting in fluid accumulation inside the lungs (pulmonary edema). When this occurs, it is referred to as "congestive heart failure" or CHF. Pulmonary edema makes breathing very difficult since normally the lungs should be filled with air, rather than fluid.

At this time, **B6** heart disease is not progressed to the point of congestive heart failure, but we should periodically monitor for further progression and the above clinical signs - as the disease worsens over time. Much of this monitoring can be performed at **B6** **B6** as chest x-rays will be a good screening tool. Less frequently, echocardiograms will allow for more specific assessment of heart valvular and muscle function as well as chamber sizes.

Clinical signs associated with CHF include lethargy, weakness, decreased activity level, coughing and/or increased breathing rate (>40 breaths per minute AT REST) or increased breathing effort. If any of these signs are noted, a veterinarian should be contacted immediately.

OCCASIONAL ARRHYTHMIA:

Based on today's testing, **B6** has abnormal heart beats coming from the bottom heart chambers (ventricles). Normally, the heart has a very organized electrical system that tells the muscle when/where to contract. Occasionally, diseases will disrupt the heart's electrical system and cause inappropriate areas of the heart to fire off electrical signals that can affect the heartbeat. In **B6** case, these arrhythmias do not appear overly dangerous and are only occurring as single premature beats (ventricular premature complexes/VPC). There are many causes of mild ventricular arrhythmias and include both cardiac and non-cardiac disease. While some breeds (Boxers and Dobermans) are prone to primary heart diseases, most other breeds have non-cardiac disease as the primary cause of arrhythmias. Based on the echocardiogram performed today, there is no evidence of structural heart disease in **B6**. We cannot completely rule out that a tiny, microscopic area of the heart is producing these beats because that will not show up on any available testing.

More likely, non-cardiac disease could be affecting heart rhythm. These include benign causes like anxiety/stress. Or other issues like increased blood pressure, systemic inflammatory conditions, abdominal diseases (tumors of spleen, liver, adrenal glands), or nervous system diseases. We checked a blood pressure today and it was a little increased - but still within the range of what can be seen with stress. I recommend rechecking blood pressure in 1-2 months to make sure it is repeatably high. Also, if not performed recently, full bloodwork is recommended to make sure there's no evidence of inflammation in her body or kidney disease (which can cause high blood pressure). From the next recheck, we can discuss if further treatment or evaluation is needed for the arrhythmias or persistent hypertension.

Medications:

No cardiac medications are warranted at this time.

Recheck:

For arrhythmia/hypertension:

Consider full bloodwork with [B6] to check for any evidence of kidney or inflammatory diseases

Recheck ECG and blood pressure in 1-2 months to make sure arrhythmias/hypertension are persistently noted - further therapy may be discussed at that time based on testing results

For mild valvular disease:

Recheck thoracic radiographs (x-rays) every 12 months, sooner if clinical signs occur - this may be performed with [B6] or here at [B6]

Recheck echocardiogram in 1-2 years

Thank you,

B6

B6

DVM, DACVIM-Cardiology

Call & ask to speak w/
Cardio in order to
Schedule recheck

B6

B6

Client ID: **B6**

Invoice #: 1413284

Date: **B6**

Patient ID: B6	Species: Canine	Weight: 24.90 kilograms
Patient Name: B6	Breed: Shepherd, Australian	Birthday: B6 Sex: Spayed Female

Description	Staff Name	Quantity
B6 Consultation, Cardiology	B6 DVM, DA	0.95
Echocardiogram Complete		0.95
Blood Pressure, Indirect		0.50
For Office Use Only		1.00

Patient Subtotal:

Invoice Total:

Total: _____

Balance Due: _____

Previous Balance: _____

Balance Due: _____

American Express 1: _____

Less Payment: _____

Balance Due: _____

B6

B6 supports **B6** a foundation that assists the neediest families with their pets' life-saving medical treatments. We can accept your tax-deductible donation or visit **B6**

B6

Address

Sold by

ed by

Quantity

10

100

100

20

1

1

1

1

B6

ce

Amount

mg

B6

B6

B6

Date 03/07/2019

B6

Age 7 years
Gender Male
Weight 34.1 kg
Species/Breed K9 Golden Retriever

2D

IVSd
LVIDd
LVPWd
LVIDs
%FS
Ao Diam
LA Diam
LA/Ao
RPAs
RPA
RPA
Distensibility
LVLd A4C
LVEDV MOD
A4C
LVLs A4C
LVESV MOD
A4C
LVEF MOD A4C
SV MOD A4C

M-Mode

B6

Doppler

MV E Vel
MV A Vel
MV E/A Ratio
MR Vmax
MR maxPG
AV Vmax
AV maxPG
PV Vmax
PV maxPG
PV AccT
PV Acc Slope
PVET
PV AccT/ET

B6

Case History

Recheck. Hx of R-CHF, DCM, mild PH, taurine deficiency in association with grain-free diet consumption (lifelong) under my care at AERA in 2018 (initial dx in July). CHF resolved with therapy, taurine level normalized with supplementation. Slight improvement in systolic function suspected on November recheck echo, not significant. Clinically stable at home, excellent energy level as per owner, E/D well, eupneic.

Current medications:

Taurine 1000 mg PO q 12h
L-carnitine 2000 mg PO q 8h
Furosemide 40 mg PO q 12h
Pimobendan 10 mg PO q 12h
Benazepril 15 mg PO q 24h

Current diet: Purina Pro Plan Chicken dry, 2 cups BID

Cardiovascular Examination

BAR! Panting, excited. T: 101.2F. MM pk/m, CRT 1-2s. RR: panting, eupneic. HR: 130 bpm, sinus arrhythmia, no murmur/arr. Lungs clear all fields. Femoral pulses mod/synch. Abd soft/compliant w/no distension. LN wnl. Amb x 4. BCS 6/9, MCS 5/9.

Electrocardiography

Sinus rhythm in lead II during echocardiogram.

Print Date: 03/07/2019

Thoracic Radiography

B6

Additional Diagnostic Testing

B6

Diagnosis

Hx of congestive heart failure, right sided (July 2018 - controlled)
Hx of pulmonary hypertension (mild) (resolved)
Dilated cardiomyopathy (DCM) - taurine deficiency associated
Mitral regurgitation (mild)
Taurine deficiency - hx of grain-free diet consumption

Assessment/Prognosis

Patient remains clinically stable with excellent QOL. No further improvement in left ventricular systolic function is noted thus far, which remains poor overall.

Treatment/Outcome**Medications at Discharge**

Continue current medications/doses

Follow-up

Taurine, renal profile pending
Recheck echocardiogram in 4-6 months

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: 'Jones, Jennifer L (Jennifer.Jones@fda.hhs.gov)'
CC: Norris, Anne
BCC: ajfascetti@ucdavis.edu; jstern@ucdavis.edu; Freeman, Lisa; ADIN,DARCY BRITTAIN; Steven Rosenthal
Sent: 6/27/2019 3:10:45 PM
Subject: FDA DCM Update Links-Live 6/27/2019

Good morning,
I wanted to let you know that FDA Consumer update about DCM when live this morning. Here are the links:
CVM Update

Web Update – DCM Investigation

Web QA (Updated)

Vet-LIRN Update

DCM Complaint Spreadsheet – 1/1/14 - 4/30/19

If you have any questions about the content, please direct them to: AskCVM@fda.hhs.gov

Thank you and take care,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogenesis, Martine; Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/5/2018 6:59:03 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: Slides for MH.pptx

B5

Thanks, Lee Anne

From: Palmer, Lee Anne
Sent: Thursday, July 5, 2018 1:50 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
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Hello – **B6** and working my way through emails. To answer these 2 questions:

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Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

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Anne

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<https://academic.oup.com/in/article/131/2/276/4687012>

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Sent: Friday, June 15, 2018 8:51 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Leeanne.palmer@fda.hhs.gov



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B5

Thanks,
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Lauren is correct, the complaint file is ONLY for complaints that came into FDA (all had come via the SRP) as of the end-date they were pulled –

B5

B5

Please ask me questions you have if I haven't made sense.

Thanks, Lee Anne

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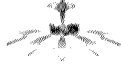
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CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/6/2018 2:27:31 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: 2018-AVMA-VetLIRN DCM.pptx

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

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

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

Subject: RE: Redacted complaint file for the DCM webposting

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Martine

From: Norris, Anne

Sent: Monday, July 02, 2018 3:57 PM

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

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

Subject: FW: Redacted complaint file for the DCM webposting

Importance: High

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

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Thanks,
Anne

From: Palmer, Lee Anne

Sent: Friday, June 15, 2018 8:51 AM

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

Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

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

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Taurine deficiency in dogs with dilated cardiomyopathy: 12 cases (1997–2001)

Andrea J. Fascetti, VMD, PhD, DACVN, DACVIM; John R. Reed, DVM, MS, DACVIM;
Quinton R. Rogers, PhD, DACVN; Robert C. Backus, DVM, PhD

Objective—To determine signalment, history, clinical signs, blood and plasma taurine concentrations, electrocardiographic and echocardiographic findings, treatment, and outcome of dogs with low blood or plasma taurine concentrations and dilated cardiomyopathy (DCM).

Design—Retrospective study.

Animals—12 client-owned dogs with low blood or plasma taurine concentrations and DCM.

Procedure—Medical records were reviewed, and clinical data were obtained.

Results—All 12 dogs were being fed a commercial dry diet containing lamb meal, rice, or both as primary ingredients. Cardiac function and plasma taurine concentration improved with treatment and taurine supplementation. Seven of the 12 dogs that were still alive at the time of the study were receiving no cardiac medications except taurine.

Conclusions and Clinical Relevance—Results suggest that consumption of certain commercial diets may be associated with low blood or plasma taurine concentrations and DCM in dogs. Taurine supplementation may result in prolonged survival times in these dogs, which is not typical for dogs with DCM. Samples should be submitted for measurement of blood and plasma taurine concentrations in dogs with DCM, and taurine supplementation is recommended while results of these analyses are pending. (*J Am Vet Med Assoc* 2003;223:1137–1141)

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Congestive Cardiomyopathy in the Canine


Claire E. Rojohn II

Iowa State University

Brian L. Hill

Iowa State University

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Congestive Cardiomyopathy in the Canine

Claire E. Rojohn II, BS, DVM*

Brian L. Hill, DVM, MS**

Introduction

Diseases of the myocardium can be classified either as primary or secondary. Primary cardiomyopathies include idiopathic congestive or hypertrophic forms. Causes of secondary cardiomyopathies are primary, systemic diseases, the most common of which are infectious, metabolic, toxic, ischemic, and neoplastic diseases that cause some myocardial damage.

Idiopathic congestive cardiomyopathy of dogs was first recognized as a specific disease in 1970.¹ This disease is characterized by a progressive dilation of all cardiac chambers which results in decreased contractility and cardiac output. This leads to congestive heart failure and its compensatory mechanisms. As the atria continue to dilate, arrhythmias can be seen, the most common being fibrillation and premature ventricular contraction. These arrhythmias cause further reduction in cardiac output, thus increasing the degree of congestive heart failure.²

Congestive cardiomyopathy is also known to occur in other species as well as humans. Specific forms of the disease have been described in boxers and Doberman pinschers.^{2,3}

Incidence

Idiopathic congestive cardiomyopathy is the most common cardiomyopathy in the dog. Generally, the disease is seen most often in large and giant breed dogs. The most common breeds are listed as Great Dane, Doberman pinscher, Saint Bernard, Irish setter, English bulldog, Newfoundland, standard poodle, Great Pyrenees, Afghan hound, Scottish deerhound, bull-mastiff, Bouvier des Flandres,

greyhound, Labrador retriever, Chesapeake Bay retriever, and Gordon setter.¹

The disease may strike dogs between the ages of four months and 11 years, but it most commonly occurs in the middle years of three through eight.^{1,3,6} The incidence is much higher in males than females.

History

The historical complaints many times give a vague picture of illness. These dogs often present with anorexia, weight loss, weakness and general debility.⁴ The signs can be descriptive of right, left or combined heart failure. They would include abdominal distention caused by ascites, hepatomegaly, or splenomegaly, or even loose stools as a result of venous stasis in the gut.⁷ Owners may also describe respiratory signs such as coughing, hacking, and dyspnea.^{1,6} Other possible complaints are exercise intolerance and syncope.

The onset is usually subacute, including a gradual deterioration over a one to three week period. Also possible is a more acute type onset over a two or three day period. Most likely the sudden onset occurs after a prolonged period of subclinical disease, and leads finally to atrial fibrillation which forces a rapid decompensation and resulting signs of heart failure.²

Physical Exam

The physical exam often includes weakness, depression and general malaise. Respiratory signs will include dyspnea, orthopnea, and a moist, productive cough.^{2,8} Decreased capillary refill time and cyanotic mucous membranes are sometimes noted. The pulse is rapid (150–250 beats per minute) and irregular in rate and strength. During atrial fibrillation or ventricular premature contractions, there will be a pulse deficit. Ascites may be detected by abdominal distention and a fluid wave on bal-

*Dr. Rojohn is a 1984 graduate of the College of Veterinary Medicine at Iowa State University.

**Dr. Hill is an associate professor of Veterinary Clinical Sciences at Iowa State University.

lottement.² Also seen are venous distention, engorgement of subcutaneous veins, and jugular pulses if tricuspid insufficiency has developed. On abdominal palpation hepatosplenomegaly is frequently present.

Auscultation

Over the lung fields coarse bubbling rales are heard, suggestive of pulmonary alveolar edema.¹ Often pleural fluid is recognized by muffled lung sounds below a fluid line.⁸

The heart sounds may be hard to evaluate due to the loud background respiratory noise and the rapid heart rate. An irregular tachycardia (up to 280 beats per minute) with detectable pulse deficit is often found. Dilatation of the heart may cause a moderate systolic murmur over the mitral valve area or a diastolic gallop.^{1,2} Characteristically with atrial fibrillation, the first heart sound intensity will vary from one beat to the next.³

Clinical Diagnostics

Blood serum parameters are usually not grossly abnormal, but severe congestive heart failure can cause some abnormal values. Prerenal azotemia can be caused by decreased renal perfusion. Hypoproteinemia and hyponatremia are the results of simple dilution of the fluid retained by the kidneys with decreased perfusion.⁸ Hepatic congestion may result in liver enzyme leakage. Elevated SGOT and LDH values are probably due to liver congestion rather than cardiac muscle disease.² Pleural and abdominal fluid are generally evaluated as true or modified transudates.²

Hypothyroidism has been reported as being a related condition in idiopathic congestive cardiomyopathy.^{2,8} Thyroid function tests may give interesting data, but the relative diagnostic significance, insofar as this disease is concerned, is as yet undetermined.²

Radiographically the major abnormality found is a moderately large to large cardiac shadow on chest films. Also, pulmonary venous distention two to three times normal size with rapidly diminishing size as the veins extend into the lung fields is a helpful diagnostic lesion.⁸ Left atrial enlargement can become big enough to displace the left main stem bronchus dorsally.⁸ On angiocardiography, researchers have found dye retention in the ventricles with no difference between end-systolic and end-diastolic volumes.⁹

Chest radiographs will often have evidence of pulmonary edema and pleural fluid. The ab-

normal findings are described as alveolar patterns or interstitial-alveolar patterns. If abdominal films are taken, hepatomegaly and the "ground glass" density of ascites are common findings.

The electrocardiograms of congestive cardiomyopathy dogs are generally helpful in diagnosis. By far the most common arrhythmia seen is atrial fibrillation. Atrial fibrillation is a supraventricular arrhythmia recognized by tachycardia (180–280 beats per minute), random R-R intervals, absence of P waves, and baseline fluctuations called F waves.^{2,8} The QRS complex can be normal or increased in amplitude and/or duration with left ventricular enlargement. Also, in the absence of atrial fibrillation, atrial enlargement (P mitrale or P pulmonale) can be seen.⁸ Generally, the mean electrical axis will be normal in these dogs.² In a smaller percentage of the cases (approximately 20%), and often late in the disease, ventricular premature contractions have been observed.^{5,8} S-T segment depression and T wave changes have also been observed.²

These findings may be the result of myocardial degeneration, or hypoxia and microinfarctions due to decreased coronary circulation.¹ Also described in rare cases is evidence of conduction disturbances.⁸

Differential Diagnosis

Other causes of right heart failure and ascites must be ruled out when diagnosing congestive cardiomyopathy. Dirofilariosis is an important differential diagnosed by microfilariaemia, right axis deviation on the ECG, and specific changes in pulmonary artery configuration on chest radiographs. Sometimes an occult heartworm test is needed to confirm dirofilariosis. Pericardial effusion or restrictive pericarditis should be considered with muffled heart sounds, cardiac friction rub, or elevated central venous pressure. Other rule-outs would include congenital cardiac anomalies as cause for heart failure or abdominal neoplasia and hypoproteinemia for ascites.¹

Therapy

Congestive cardiomyopathy has no specific cure, so therapy is aimed at clinical management for symptomatic improvement. Generally, the disease is managed as a congestive heart failure.⁷

There are four major goals of therapy to serve as guidelines: (1) attempt to strengthen

the heart muscle as a pump; (2) decrease the workload of the heart thereby sparing the pump; (3) prevent secondary damage to other organs as a result of heart failure; and (4) promote recovery of myocardial function.¹ Therapy will ultimately be a combination of treatments with each case being managed individually.⁸ In the acutely symptomatic patient, it is important to avoid stress to the dog, which might result in further decompensation. If necessary, acepromazine or morphine may be administered to reduce anxiety.

To strengthen the heart muscle as a pump, digoxin is used. Digoxin will reduce the heart rate making the pump more efficient. Also, the contractile strength of the heart is increased.⁷ The speed of digitalization is dependent on the severity of the condition. Rapid intravenous digitalization is reserved for life-threatening situations.⁶ It should be remembered that large breed dogs require smaller doses of digoxin per pound than used for other dogs.

Positive signs of effective digitalization are diuresis and reduced heart rate.^{8,10} The heart rate at full digitalization should be in the 80–120 beats per minute range. Also signs of toxicity, such as anorexia, vomiting, diarrhea, and cardiac arrhythmias, should be monitored.^{8,10}

If the heart rate is effectively altered with digoxin, a beta-adrenergic blocker such as propranolol can be used. Propranolol will help slow the heart rate, suppress ventricular premature contractions, and help restore normal sinus rhythm to atrial contractions.⁷ However, propranolol has a negative inotropic effect on the heart muscle, and thus should only be used with or following digoxin therapy.⁸

Decreasing the workload of the heart is an important objective of therapy, and this can be done in more than one way. Afterload can be decreased by vasodilators such as acepromazine. Preload can be reduced with diuretics.¹ Diuretics can also help reduce pulmonary edema and thus increase blood oxygenation.¹ Furosemide given intravenously is used in critical patients.⁶

In preventing secondary damage to other organs, perfusion and oxygenation are the keys. Digoxin and diuretics help considerably towards this goal; however, if the dog is cyanotic or severely dyspneic, oxygen therapy is indicated.⁶

To promote recovery of myocardial function, long-term management must be considered.

Dietary management with low salt or low sodium content feeds is advised to reduce the resulting fluid retention.¹⁰ These diets can be home-prepared or commercially obtained.¹⁰ Exercise restrictions also are necessary in long-term management to keep the cardiac work load down and to avoid catecholamine and sympathetic effects on a now-irritable myocardium.

Pathology

The most significant gross pathological findings are in the heart. Cardiac lesions include a large rounded heart, thin-walled, dilated chambers, ruptured chordae tendineae, endocardial jet lesions, dilated atrioventricular annular rings, and disseminated foci of myocardial necrosis.^{2,18,11}

The rest of the gross pathology found is generally related to a failing heart muscle. These findings include hepatic congestion, pulmonary congestion, ascites, hydrothorax, and infarcts in multiple organs.^{3,11}

On histological sections of cardiac muscle, the lesions found are subendocardial necrosis and scattered myocardial necrosis and fibrosis.¹¹ Also seen in cardiac muscle are irregularly-sized muscle fibers.³ Small to medium sized myocardial arteries have intimal and medial hyperplasia. Ultrastructural changes in the myocardial cells include sarcoplasmic vacuoles, lipofuscin granules, proliferated elements of sarcoplasmic reticulum and mitochondrial alterations.^{3,11} None of these ultrastructural changes are considered pathognomonic for congestive cardiomyopathy; however, many of these nonspecific changes of myocardial necrosis are seen in similar cardiac diseases in cats and humans.^{11,12}

Prognosis

Long-term survival of these dogs is unlikely, with most authors suggesting 6–12 months maximum survival time.^{1,7,8} It has been observed that the prognosis is generally worse in Doberman pinschers. Considering the grave prognosis, emphasis should be placed on correct diagnosis and therapeutic management as long as the dog can be kept comfortable. At that point in the progression of the disease, where the animal is judged to be suffering from decompensation unresponsive to treatment, the humane option may be euthanasia.

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In the beginning...

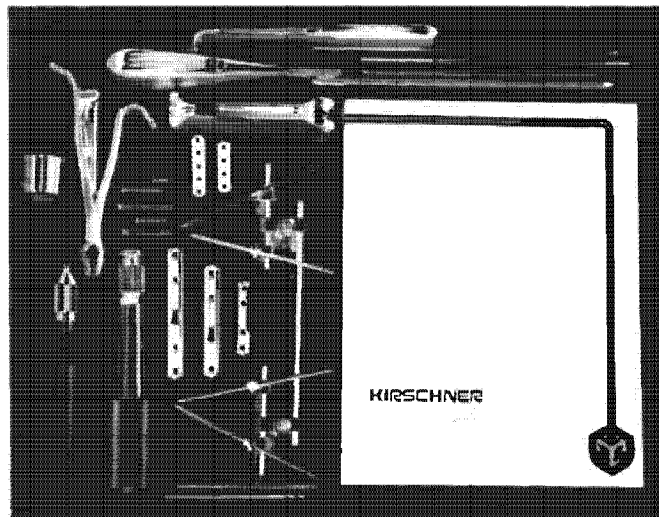
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Effects of dietary fat and L-carnitine on plasma and whole blood taurine concentrations and cardiac function in healthy dogs fed protein-restricted diets

Sherry L. Sanderson, DVM, PhD; Kathy L. Gross, PhD; Phillip N. Ogburn, DVM, PhD; Clay Calvert, DVM; Gil Jacobs, DVM; Stephen R. Lowry, PhD; Kathy A. Bird; Lori A. Koehler; Laurie L. Swanson

Objective—To evaluate plasma taurine concentrations (PTC), whole blood taurine concentrations (WBTC), and echocardiographic findings in dogs fed 1 of 3 protein-restricted diets that varied in fat and L-carnitine content.

Animals—17 healthy Beagles.

Design—Baseline PTC and WBTC were determined, and echocardiography was performed in all dogs consuming a maintenance diet. Dogs were then fed 1 of 3 protein-restricted diets for 48 months: a low-fat (LF) diet, a high-fat and L-carnitine supplemented (HF + C) diet, or a high-fat (HF) diet. All diets contained methionine and cystine concentrations at or above recommended Association of American Feed Control Officials (AAFCO) minimum requirements. Echocardiographic findings, PTC, and WBTC were evaluated every 6 months.

Results—The PTC and WBTC were not significantly different among the 3 groups after 12 months. All groups had significant decreases in WBTC from baseline concentrations, and the HF group also had a significant decrease in PTC. One dog with PT and WBT deficiency developed dilated cardiomyopathy (DCM). Taurine supplementation resulted in significant improvement in cardiac function. Another dog with decreased WBTC developed changes compatible with early DCM.

Conclusions and Clinical Relevance—Results revealed that dogs fed protein-restricted diets can develop decreased taurine concentrations; therefore, protein-restricted diets should be supplemented with taurine. Dietary methionine and cystine concentrations at or above AAFCO recommended minimum requirements did not prevent decreased taurine concentrations. The possibility exists that AAFCO recommended minimum requirements are not adequate for dogs consuming protein-restricted diets. Our results also revealed that, similar to cats, dogs can develop DCM secondary to taurine deficiency, and taurine supplementation can result in substantial improvement in cardiac function. (*Am J Vet Res* 2001;62:1616–1623)

Received Oct 10, 2000.

Accepted Jan 2, 2001.

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Department of Molecular Biosciences, School of Veterinary Medicine, University of California, Davis, CA, USA

Taurine status in normal dogs fed a commercial diet associated with taurine deficiency and dilated cardiomyopathy

By C. L. TÔRRES, R. C. BACKUS, A. J. FASCETTI and Q. R. ROGERS

Summary

Taurine (Tau) deficiencies have been associated with the feeding of commercial lamb-meal and rice diets to dogs. We hypothesized that the poor digestibility of some lamb-meals may limit sulphur amino acids availability for Tau synthesis and/or increase of Tau degradation in the gut. Growing dogs were fed either a lamb-meal-based (Diet A) or poultry by-product-based (Diet B) commercial diet. Plasma, whole blood and urinary Tau were measured for 22 weeks. Plasma and whole blood Tau concentrations were similar between the groups throughout the study. Urinary excretion of Tau in dogs fed diet A was 3.2 times greater than that from dogs fed Diet B, suggesting greater renal reabsorption and the need for conservation of Tau in the Diet A group. Food restriction affected Tau status as indicted by a positive correlation of food intake and urinary Tau. Dogs fed Diet A were given antibiotics to inhibit bacterial activity in the gut. Increases in breath hydrogen, indicative of increased bacterial activity, correlated negatively with urinary Tau. Urinary Tau increased by 54% when methionine (Met) was supplemented to Diet A, supporting the suggestion of a low bioavailability of sulphur amino acids and/or an increased fecal loss of Tau in dogs consuming Diet A.

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Determination of the prevalence of whole blood taurine in Irish wolfhound dogs with and without echocardiographic evidence of dilated cardiomyopathy[☆]

Andrea C. Vollmar, DVM^{a,b}, Philip R. Fox, DVM, MSc^{c,*},
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KEYWORDS

Canine;
Nutrition;
Cardiomyopathy

Abstract Objectives: Taurine plays an important role in maintaining myocardial function. Irish wolfhound dogs (IW) are at risk for dilated cardiomyopathy (DCM), but a relationship between whole blood taurine (WBT) deficiency and DCM has not been established. Our aim was to determine prevalence of WBT deficiency in IW with and without DCM and assess its association with diet.

Animals: 115 privately owned IW.

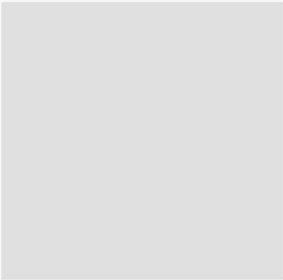
Methods: Whole blood taurine was measured in IW that received cardiovascular examination. Dietary history was recorded; crude protein and energy intake were estimated.

Results: Forty-nine (42.6%) had DCM; 66 (57.4%) had no DCM. Dogs with DCM were older ([median; inter-quartile range or IQR] 5.3; 4.3, 6.2 years) than dogs without heart disease (3; 2, 4 years; $P < 0.001$). There was no significant relationship between WBT concentration and age ($P = 0.64$). Whole blood taurine was severely reduced (<130 nmol/mL) in 8 dogs (4 with and 4 without DCM) and moderately reduced (130–179.9 nmol/mL) in 32 dogs (12 with DCM and 20 without DCM). Follow

[☆] Presented in part as an abstract at the European College of Veterinary Internal Medicine forum, Barcelona, Spain, September 2004.

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up of dogs without DCM revealed that a higher proportion of dogs with any degree of WBT deficiency developed DCM later compared to dogs with normal WBT ($P < 0.001$).

Conclusions: Whole blood taurine deficiency occurred in IW with and without DCM. Based on taurine measurement on a single occasion, there was no clear relationship between low WBT and presence of DCM in this population. Regardless of WBT, DCM affected predominantly older dogs, suggesting a relatively late onset disease in the IW.

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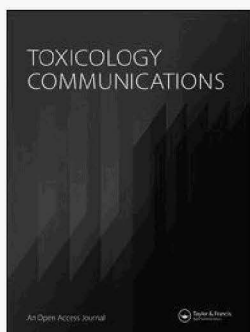
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Comparison of mycotoxin concentrations in grain versus grain-free dry and wet commercial dog foods

John H. Tegzes, Brian B. Oakley & Greg Brennan

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Comparison of mycotoxin concentrations in grain versus grain-free dry and wet commercial dog foods

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ABSTRACT

Mycotoxins are secondary fungal metabolites that cause both acute and chronic disease in humans and animals. Grains are a common substrate for molds and the production of mycotoxins. This study compared mycotoxin concentrations between grain and grain-free commercial dog foods. In total, 60 samples of dry and wet dog foods produced by five major manufacturers within the US were purchased from pet food retailers in southern California. A standard mycotoxin panel was performed by a reference laboratory in Seattle using industry standard methodology for pet foods. Results of the study demonstrated measurable mycotoxin concentrations in dry dog foods containing grains but not in grain-free dry dog foods, or in wet foods either containing grains or grain-free. This study suggests that the risk of mycotoxin exposure is higher in dry dog foods containing grains. To mitigate this risk, dog food manufacturers could incorporate grains that are categorized as US No. 1 by the USDA and therefore less susceptible to mycotoxin formation.

KEYWORDS

Mycotoxin; dog food; grain; grain-free; fumonisin



Introduction

Grains, particularly corn and wheat, have been used as sources of carbohydrates in pet food formulations for decades [1]. Recently, grain co-products from corn, such as corn gluten meal, or bran derived from whole grains like barley and oats, are also commonly added to pet foods as indigestible fiber sources [1]. In recent years grain-free diets for companion animals have been gaining popularity among pet owners [2, 3] who often choose grain-free diets because of perceived health benefits. Sales of grain-free pet foods increased by 28% in US pet stores during a one-year period from September 2012 to September 2013. In 2015, 45% of all new pet food items introduced were grain-free [2, 3]. Despite this increasing popularity of grain-free diets, there are very few scientific studies determining what, if any, benefits these diets may provide.

One of these perceived health benefits of grain-free diets is the possibility to reduce grain consumption by companion animals, theoretically reducing the risk of potential exposure to mycotoxins [4]. Mycotoxins are secondary metabolites produced by filamentous fungi that can contaminate grains, often due to improper grain storage. The most common contaminants of feed

include aflatoxins, fumonisins, ochratoxin A, zearalenone, and the trichothecenes deoxynivalenol, T-2 toxin, and HT-2 toxin. These mycotoxins have a variety of harmful cytotoxic mechanisms [5].

Raw grains, feed ingredients, and finished feed are governed by specific regulatory guidelines [6, 7] but mycotoxin contamination is particularly difficult to avoid because mycotoxins are relatively robust to heat and chemical inactivation processes in downstream processing steps [7, 8]. A study conducted in Poland found multiple mycotoxins in dry veterinary diets for dogs [9]. Among the various mycotoxins detected in the veterinary diets zearalenone was detected in 69% of samples, deoxynivalenol (DON) in 52%, fumonisin B1 in 33%, and nivalenol in 26% [9]. The clinical effects of mycotoxins vary based on type, concentration, and frequency of exposure. Some mycotoxins cause morbidity and mortality both acutely due to high dose exposures and chronically after prolonged low-dose exposures. Effects can include acute toxicosis such as acute hepatic injury presenting as anorexia, depression, gastrointestinal hemorrhage, jaundice or seizures [10, 11]. Chronic diseases such as liver and kidney fibrosis, infections resulting from immunosuppression,

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and cancer have been associated with low-dose, chronic mycotoxin exposure [10, 11]. In one clinical study, a combination of mycotoxins including aflatoxin B1, aflatoxin B2, fumonisin B1, fumonisin B2, ochratoxin A, and zearalenone induced immunotoxicity on canine peripheral blood mononuclear cells [5]. Therefore, the potential for mycotoxin contamination in pet food poses a serious health threat [12].

Regulations regarding permissible concentrations of mycotoxins in animal feeds focus mainly on farm animals used for food production. While much of what is known about mycotoxins in animals is based on toxicological data demonstrating adverse effects in farm and laboratory animals exposed to naturally occurring concentrations of mycotoxins, there is perhaps even more concern for companion animals who are often maintained and fed for longer periods of time on a homogeneous, grain-containing diet and thus more likely to have chronic exposures to pet foods contaminated with either single mycotoxins, or multiple mycotoxins in various combinations [4]. Maximum concentrations permitted in pet foods are generally extrapolated from a generalized "other animal" category, meaning non-food animal guidelines rather than pet-specific regulations [4]. However, these concentrations do not necessarily indicate "safe levels" for mycotoxin exposure in companion animals [13] since very few studies have been conducted in pets. Moreover, none of these studies have investigated the long-term chronic exposures that likely occur if pets are fed a contaminated feed over a typical lifespan [4, 13]. Due to this uncertainty, one of the perceived health benefits of grain-free diets might be due to the elimination of low-dose chronic exposures to mycotoxins, as grains in pet food are presumed to be the main source of mycotoxin contamination [4]. However, the true prevalence of mycotoxins in either grain-containing or grain-free pet food has not been systematically examined.

While there have been only a few reports, previous studies have detected mycotoxins in dog foods, especially dry foods. Dry dog foods contain 3–11% moisture, while wet dog foods contain 60–87% moisture [14]. DON contamination was common in studies conducted in Austria [15] and Italy [16]. In both of these studies, measurable concentrations of DON were detected in all dry food samples. A broad range of DON concentrations in dry food were found in the Austrian study and 27% of wet food samples also contained detectable concentrations of DON [15]. A second study conducted in Austria found similar patterns of DON, fumonisins, and zearalenone [4].

A study conducted in Brazil also reported low-levels of multiple mycotoxins in dry dog foods [8]. In all four of these studies mycotoxins produced by *Fusarium* species of fungi were most common, often contaminating the same dog food with three different types of mycotoxins [8].

In the current study, we sampled wet and dry commercial dog foods produced by five different manufacturers with and without grains and measured the concentrations of 11 mycotoxins in these samples.

Methods

Samples were obtained from five different brands in an attempt to broadly sample commercially available dog food from different supply chains. All pet foods sampled were manufactured in the U.S. following US guidelines for the manufacturing of dog food. Formulations from the same brand were paired such that the only significant difference in the ingredients list was the presence or absence of grain. For example, adult maintenance formulations were chosen by the same product name clearly labeled as either containing grains, or as grain-free, ensuring brand consistency across all paired samples. Six dry food (three containing grains and three grain-free) and six wet food samples (three containing grains and three grain-free) were obtained for each manufacturer except for one manufacturer that does not formulate any dry foods. Because the number of samples was constrained by cost, we ignored brand designation in all analyses, clustering the samples only as dry versus wet food and grain-containing or grain-free food.

A total of 60 dog food samples were analyzed for 11 different mycotoxins using stable isotope dilution LC-MS/MS methodology at IEH Laboratories (Seattle, WA) [17, 18]. Analytical detection limits ranged from 1.0 ppb to 0.10 ppm depending on the mycotoxin (Table 1).

Table 1. Detection limits for each mycotoxin analyzed.

Mycotoxin	Reporting Limit
Aflatoxin B1	1.0 ppb
Aflatoxin B2	1.0 ppb
Aflatoxin G1	1.0 ppb
Aflatoxin G2	1.0 ppb
Deoxynivalenol	0.10 ppm
Fumonisin B1	0.10 ppm
Fumonisin B2	0.10 ppm
HT-2 Toxin	0.10 ppm
Ochratoxin A	2.0 ppb
T-2 Toxin	0.10 ppm
Zearalenone	20 ppb

Results

Only dry dog foods containing grains had detectable mycotoxin contamination, and only mycotoxins that are products of the *Fusarium* genus were detected (Table 2). Of the 12 dry dog foods containing grains that were analyzed, nine of the twelve had at least one detectable *Fusarium* mycotoxin (Table 3). For DON and fumonsin B1, 9/12 dry grain foods were above detection limits while 8/12 samples were positive for fumonsin B2 and 4/12 samples tested positive for zearalenone (Table 3). These results are consistent with findings from studies conducted in Austria [4, 15], Italy [16], and Brazil [8]. None of the 60 samples tested had concentrations above the detection limits for aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, HT-2 toxin, ochratoxin A, or T-2 toxin. When considered by brand, at least one of the four *Fusarium* mycotoxins was found in each of the four brands of dry grain foods (Table 4). For two brands (Brand 4 and Brand 5), at least one of the three samples tested were positive for all four *Fusarium* mycotoxins (Table 4).

The US Food and Drug Administration (FDA) has published guidance concentrations for pet foods, but not regulatory limits, for aflatoxin, fumonisin, and DON [6]. The guidance concentration is 10 ppm for

Table 2. Number of samples with values above the detection threshold for deoxynivalenol, fumonisin B1, fumonisin B2, and zearalenone respectively, according to grain and food type for all samples.

	Dry	Wet
Grain	9, 9, 8, 4 (<i>n</i> = 12)	0, 0, 0, 0 (<i>n</i> = 18)
Grain-free	0, 0, 0, 0 (<i>n</i> = 12)	0, 0, 0, 0 (<i>n</i> = 18)

For the only category with positive values (Dry Grain; shown as shaded) the data are shown in more detail by brand in Table 4.

Table 3. Concentration ranges and number of positive samples for mycotoxins detected in dry dog food.

Dry Dog Food	Deoxynivalenol (0.10 ppm)	Fumonisin B1 (0.10 ppm)	Fumonisin B2 (0.10 ppm)	Zearalenone (20 ppb)
Grain (<i>n</i> = 12)	<i>n</i> = 9	<i>n</i> = 9	<i>n</i> = 8	<i>n</i> = 4
Concentration Range	0.12–0.32 ppm	0.32–3.2 ppm	0.21–1.6 ppm	24–65 ppb
Grain-free (<i>n</i> = 12)	0	0	0	0

Analytical detection limits are shown in parentheses for each mycotoxin.

Table 4. Number of samples with values above the detection threshold for deoxynivalenol, fumonisin B1, fumonisin B2, and zearalenone respectively, according to brand for dry grain samples.

	Dry, Grain
Brand 1	3, 0, 0, 0 (<i>n</i> = 3)
Brand 2	<i>n</i> = 0
Brand 3	3, 3, 2, 0 (<i>n</i> = 3)
Brand 4	2, 3, 3, 3 (<i>n</i> = 3)
Brand 5	1, 3, 3, 1 (<i>n</i> = 3)

For Brand 2, no dry grain product is sold. For each of the four other brands three samples were tested. N/A = not applicable.

total fumonisins (fumonisin B1 + fumonisin B2 + fumonisin B3). The concentrations detected in this study were below the 10 ppm guidance value (Figures 1–4).

Discussion

In this study, we identify low-level *Fusarium*-derived mycotoxin contamination in grain-containing dry dog food but did not detect any mycotoxin contamination in either grain-free dry dog food or wet dog food. In addition, none of the analyzed samples contained aflatoxins in detectable concentrations, which may reflect how regulatory and control strategies have been effective in reducing the incidence of aflatoxins in dry commercial dog foods. The presence of *Fusarium* mycotoxins highlights the need to establish similar control strategies targeting these mycotoxins, especially for the manufacture of dry dog foods. We found *Fusarium*-derived mycotoxin concentrations well below amounts considered to be acutely toxic to dogs, but these data support the possibility that feeding grain-containing pet food may result in chronic exposure to a variety of mycotoxins. The effects of chronic low-level mycotoxin exposure in dogs remain unknown but merit further study [4].

Dry dog foods contain higher amounts of grains than wet dog foods, potentially explaining the higher levels of mycotoxins in grain-containing foods. Grains in these dog foods are the most likely source of mycotoxin contamination, although we cannot be certain of the source because we only analyzed end products in this study. When grains are incorporated into dog food formulations it is important that high quality grain is used. Grain quality is correlated with

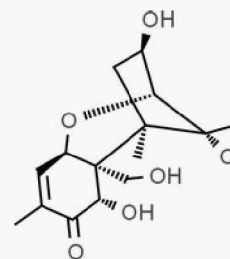


Figure 1. Deoxynivalenol [19]

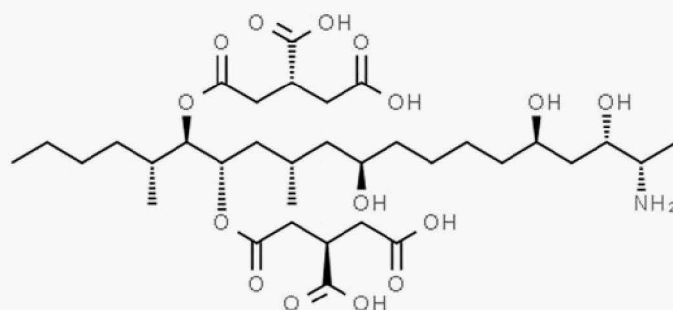


Figure 2. Fumonisin B1 [20]

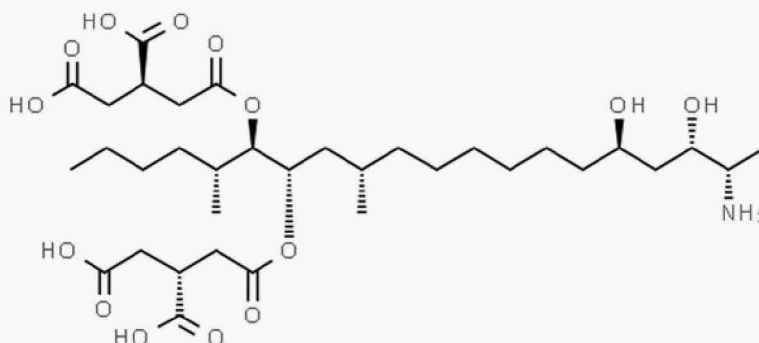


Figure 3. Fumonisin B2 [21]

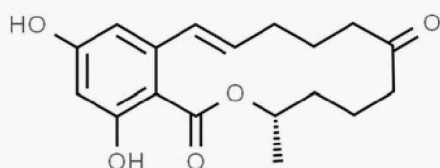


Figure 4. Zearalenone [22]

mycotoxin contamination as lower grade grains often contain broken and fragmented grains which are much more susceptible to mold growth and subsequent mycotoxin production [23]. Grains are numerically graded based on factors such as test weight, proportion of damaged or broken kernels, presence of foreign odors, or heat-damage [24]. Any of these factors can contribute to mold growth and mycotoxin production. However, pet food manufacturers may choose grains unfit for human consumption as a cost-cutting strategy [25]. Using only grains graded as US No. 1 by the USDA could be a control strategy to minimize mycotoxin contamination from ingredients incorporated into pet food. Currently, there is no requirement to reveal the grade of grain incorporated into pet food, but noting the grade of grains used on the ingredients list could help consumers choose pet foods with more confidence.

We did not test any cat foods in this study. Cats are obligatory carnivores and grains are less frequently

incorporated into dietary formulations. It has been proposed that finding measurable mycotoxins in cat foods is indicative of high grain content [25]. Further studies could assess the frequency of mycotoxins found in cat foods and correlate findings with the presence of grains.

While the results of this study might suggest that grain incorporation into dog food formulations has risks, we do not conclude that it is inappropriate to use them in dog foods. Grain-free dog foods need to be carefully formulated to meet nutritional requirements. A recent study demonstrated evidence of partially reversible cardiomyopathy in some dogs fed grain-free diets. While the exact associations with grain-free diets remains unclear, the data suggested that the condition could be reversed after a diet change [26]. Additionally, more work needs to be done to assess the effects of mycotoxins in combinations and in low, chronic concentrations in dogs, perhaps studying them in multi-year long-term research studies. Also, there is a need to continue to explore strategies to minimize the concentrations of all mycotoxins in the manufacturing of dog food. Perhaps requiring grain grades on ingredient lists could increase understanding about the potential sources of mycotoxins, inform consumer choice, and provide insights to other strategies to further minimize contamination.

Disclosure statement

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