

**Report Details - EON-375168**

ICSR:	2060761
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-01-02 12:27:46 EST
Reporter is the Animal Owner:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Female spayed dog in excellent health developed DCM and died from it. ( [ B6 ] months old) [ B6 ] 12 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.
	<b>Date Problem Started:</b>	03/01/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Died Euthanized
	<b>Date of Death:</b>	[ B6 ]

<b>Product Information:</b>	<b>Product Name:</b>	4Health beef and potato and 4health untamed lamb and Lentil		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Package Size:</b>	25 Pound		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Storage Conditions:</b>	product stored in an plastic air tight dog food storage container		
	<b>Product Use Information:</b>	<b>Description:</b>	served twice daily 2 cups each serving.	
		<b>Time Interval between Product Use and Adverse Event:</b>	2 Years	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
		<b>Adverse Event Abate After Product Stop:</b>	No	
		<b>Product Use Started Again:</b>	No	
		<b>Perceived Relatedness to Adverse Event:</b>	Definitely related	
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No	
<b>Manufacturer /Distributor Information:</b>				
<b>Purchase Location Information:</b>	<b>Name:</b>	Tractor Supply		
	<b>Address:</b>	[ B6 ]		

			<b>B6</b> United States	
<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b> and <b>B6</b>		
	<b>Type Of Species:</b>	Dog		
	<b>Type Of Breed:</b>	Griffon - French Wire-haired Pointing		
	<b>Gender:</b>	Female		
	<b>Reproductive Status:</b>	Neutered		
	<b>Weight:</b>	52 Pound		
	<b>Age:</b>	5 Years		
	<b>Assessment of Prior Health:</b>	Excellent		
	<b>Number of Animals Given the Product:</b>	2		
	<b>Number of Animals Reacted:</b>	2		
	<b>Owner Information:</b>			
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	<b>B6</b>	
		<b>Contact:</b>	<b>Name:</b>	<b>B6</b>
<b>Phone:</b>			<b>B6</b>	
<b>Other Phone:</b>			<b>B6</b>	
<b>Address:</b>		<b>B6</b> United States		
<b>Type of Veterinarian:</b>		Primary/regular veterinarian		
<b>Date First Seen:</b>		03/01/2018		
<b>Permission to Release Records to FDA:</b>	Yes			
<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>		
	<b>Address:</b>	<b>B6</b> United States		
	<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>	
		<b>Other Phone:</b>	<b>B6</b>	
		<b>Email:</b>	<b>B6</b>	
	<b>Reporter Wants to Remain Anonymous:</b>	No		
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
<b>Reported to Other Parties:</b>	Store/Place of Purchase			
<b>Additional Documents:</b>				

**Report Details - EON-374758**

<b>ICSR:</b>	2060587
<b>Type Of Submission:</b>	Followup
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2018-12-26 18:26:22 EST
<b>Initial Report Date:</b>	11/12/2018
<b>Parent ICSR:</b>	2058754
<b>Follow-up Report to FDA Request:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	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
	<b>Date Problem Started:</b>	09/20/2018
	<b>Date of Recovery:</b>	12/26/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	Purina One Smartblend Chicken and Rice Formula (this diet gets mixed into Purina ProPlan Savor food and has been transitioned to since the patient was initially diagnosed with cardiac disease).	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>	<b>Lot Number:</b>	83071085 1237L02
		<b>Expiration Date:</b>	05/31/2020
	<b>UPC:</b>	0 1780047555 6	
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	1.81 kilogram	
	<b>Possess Opened Product:</b>	Yes	
	<b>Storage Conditions:</b>	in the original bag	
	<b>Product Use Information:</b>	<b>Description:</b>	Mixed with Purina Proplan Savor dry food
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>		
	<b>Product Name:</b>	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)	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>	<b>Lot Number:</b>	82871085 1039L09
		<b>Expiration Date:</b>	04/30/2020
	<b>UPC:</b>	3810013054	
	<b>Package Type:</b>	BAG	
<b>Package Size:</b>	2.72 kilogram		
<b>Possess Opened Product:</b>	Yes		
<b>Storage Conditions:</b>	Food kept in bag		
<b>Product Use Information:</b>	<b>Other Foods or Products Given to the Animal</b>	Yes	

		<b>During This Time Period:</b>	
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>		
	<b>Product Name:</b>	4health optimal nutrition for optimal health weight management formula for dogs	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>	<b>Lot Number:</b>	WHH0504-18 HMS
		<b>Expiration Date:</b>	05/31/2019
	<b>UPC:</b>	7 49394 14888 1	
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	3.63 kilogram	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	Yes	
	<b>Product Use Information:</b>	<b>Description:</b>	fed exclusively since March 2018
		<b>First Exposure Date:</b>	03/05/2018
		<b>Last Exposure Date:</b>	11/11/2018
		<b>Time Interval between Product Use and Adverse Event:</b>	6 Months
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Probably related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Unknown
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>		
<b>Animal Information:</b>	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Hound - Afghan	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Unknown	
	<b>Weight:</b>	40.6 Kilogram	
	<b>Age:</b>	6 Years	
	<b>Assessment of Prior Health:</b>	Good	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b>	Yes

		<b>Contact: Name:</b> B6	
		<b>Phone:</b> B6	
	<b>Address:</b>	B6 United States	
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6
		<b>Contact: Name:</b>	B6
		<b>Phone:</b>	B6
		<b>Email:</b>	B6
		<b>Address:</b>	B6 United States
		<b>Practice Name:</b>	B6
		<b>Contact: Name:</b>	B6
	<b>Phone:</b>	B6	
	<b>Type of Veterinarian:</b>	Referred veterinarian	
	<b>Permission to Release Records to FDA:</b>	Yes	
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6 United States	
	<b>Contact: Phone:</b>	B6	
	<b>Email:</b>	B6	
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
<b>Additional Documents:</b>	<b>Attachment:</b>	Purina Proplan Savor Chicken and Rice Formula- back of bag.jpg	
	<b>Description:</b>	photo of back of bag	
	<b>Type:</b>	Photograph	
	<b>Attachment:</b>	Purina ProPlan Savor Chicken and Rice Formula- photo of ingredients guaranteed analysis.jpg	
	<b>Description:</b>	photo of guaranteed analysis and ingredients list	
	<b>Type:</b>	Photograph	
	<b>Attachment:</b>	Purina One Smartblend Chicken and Rice Formula- photo of back of bag.jpg	
	<b>Description:</b>	Back of bag photo	
	<b>Type:</b>	Photograph	
	<b>Attachment:</b>	Purina One Smartblend Chicken and Rice Formula- photo of guaranteed analysis and ingredients.jpg	
	<b>Description:</b>	photo of guaranteed analysis/ingredient list	
	<b>Type:</b>	Photograph	
	<b>Attachment:</b>	B6 Report 12-16-18.pdf	
	<b>Description:</b>	Medical Records/Report from 6 week follow-up visit following initial diagnosis of	

cardiac disease and diet change

**Type:** Medical Records

**B6**

Animal No: **B6**  
 Animal Wt: 40.6 kgs  
 Clinical No:  
 Record Date:  
 Date Range: 12-26-2018 -  
 Printed On: 12-26-2018  
 Consulting Doctor:

**Client Details**

Name **B6** Phone **B6**  
 Address **B6**

**Patient Details**

Name **B6** Age **B6**  
 Species Canine Sex Female  
 Breed Afghan Hound Referral **B6**

**Client Summary**

# Cardiac Evaluation Report

**Exam Date: 12-26-2018**

**Diagnosis**

- Dilated cardiomyopathy
  - Rule out: nutritional, idiopathic, hypothyroid related, other - previously on a grain-free diet
- Previous echocardiographic findings (11/12/18)
  - Mild to moderate mitral valve regurgitation
  - Moderately dilated left atrial dimensions
  - Severely dilated left ventricular dimensions with severely decreased heart muscle function
  - Moderate right heart enlargement
- Atrial fibrillation - improved rate control of 90-110 bpm today
- Bi-ventricular congestive heart failure - symptoms controlled at this time

*Concurrent Conditions:*

- Hypoalbuminemia - resolved
- Mildly elevated bilirubin on last labwork - diagnosis open
- Hypothyroidism
  - Over-supplemented on initial recheck > not yet re-assessed since dose was decreased

**Medications**

**B6**

# B6

Please note

- **Please allow 24-48 hours for CVCA to process prescription refill requests.**
- **Refill all medications indefinitely unless directed by CVCA or your primary care veterinarian.**
- **Please check all medications and dosages on your discharge report against the pharmacy labels.**

## Additional Recommendations

- Please see our website [www.cvcavets.com](http://www.cvcavets.com) for more information about **B6** dilated cardiomyopathy and heart failure.

Nutrition:

- Continue Purina One Chicken and Rice Formula, and Purina ProPlan Savor Adult Chicken and Rice formula.
- For more information about nutrition and cardiac disease in pets go to: <http://vetmed.tufts.edu/heartsmart/diet/> or <https://www.cvcavets.com/for-pet-owners/nutrition-grain-free/>

Activity:

- **B6** may continue activity as she wants and is able to do. Please allow **B6** to take more breaks and rest during activity.
- For dogs at risk for sudden death, there is an increased risk for sudden death during activity, but dogs have been noted to die suddenly at rest and with normal daily activity. We recommend allowing a level of activity that maintains the best quality of life for **B6**

At Home Monitoring:

- At high risk for symptoms from congestion (fluid in the lungs and/or abdomen) or the development/worsening of an arrhythmia (irregular heartbeat), including **difficulty breathing, lethargy, weakness, anxiety, collapse, abdominal distension, or dark or blue discoloration of the tongue or gums.**
- Please monitor **B6** breathing rate when she is sleeping to help detect early fluid developing in the lungs. **The normal breathing rate for a sleeping dog is fewer than 35 breaths per minute.** One rise and one fall of the chest is one breath. If you notice that the breathing rate is consistently higher than 35 breaths per minute, you can give additional Lasix as outlined above.
- Congestive heart failure is a life threatening condition. If symptoms do not improve within 1-2 hours with the additional Lasix, the breathing is labored, or collapse is noted, please seek emergency veterinary evaluation.

Anesthesia/Fluid/Steroid Risk:

- **B6** is at high risk for cardiac-related complications. Elective anesthesia should be avoided.
- If anesthesia is emergent, consider the following recommendations: no benazepril for 24 hours prior to anesthesia, thoracic radiographs prior to induction, judicious use of IV fluids (1-3 ml/kg/hr, or as clinically indicated), caution with drugs with profound effects on heart rate and blood pressure (i.e. dexmedetomidine, ketamine, telazol, acepromazine, or atropine [unless indicated by bradycardia]), and careful monitoring of heart rate and rhythm, blood pressure, and oxygen status during the procedure. If a pressor is indicated, consider a CRI of dobutamine starting at 5 ug/kg/min and titrated to maintain a systolic blood pressure >90-100 mmHg. Monitor closely for several hours upon recovery and consider repeat thoracic radiographs if there are any concerns. There is risk with any anesthetic event. If arrhythmic, ECG monitoring should continue until **B6** is fully recovered and awake. For additional recommendations, strongly consider consultation with an anesthesiologist.
- Caution with intravenous or subcutaneous fluid therapy and steroid use. **B6** is at a high risk for secondary fluid overload. If fluids are needed, they should be given conservatively and the breathing carefully monitored as outlined

above. Nasoesophageal fluids may be better tolerated than parenteral fluids. Steroids should only be given if necessary and at the lowest effective dosage while monitoring the breathing carefully. Long-acting steroids, such as Depo-Medrol, should be avoided.

## Reevaluation

- Please recheck with [B6] in 4-6 weeks for a follow up physical exam and recheck [B6]
  - We have submitted a blood chemistry today. *If the cardiac medications need to be adjusted based on today's blood work results, we may recommend additional follow-up blood chemistries, but we will call you once we have that information.*
- Please recheck with **CVCA in ~5 months** for a follow up physical exam, echocardiogram, and last collection of samples for the FDA study (blood for amino acid testing [whole blood and plasma], urine, and feces (collected and frozen within 48hrs of visit). The cost of the echocardiogram, examination, and specific samples that will be sent for the DCM study will be covered by the FDA.
  - Any additional testing (ECG, other blood work not utilized in the study, etc.) will be charged to you directly.
  - Unless otherwise notified, don't worry about trying to schedule the appointment 3-5 hours after [B6] has a "normal meal" since she is an eater that likes to graze. Her initial and 6 week follow-up appointments had samples that were taken > 20 hours after her last full meal. Ideally, try to make sure that she has not had a "large" meal within the 3-5 hours prior to her next appointment.
  - Please contact us or schedule an earlier appointment if [B6] has any problems or symptoms indicative of worsening heart disease or if recommended by [B6]

We thank you for trusting in CVCA to care for [B6] today. Please feel free to call us with any questions or concerns.

Sincerely,

[B6] VMD, DACVIM (Cardiology)

Team Leader: [B6] LVT

[B6] Support Staff: [B6]

## Primary Care Summaries

### Visit Summary

**History:** [B6] is presenting for her first recheck exam + ECG (per FDA study requirements) after initial diagnosis of DCM and CHF in mid-November; [B6]

[B6]

A chemistry showed normal renal values and [B6] was also added at that time. She was also switched from a grain free diet (4 Health Grain Free) to a mix of Purina One and Purina ProPlan Chicken and Rice formulas. Since starting all meds and supplements she is much improved w/normal RR/RE, great energy level, improved abdominal distension. She continues to have a grazer appetite (never really eats full meals). No v/d reported.

*Initial presentina history Nov 2018:* Cough first noted 9/20 after boarding for several days. Did not improve and subsequently started on [B6] and cough tabs with minimal improvement. Yesterday was listless and anorexic and taken to [B6] C and diagnosed with cardiomegaly, ascites, and suspected CHF; 1.6L removed via abdominocentesis, given lasix injection and cardiology consult recommended. Diet changed in March to a grain free diet. No V/D/S reported. O reports PU/PD over the past two weeks.

**Diet:** Purina One and Purina ProPlan - Both Chicken /Rice based diets

[B6]

**Referral Diagnostics:**

- *Most recent labwork (11/27/18):*

**B6**

**CVCA Diagnostics and/or procedures:**

- *Diagnostic ECG:* Atrial fibrillation with controlled response rate (90-110 bpm); no ventricular ectopy noted
- *Blood chemistry* - pending

**Echocardiographic Findings**

*No echocardiogram performed today*

**B6**

**Comments**

**B6**

Thank you for sending **B6** to see us with **B6** for her recheck today. Fortunately, **B6** has been clinically doing very well with improved atrial fibrillation rate on ECG, clear lung sounds, and no evidence of abdominal effusion or clinical heart failure noted on examination today. We pulled samples for submission to the FDA today as part of a continuing study looking at DCM suspected to be secondary to grain-free diets in dogs. **B6**

**B6**

the current dosages, and plan to reassess her echocardiogram in May. We hope that she will continue to do well and look forward the results of your follow-up reports in the interim.

We appreciate your continued referrals and the trust you place in CVCA to co-manage your cardiac patients. We look forward to working with you on this case and others. In an effort to continue to improve CVCA's service to both you and your clients, please visit our website at [www.cvcavets.com](http://www.cvcavets.com) and complete our online referring veterinarian survey.

Sincerely,

**B6**

VMD, DACVIM (Cardiology)

Report Details - EON-374786		
ICSR:	2060599	
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:	2018-12-27 10:09:22 EST	
Reported Problem:	<b>Problem Description:</b> 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 taurin [ B6 ]	
	<b>Date Problem Started:</b> 08/20/2018	
	<b>Concurrent Medical Problem:</b> Yes	
	<b>Pre Existing Conditions:</b> Hypothyroidism, incontinence, history of UTIs/crystalluria	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Acana Free Run Poultry dry	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b> <b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> [ B6 ]	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Doberman Pinscher	
	<b>Gender:</b> Female	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 38.1 Kilogram	
	<b>Age:</b> 10 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 2	
	<b>Number of Animals Reacted:</b> 2	
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b> <b>Name:</b> [ B6 ]
		<b>Phone:</b> [ B6 ]
		<b>Email:</b> [ B6 ]
		<b>Address:</b> [ B6 ] United States
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine	
	<b>Contact:</b> <b>Name:</b> Lisa Freeman	

			<b>Phone:</b> (508) 887-4523	
			<b>Email:</b> lisa.freeman@tufts.edu	
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			
<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b>	medical records.pdf	
	<b>Description:</b>	Medical records		
	<b>Type:</b>	Medical Records		

**Report Details - EON-376195**

ICSR:	2061133
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:	2019-01-12 05:33:11 EST
Reporter is the Animal Owner:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Fed our dog <b>B6</b> ACANA lamb and apple. Our dog presented with a hacking cough, eventually very quickly became lethargic and refused to eat. Took her to the ER and she was diagnosed with heart failure, she stayed in the ICU for three days and was diagnosed by her cardiologist there with nutritional cardiomyopathy. She has since been removed from the food, on medications, and supplements and has responded well. She still has severe damage to her heart and it is severely enlarged. Her cardiologist attributes this to the dog food that she was eating and she had no health problems before hand and it was late onset at the age of 11 to be diagnosed with DCM.
	<b>Date Problem Started:</b>	10/22/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Unknown

<b>Product Information:</b>	<b>Product Name:</b>	ACANA Lamb and Apple Singles Formula	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	25 Pound	
	<b>Purchase Date:</b>	10/01/2018	
	<b>Number Purchased:</b>	1	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	Yes	
	<b>Storage Conditions:</b>	Stored in the bag with a clip to seal it shut.	
	<b>Product Use Information:</b>	<b>Description:</b>	Fed <b>B6</b> two cups in the am and two cups in the pm daily
		<b>First Exposure Date:</b>	10/01/2018
		<b>Last Exposure Date:</b>	11/04/2018
<b>Time Interval between Product Use and Adverse Event:</b>		1 Years	
<b>Product Use Stopped After the Onset of the Adverse Event:</b>		Yes	
<b>Adverse Event Abate After Product Stop:</b>		Unknown	
<b>Product Use Started Again:</b>		No	
<b>Perceived Relatedness to Adverse Event:</b>		Definitely related	
<b>Other Foods or</b>	No		

		Products Given to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	B6 United States
Animal Information:	Name:	B6	Pitbull Terrier Mix
	Type Of Species:	Dog	
	Type Of Breed:	Pit Bull	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	52 Pound	
	Age:	11 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
		Address:	B6 United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	11/04/2018
		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	
	Preferred Method Of Contact:	Phone	
	Reported to Other	Other	

Parties: Manufacturer

Additional Documents:

**Report Details - EON-375208**

ICSR: 2060775  
 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: 2019-01-02 15:28:26 EST

**Reported Problem:**  
**Problem Description:** Congestive heart failure, hypotension/cardiogenic shock, thrombocytopenia,  
**Date Problem Started:** B6  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Hydrocodone/acetaminophen, hydrocodone/homeatropine, prednisone, phenobarbitol  
**Outcome to Date:** Died Euthanized  
**Date of Death:** B6

**Product Information:**  
**Product Name:** Arcana lamb and apple - grain free  
**Product Type:** Pet Food  
**Lot Number:**  
**Possess Unopened Product:** Unknown  
**Possess Opened Product:** Unknown  
**Product Use Information:**  
**Description:** Fed as primary diet for years  
**Product Use Stopped After the Onset of the Adverse Event:** No  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Weimaraner  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Age:** 8 Years  
**Assessment of Prior Health:** Unknown  
**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

	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	<b>B6</b>		
<b>Sender Information:</b>		<b>Name:</b>	<b>B6</b>		
		<b>Address:</b>	<b>B6</b> United States		
		<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>	
			<b>Other Phone:</b>	<b>B6</b>	
			<b>Email:</b>	<b>B6</b>	
<b>Permission To Contact Sender:</b>	Yes				
<b>Preferred Method Of Contact:</b>	Email				
<b>Additional Documents:</b>					

**Report Details - EON-377465**

ICSR: 2061751  
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: 2019-01-25 09:02:33 EST  
Reporter is the Animal Owner: Yes

**Reported Problem:** **Problem Description:** [Redacted] B6 [Redacted] B6  
Referring Hospital: [Redacted] B6  
B6 Examination Date: [Redacted] B6 TIME: Patient: B6  
Boufford 5 year, male, English Lab Re: Client: [Redacted] B6  
[Redacted] 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  
[Redacted] B6  
[Redacted] B6 seem weak. He has large thyroid cartilages in his larynx but it is bilaterally symmetrical and is nonpainful. No stridor I)agnostics: RV ran CBC, profile today- all wnl RV sent two upper cervical xrays 3 view chest- marked cardiac enlargement with severe pulmonary infiltrate, no effusion 2 view abdomen- stomach empty no ascites, no masses, no significant findings FAST SCAN US of thorax- dilated chambers with very poor contractility, no pericardial effusion seen abdomen- no ascites noted Laboratory: Treatment: I called owner and advised that [Redacted] B6 is in CHF and likely has DCM. Discussed treatment for CHF. Owner wants to proceed. Gave owner [Redacted] B6 er,  
[Redacted] B6  
[Redacted] B6 Continued CPR and advised owner of the situation. Owner elected to stop CPR time of death: B6  
Diagnosis: Fulminating Congestive heart failure. Suspect DCM Thank you very much for the referral, if you have any questions regarding [Redacted] B6 or any other case, please do not hesitate to call me. [Redacted] B6 DVM [Redacted] B6  
DVM, [Redacted] B6

**Date Problem Started:** [Redacted] B6  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Died Other  
**Date of Death:** [Redacted] B6

**Product Information:**  
**Product Name:** BLUE BUFFALO GRAIN FREE LAMB AND POTATO  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Package Size:** 40 Pound  
**Purchase Date:** 10/31/2015  
**Number Purchased:** 1

	<b>Possess Unopened Product:</b>	No																					
	<b>Possess Opened Product:</b>	No																					
	<b>Storage Conditions:</b>	IN BAG																					
	<b>Product Use Information:</b>	<table border="1"> <tr> <td><b>Description:</b></td> <td>DOG FOOD GIVEN EACH DAY FOR 3 YEARS</td> </tr> <tr> <td><b>First Exposure Date:</b></td> <td>11/01/2015</td> </tr> <tr> <td><b>Last Exposure Date:</b></td> <td>B6</td> </tr> <tr> <td><b>Time Interval between Product Use and Adverse Event:</b></td> <td>3 Years</td> </tr> <tr> <td><b>Product Use Stopped After the Onset of the Adverse Event:</b></td> <td>Yes</td> </tr> <tr> <td><b>Adverse Event Abate After Product Stop:</b></td> <td>Not Applicable</td> </tr> <tr> <td><b>Product Use Started Again:</b></td> <td>Unknown</td> </tr> <tr> <td><b>Perceived Relatedness to Adverse Event:</b></td> <td>Definitely related</td> </tr> <tr> <td><b>Other Foods or Products Given to the Animal During This Time Period:</b></td> <td>No</td> </tr> </table>	<b>Description:</b>	DOG FOOD GIVEN EACH DAY FOR 3 YEARS	<b>First Exposure Date:</b>	11/01/2015	<b>Last Exposure Date:</b>	B6	<b>Time Interval between Product Use and Adverse Event:</b>	3 Years	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	<b>Adverse Event Abate After Product Stop:</b>	Not Applicable	<b>Product Use Started Again:</b>	Unknown	<b>Perceived Relatedness to Adverse Event:</b>	Definitely related	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No			
<b>Description:</b>	DOG FOOD GIVEN EACH DAY FOR 3 YEARS																						
<b>First Exposure Date:</b>	11/01/2015																						
<b>Last Exposure Date:</b>	B6																						
<b>Time Interval between Product Use and Adverse Event:</b>	3 Years																						
<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes																						
<b>Adverse Event Abate After Product Stop:</b>	Not Applicable																						
<b>Product Use Started Again:</b>	Unknown																						
<b>Perceived Relatedness to Adverse Event:</b>	Definitely related																						
<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No																						
	<b>Manufacturer /Distributor Information:</b>																						
	<b>Purchase Location Information:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>CHEWY</td> </tr> <tr> <td><b>Address:</b></td> <td>United States</td> </tr> </table>	<b>Name:</b>	CHEWY	<b>Address:</b>	United States																	
<b>Name:</b>	CHEWY																						
<b>Address:</b>	United States																						
<b>Animal Information:</b>	<b>Name:</b>	B6																					
	<b>Type Of Species:</b>	Dog																					
	<b>Type Of Breed:</b>	Retriever (unspecified)																					
	<b>Gender:</b>	Male																					
	<b>Reproductive Status:</b>	Neutered																					
	<b>Weight:</b>	87 Pound																					
	<b>Age:</b>	5 Years																					
	<b>Assessment of Prior Health:</b>	Excellent																					
	<b>Number of Animals Given the Product:</b>	2																					
	<b>Number of Animals Reacted:</b>	1																					
	<b>Owner Information:</b>																						
	<b>Healthcare Professional Information:</b>	<table border="1"> <tr> <td><b>Practice Name:</b></td> <td colspan="3">B6</td> </tr> <tr> <td rowspan="4"><b>Contact:</b></td> <td><b>Name:</b></td> <td>B6</td> <td></td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> <td></td> </tr> <tr> <td><b>Other Phone:</b></td> <td>B6</td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> <td></td> </tr> <tr> <td><b>Address:</b></td> <td colspan="3">B6</td> </tr> </table>	<b>Practice Name:</b>	B6			<b>Contact:</b>	<b>Name:</b>	B6		<b>Phone:</b>	B6		<b>Other Phone:</b>	B6		<b>Email:</b>	B6		<b>Address:</b>	B6		
<b>Practice Name:</b>	B6																						
<b>Contact:</b>	<b>Name:</b>	B6																					
	<b>Phone:</b>	B6																					
	<b>Other Phone:</b>	B6																					
	<b>Email:</b>	B6																					
<b>Address:</b>	B6																						

			<b>B6</b> United States	
		<b>Type of Veterinarian:</b>	Referred veterinarian	
		<b>Date First Seen:</b>	<b>B6</b>	
		<b>Permission to Release Records to FDA:</b>	Yes	
<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>		
	<b>Address:</b>	<b>B6</b> United States		
	<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>	
		<b>Other Phone:</b>	<b>B6</b>	
		<b>Email:</b>	<b>B6</b>	
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
<b>Reported to Other Parties:</b>	Other Manufacturer Store/Place of Purchase			
<b>Additional Documents:</b>	<b>Attachment:</b>	OVRs REPORT.pdf		
	<b>Description:</b>	OVRs REPORT of diagnosis and treatment of <b>B6</b>		
	<b>Type:</b>	Letter		

**Report Details - EON-374327**

ICSR:	2060407
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:	2018-12-19 17:20:05 EST
Reporter is the Animal Owner:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	<b>B6</b> began acting strange (lathargic, lack of appetite, breathing hard) since around thanksgiving. His primary vet - chicago pet clinic, ran multiple tests and did an xray- 2 visits from: <b>B6</b> left him stumped. We were referred to an internal specialist for an ultrasound who determined there is fluid build up, an enlarged right side of the heart, and low function of the heart. <b>B6</b> has been in our family since he was a pup and has never had any significant medical issues until this event. He has also exclusively been fed grain free blue buffalo (call of the wild) dog food through out his life. The internal specialist believes: <b>B6</b> has CDM, and that we need to see a cardiologist immediately. <b>B6</b> has already been taken off his grain free diet and now we anxiously wait to see a cardiologist.
	<b>Date Problem Started:</b>	11/24/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Worse/Declining/Deteriorating

<b>Product Information:</b>	<b>Product Name:</b>	BLUE Wilderness with Chicken for Adult Dogs		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Purchase Date:</b>	11/06/2018		
	<b>Number Purchased:</b>	1		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Storage Conditions:</b>	Stored in pet food bin with lid closed.		
	<b>Product Use Information:</b>	<b>Description:</b>	Purchased through amazon. Stored in closed pet food bin, 1.5 cups given at meal time.	
		<b>First Exposure Date:</b>	11/07/2018	
		<b>Last Exposure Date:</b>	12/15/2018	
		<b>Time Interval between Product Use and Adverse Event:</b>	6 Years	
<b>Product Use Stopped After the Onset of the Adverse Event:</b>		Yes		
<b>Adverse Event Abate After Product Stop:</b>		Unknown		
<b>Product Use Started Again:</b>		No		
<b>Perceived Relatedness to Adverse Event:</b>		Definitely related		
<b>Manufacturer:</b>				

	<b>/Distributor Information:</b>			
<b>Animal Information:</b>	<b>Purchase Location Information:</b>	<b>Name:</b>	Amazon	
		<b>Address:</b>	United States	
	<b>Name:</b>	B6		
	<b>Type Of Species:</b>	Dog		
	<b>Type Of Breed:</b>	American Pit Bull Terrier		
	<b>Gender:</b>	Male		
	<b>Reproductive Status:</b>	Neutered		
	<b>Weight:</b>	71 Pound		
	<b>Age:</b>	6 Years		
	<b>Assessment of Prior Health:</b>	Excellent		
	<b>Number of Animals Given the Product:</b>	2		
	<b>Number of Animals Reacted:</b>	1		
	<b>Owner Information:</b>			
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6	
		<b>Contact:</b>	<b>Name:</b>	B6
			<b>Phone:</b>	B6
		<b>Address:</b>	B6	
			United States	
<b>Type of Veterinarian:</b>		Primary/regular veterinarian		
<b>Date First Seen:</b>		11/26/2018		
<b>Permission to Release Records to FDA:</b>		Yes		
		<b>Practice Name:</b>	B6	
<b>Contact:</b>		<b>Name:</b>	B6	
		<b>Phone:</b>	B6	
<b>Type of Veterinarian:</b>		Referred veterinarian		
<b>Date First Seen:</b>	12/19/2018			
<b>Permission to Release Records to FDA:</b>	Yes			
<b>Sender Information:</b>	<b>Name:</b>	B6		
	<b>Address:</b>	B6		
		United States		
	<b>Contact:</b>	<b>Phone:</b>	B6	
		<b>Email:</b>	B6	
	<b>Reporter Wants to Remain Anonymous:</b>	No		
<b>Permission To Contact Sender:</b>	Yes			
<b>Preferred Method Of Contact:</b>	Email			

Reported to Other Parties: None

Additional Documents:

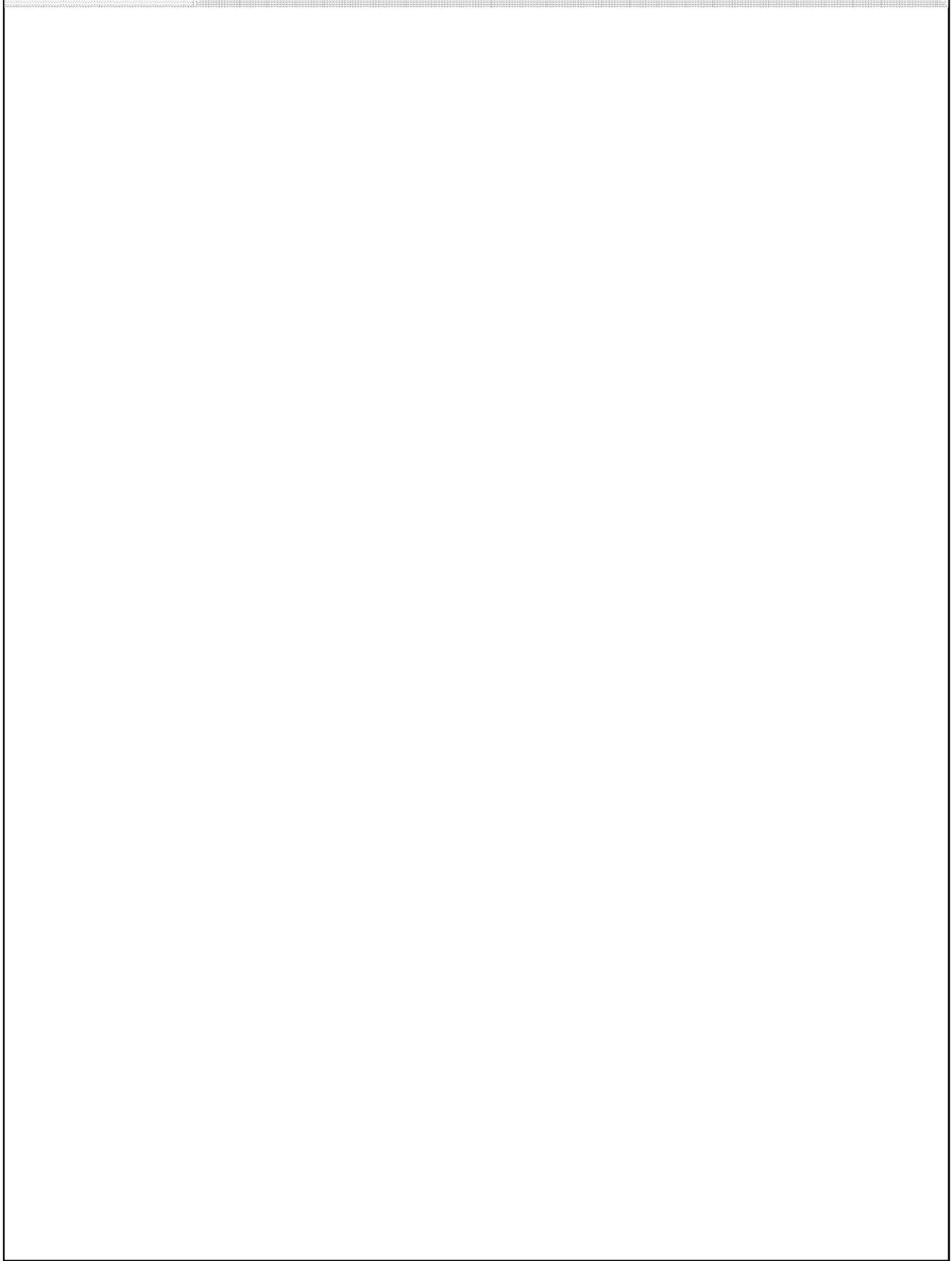
**Report Details - EON-375880**

ICSR:	2060996
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-01-08 21:46:26 EST
Reporter is the Animal Owner:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	I became aware of a possible link between feeding grain free food and low Taurine levels/DCM. Since my dog had been on Canidae grain free for a year (May 2017 - early June 2018), I tested her whole blood Taurine level on 6/21/18. Her whole blood Taurine level was <b>B6</b> which is considered low for Golden Retrievers. I changed her food to grain inclusive and retested her on 10/1/2018. Her whole blood Taurine level increased to <b>B6</b> still slightly below "normal" for Golden Retrievers. She got an echocardiogram on 10/27/2018 and was found to have a "normal" heart.
	<b>Date Problem Started:</b>	06/21/2018
	<b>Date of Recovery:</b>	10/01/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	Canidae Grain Free Pure Wild Dry Dog Food with Wild Boar Grain Free Limited Ingredient Diet		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Storage Conditions:</b>	After purchase, I store the open bag in a sealed container that's in my pantry.		
	<b>Product Use Information:</b>	<b>Description:</b>	Fed as meals, three times a day. Sometimes the kibble was also used as training treats.	
		<b>First Exposure Date:</b>	05/14/2017	
		<b>Last Exposure Date:</b>	05/20/2018	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
		<b>Adverse Event Abate After Product Stop:</b>	Yes	
		<b>Product Use Started Again:</b>	No	
<b>Perceived Relatedness to Adverse Event:</b>		Probably related		
<b>Other Foods or Products Given to the Animal During This Time Period:</b>		Yes		
<b>Manufacturer /Distributor Information:</b>				

	<b>Purchase Location Information:</b>	<b>Name:</b> Petco	
		<b>Address:</b> B6 United States	
<b>Animal Information:</b>	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Retriever - Golden	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	48 Pound	
	<b>Age:</b>	3 Years	
	<b>Assessment of Prior Health:</b>	Excellent	
	<b>Number of Animals Given the Product:</b>	1	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6
		<b>Contact:</b>	<b>Name:</b> B6
			<b>Phone:</b> B6
<b>Address:</b>		B6 United States	
<b>Type of Veterinarian:</b>		Primary/regular veterinarian	
<b>Date First Seen:</b>		06/21/2018	
<b>Permission to Release Records to FDA:</b>		Yes	
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6 United States	
	<b>Contact:</b>	<b>Phone:</b> B6	
		<b>Email:</b> B6	
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
	<b>Reported to Other Parties:</b>	None	
<b>Additional Documents:</b>	<b>Attachment:</b>	Taurine test 6-21-2018.pdf	
	<b>Description:</b>	B6 Taurine test result	
	<b>Type:</b>	Laboratory Report	
	<b>Attachment:</b>	Taurine test result 10-1-2018.pdf	
	<b>Description:</b>	B6 whole blood Taurine test result	
	<b>Type:</b>	Laboratory Report	



**Report Details - EON-375771**

<b>ICSR:</b>	2060959
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-08 09:16:48 EST
<b>Reporter is the Animal Owner:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	For 3.5 years, dog was fed Canidae Pure Land Bison dry dog food. Upon release of FDA warning that heart disease was caused in dogs eating Grain Free food, dog was taken off diet as of July 2018 and switched to Royal Canin Prescription Gastrointestinal. However, at routine physical on November 30, 2018, a grade 1-2 heart murmur was discovered in dog. Upon this finding, an echocardiogram was performed by a licensed veterinary internist, [REDACTED] <b>B6</b> who concluded that dog has early-stage DCM.
	<b>Date Problem Started:</b>	11/30/2018
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	Dog had environmental allergies - was taking Benadryl as prescribed and VARL Liquid Gold to desensitize from allergies. Overall, allergies were in check and dog was in excellent health. Dog also took Bravecto and Heartgard to protect from fleas, ticks, and heart worm.
	<b>Outcome to Date:</b>	Stable

<b>Product Information:</b>	<b>Product Name:</b>	CANIDAE Grain-Free PURE Land with Bison Limited Ingredient Diet Adult Dry Dog Food		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>UPC:</b>	640461015870		
	<b>Package Type:</b>	BAG		
	<b>Package Size:</b>	21 Pound		
	<b>Purchase Date:</b>	07/01/2018		
	<b>Number Purchased:</b>	1		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Storage Conditions:</b>	Before opening, product was stored in bag on main living floor in kitchen pantry. After opening, product was stored in an air-tight bin on main living floor in kitchen pantry.		
	<b>Product Use Information:</b>	<b>Description:</b>	1 cup of food was administered twice a day in a slow-feed bowl over the course of 3 to 3.5 years.	
		<b>Last Exposure Date:</b>	07/16/2018	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
		<b>Adverse Event Abate After Product Stop:</b>	Unknown	
<b>Product Use Started Again:</b>		No		
<b>Perceived Relatedness to Adverse Event:</b>		Definitely related		

<b>Manufacturer /Distributor Information:</b>	<b>Name:</b>	Canidae Corporation
	<b>Type(s):</b>	Manufacturer
	<b>Address:</b>	California United States
	<b>Contact:</b>	<b>Phone:</b> 18003981600 <b>Web Address:</b> Canidae.com
	<b>Possess One or More Labels from This Product:</b>	Yes
<b>Purchase Location Information:</b>	<b>Name:</b>	B6
	<b>Address:</b>	B6 United States
<b>Animal Information:</b>	<b>Name:</b>	B6
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Retriever - Golden
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	80 Pound
	<b>Age:</b>	4 Years
	<b>Assessment of Prior Health:</b>	Good
	<b>Number of Animals Given the Product:</b>	1
	<b>Number of Animals Reacted:</b>	1
<b>Owner Information:</b>		
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6
	<b>Contact:</b>	<b>Name:</b> B6 <b>Phone:</b> B6
	<b>Address:</b>	B6 United States
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Date First Seen:</b>	12/06/2018
	<b>Permission to Release Records to FDA:</b>	Yes
	<b>Practice Name:</b>	B6
	<b>Contact:</b>	<b>Name:</b> B6 <b>Phone:</b> B6
	<b>Address:</b>	B6 United States
	<b>Type of Veterinarian:</b>	Primary/regular veterinarian
<b>Date First Seen:</b>	11/30/2018	

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: Email

Reported to Other Parties: Other

Additional Documents:

Report Details - EON-376088													
ICSR:	2061078												
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:	2019-01-10 21:20:52 EST												
Reporter is the Animal Owner:	Yes												
Reported Problem:	<b>Problem Description:</b> B6 was eating Crave Grain Free Salmon & White Fish kibble as his main diet. After presenting to the veterinarian with a heart murmur, he was evaluated by echocardiogram and found to have severe dilated cardiomyopathy.												
	<b>Date Problem Started:</b> 12/06/2018												
	<b>Concurrent Medical Problem:</b> Unknown												
	<b>Outcome to Date:</b> Stable												
Product Information:	<b>Product Name:</b> CRAVE Dog Food with Protein from Salmon and Ocean White Fish												
	<b>Product Type:</b> Pet Food												
	<b>Lot Number:</b>												
	<b>Package Type:</b> BAG												
	<b>Package Size:</b> 22 Pound												
	<b>Possess Unopened Product:</b> No												
	<b>Possess Opened Product:</b> No												
	<b>Storage Conditions:</b> Inside of the bag in an airtight plastic container.												
	<b>Product Use Information:</b> <table border="1"> <tr> <td><b>Description:</b></td> <td>Fed to the dog twice daily, 2/3 cup per day.</td> </tr> <tr> <td><b>Product Use Stopped After the Onset of the Adverse Event:</b></td> <td>Yes</td> </tr> <tr> <td><b>Adverse Event Abate After Product Stop:</b></td> <td>No</td> </tr> <tr> <td><b>Product Use Started Again:</b></td> <td>No</td> </tr> <tr> <td><b>Perceived Relatedness to Adverse Event:</b></td> <td>Probably related</td> </tr> <tr> <td><b>Other Foods or Products Given to the Animal During This Time Period:</b></td> <td>Yes</td> </tr> </table>	<b>Description:</b>	Fed to the dog twice daily, 2/3 cup per day.	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	<b>Adverse Event Abate After Product Stop:</b>	No	<b>Product Use Started Again:</b>	No	<b>Perceived Relatedness to Adverse Event:</b>	Probably related	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
	<b>Description:</b>	Fed to the dog twice daily, 2/3 cup per day.											
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes											
<b>Adverse Event Abate After Product Stop:</b>	No												
<b>Product Use Started Again:</b>	No												
<b>Perceived Relatedness to Adverse Event:</b>	Probably related												
<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes												
<b>Manufacturer /Distributor Information:</b>													
<b>Purchase Location Information:</b>													
Animal Information:	<b>Name:</b> B6												
	<b>Type Of Species:</b> Dog												
	<b>Type Of Breed:</b> Shih Tzu												
	<b>Gender:</b> Male												
	<b>Reproductive Status:</b> Intact												
<b>Weight:</b> 13 Pound													

	<b>Assessment of Prior Health:</b>	Good																	
	<b>Number of Animals Given the Product:</b>	1																	
	<b>Number of Animals Reacted:</b>	1																	
	<b>Owner Information:</b>																		
	<b>Healthcare Professional Information:</b>	<table border="1"> <tr> <td><b>Practice Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td>B6</td> </tr> </table>   United States </td> </tr> <tr> <td><b>Type of Veterinarian:</b></td> <td>Referred veterinarian</td> </tr> <tr> <td><b>Date First Seen:</b></td> <td>12/06/2018</td> </tr> <tr> <td><b>Permission to Release Records to FDA:</b></td> <td>Yes</td> </tr> </table>	<b>Practice Name:</b>	B6	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> </table> United States	B6	<b>Type of Veterinarian:</b>	Referred veterinarian	<b>Date First Seen:</b>	12/06/2018	<b>Permission to Release Records to FDA:</b>	Yes
<b>Practice Name:</b>	B6																		
<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6														
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<b>Phone:</b>	B6																		
<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> </table> United States	B6																	
B6																			
<b>Type of Veterinarian:</b>	Referred veterinarian																		
<b>Date First Seen:</b>	12/06/2018																		
<b>Permission to Release Records to FDA:</b>	Yes																		
<b>Sender Information:</b>	<b>Name:</b>	B6																	
	<b>Address:</b>	United States																	
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Phone:</b>	B6	<b>Email:</b>	B6													
<b>Phone:</b>	B6																		
<b>Email:</b>	B6																		
	<b>Reporter Wants to Remain Anonymous:</b>	No																	
	<b>Permission To Contact Sender:</b>	Yes																	
	<b>Preferred Method Of Contact:</b>	Email																	
	<b>Reported to Other Parties:</b>	Other																	
<b>Additional Documents:</b>																			

Report Details - EON-376046		
ICSR:	2061059	
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:	2019-01-10 14:40:34 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> After changing foods to a grain-free diet, the dog went into heart failure. His heart failure onset was sudden.	
	<b>Date Problem Started:</b> 12/23/2018	
	<b>Concurrent Medical Problem:</b> Yes	
	<b>Pre Existing Conditions:</b> Food allergies leading to hot spots.	
	<b>Outcome to Date:</b> Worse/Declining/Deteriorating	
Product Information:	<b>Product Name:</b> Diamond Naturals Skin & Coat All Life Stages Dog Salmon & Potato Formula	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b> <b>Expiration Date:</b> 12/17/2019	
	<b>UPC:</b> 74198613847	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 30 Pound	
	<b>Purchase Date:</b> 11/26/2018	
	<b>Number Purchased:</b> 1	
	<b>Possess Unopened Product:</b> No	
	<b>Possess Opened Product:</b> Yes	
	<b>Storage Conditions:</b> The food was opened upon arrival. The Food was stored in a sealed cooler after being opened.	
	<b>Product Use Information:</b>	<b>Description:</b> Dog was fed 1.5 cups of food once a day.
		<b>First Exposure Date:</b> 12/03/2018
		<b>Last Exposure Date:</b> 01/07/2019
		<b>Time Interval between Product Use and Adverse Event:</b> 2 Weeks
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> No
		<b>Perceived Relatedness to Adverse Event:</b> Possibly related
<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b> <b>Name:</b> Chewy.com		

<b>Animal Information:</b>	<b>Name:</b>	B6		
	<b>Type Of Species:</b>	Dog		
	<b>Type Of Breed:</b>	Basset - Griffon Vendeen (unspecified)		
	<b>Gender:</b>	Male		
	<b>Reproductive Status:</b>	Neutered		
	<b>Weight:</b>	37 Pound		
	<b>Age:</b>	6 Years		
	<b>Assessment of Prior Health:</b>	Good		
	<b>Number of Animals Given the Product:</b>	2		
	<b>Number of Animals Reacted:</b>	1		
	<b>Owner Information:</b>			
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6	
		<b>Contact:</b>	<b>Name:</b>	B6
			<b>Phone:</b>	B6
<b>Address:</b>		B6		
		United States		
<b>Type of Veterinarian:</b>		Primary/regular veterinarian		
<b>Date First Seen:</b>		12/26/2018		
<b>Permission to Release Records to FDA:</b>	No			
<b>Sender Information:</b>	<b>Name:</b>	B6		
	<b>Address:</b>	B6		
		United States		
	<b>Contact:</b>	<b>Phone:</b>	B6	
		<b>Email:</b>	B6	
	<b>Reporter Wants to Remain Anonymous:</b>	No		
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			
<b>Reported to Other Parties:</b>	None			
<b>Additional Documents:</b>				

Report Details - EON-374687	
ICSR:	2060556
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:	2018-12-26 10:11:25 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	<b>Problem Description:</b> <b>B6</b> had <b>B6</b> As part of his recovery process, the surgeon put him on Antibiotics. He remained on those for about 3 months. After his recovery period, he was given a clean bill of health from the surgeon and he seemed fine. About a month later, he began coughing one day and the cough gradually worsened over the next few days. We took him to our regular vet. She put him on a different antibiotic stating the one from surgery may have killed off good bacteria and this one should correct that. Within 10 days, he seemed perfectly normal again. About two weeks later, his cough returned and got really bad quickly. We took him to the emergency vet hospital and they diagnosed him with an enlarged heart. We took him back two days later for an echo cardiogram and it confirmed it. His heart was more than double the normal size. He died three weeks later. Because <b>B6</b> had always had some apparent allergies, we at the suggestion of our first veterinarian, we put him on grain free dog food when he was about 3 years old. <b>B6</b> had regular check-ups, lived a great life with great care. Even when they did the <b>B6</b> surgery, they never detected any abnormalities with his heart. When this occurred, we were stunned, as this condition was usually attributed to a birth defect. Yet at no time did he ever exhibit any issues that would have led anyone to believe this was congenital. It was not until this article, that I realized that we had switched <b>B6</b> to a different grain free dog food about 12 months before he died.
	<b>Date Problem Started:</b> 04/01/2018
	<b>Concurrent Medical Problem:</b> Yes
	<b>Pre Existing Conditions:</b> He was always allergic to the grass, so he was given anti-itch medication for about 6 months., Apoquel 16 mg.
	<b>Outcome to Date:</b> Died Naturally
	<b>Date of Death:</b> <b>B6</b>
	<b>Product Information:</b>
<b>Product Name:</b>	Fromm Family From the Heartland Grain Free Dog Food
<b>Product Type:</b>	Pet Food
<b>Lot Number:</b>	
<b>UPC:</b>	Do not know
<b>Package Type:</b>	BAG
<b>Package Size:</b>	26 Pound
<b>Purchase Date:</b>	06/01/2017
<b>Number Purchased:</b>	1
<b>Possess Unopened Product:</b>	No
<b>Possess Opened Product:</b>	No
<b>Storage Conditions:</b>	We used a sealed, plastic dog food storage bin. We would pour the entire contents of the bag into the bin immediately upon opening. The bin was kept in a clean, dry area. We would completely empty the bin before adding any new food to prevent older food from accumulating in the bottom of the bin. The previous months food would then be on top and used first. We followed this method for his entire life. In addition, the question below asked of there were any other foods or products given to the animal during this time? Yes, he received grain-free dog treats from the same brand Fromm.
<b>Product Use Information:</b>	<b>Description:</b> <b>B6</b> received 2 cups of food, once per day, every day.
	<b>First Exposure</b> 06/01/2017

		Date:	
		Last Exposure Date:	B6
		Time Interval between Product Use and Adverse Event:	9 Months
		Product Use Stopped After the Onset of the Adverse Event:	No
		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 - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	100 Pound	
	Age:	8 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
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	

**Additional Documents:**

**Report Details - EON-375559**

<b>ICSR:</b>	2060907
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-05 19:04:25 EST
<b>Reporter is the Animal Owner:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	<b>B6</b> was slightly lethargic and upon veterinary examination, a new heart murmur was discovered. We scheduled an echocardiogram and she was diagnosed with Dilated Cardiomyopathy and a Mitral Valve Regurgitation. We sent her blood into UC Davis for a taurine test and her taurine levels were normal. It is suspected that her food caused this issue.
	<b>Date Problem Started:</b>	10/30/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Stable

<b>Product Information:</b>	<b>Product Name:</b>	Fromm Surf & Turf dry dog food		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Package Size:</b>	12 Pound		
	<b>Purchase Date:</b>	10/04/2018		
	<b>Number Purchased:</b>	1		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Storage Conditions:</b>	After purchase was immediately placed into a dog food storage container with air tight lid.		
	<b>Product Use Information:</b>	<b>Description:</b>	2 cups per day by mouth	
		<b>Last Exposure Date:</b>	10/18/2018	
		<b>Time Interval between Product Use and Adverse Event:</b>	1 Years	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
<b>Adverse Event Abate After Product Stop:</b>		Unknown		
<b>Product Use Started Again:</b>		No		
<b>Perceived Relatedness to Adverse Event:</b>		Probably related		
<b>Other Foods or Products Given to the Animal During This Time Period:</b>		Yes		
<b>Manufacturer</b>				

	<b>/Distributor Information:</b> <b>Purchase Location Information:</b>	<b>Name:</b> B6 <b>Address:</b> B6 United States
<b>Animal Information:</b>	<b>Name:</b> B6 <b>Type Of Species:</b> Dog <b>Type Of Breed:</b> Pit Bull <b>Gender:</b> Female <b>Reproductive Status:</b> Neutered <b>Weight:</b> 56 Pound <b>Age:</b> 8 Years <b>Assessment of Prior Health:</b> Excellent <b>Number of Animals Given the Product:</b> 1 <b>Number of Animals Reacted:</b> 1 <b>Owner Information:</b>	<b>Healthcare Professional Information:</b> <b>Practice Name:</b> B6 <b>Contact:</b> <b>Name:</b> B6 <b>Phone:</b> B6 <b>Email:</b> B6 <b>Address:</b> B6 United States <b>Type of Veterinarian:</b> Primary/regular veterinarian <b>Date First Seen:</b> 10/30/2018 <b>Permission to Release Records to FDA:</b> Yes
<b>Sender Information:</b>	<b>Name:</b> B6 <b>Address:</b> B6 United States <b>Contact:</b> <b>Phone:</b> B6 <b>Email:</b> B6 <b>Permission To Contact Sender:</b> Yes <b>Preferred Method Of Contact:</b> Email <b>Reported to Other Parties:</b> None	
<b>Additional Documents:</b>	<b>Attachment:</b> 39177; B6 Echo.pdf <b>Description:</b> B6 results from her echocardiogram. <b>Type:</b> Echocardiogram	

<b>Attachment:</b>	taurine results.pdf
<b>Description:</b>	<b>B6</b> taurine results from UC Davis
<b>Type:</b>	Laboratory Report

**Report Details - EON-375313**

ICSR: 2060813  
 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: 2019-01-03 13:30:04 EST  
 Reporter is the Animal Owner: Yes

**Reported Problem:**  
**Problem Description:** B6 has been eating grain free GO Venison since September 2014 up until November 2018 when we switched her to Hills Science Diet large breed chicken and barley. Her Taurine level in November 2017 was B6. She had an echocardiogram on December 27th and has been diagnosed with Taurine deficient dilated cardiomyopathy. It is recommended that she take Taurine and L-carnitine supplements daily and have another Taurine blood test in 3 months and a recheck cardiology examination and echocardiogram in 6 months.  
**Date Problem Started:** 12/27/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Hypothyroidism 0.6mg thyrotabs  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** GO Venison  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Purchase Date:** 11/01/2018  
**Possess Unopened Product:** No  
**Possess Opened Product:** No  
**Product Use Information:**  
**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:** 31.5 Kilogram  
**Age:** 5 Years  
**Assessment of Prior Health:** Good  
**Number of Animals Reacted:** 1  
**Owner Information:**  
**Healthcare Professional Information:**

**Sender Information:**  
**Name:** B6  
**Address:** B6

**B6**  
Canada

**Contact:** **Phone:** **B6**  
**Other 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-374789**

ICSR: 2060600  
 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: 2018-12-27 10:47:28 EST

**Reported Problem:**

**Problem 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

**Date Problem Started:** 11/15/2018

**Concurrent Medical Problem:** Yes

**Pre Existing Conditions:** History of anaplasma, von Willebrand disease, skin allergies, elevated ALT

**Outcome to Date:** Stable

**Product Information:**

**Product Name:** Homecooked diet - see diet history in medical record

**Product Type:** Other

**Lot Number:**

**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:** 40.9 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: 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

			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview.pdf	
	<b>Description:</b>	<b>B6</b>	medical records
	<b>Type:</b>	Medical Records	

**Report Details - EON-377314**

<b>ICSR:</b>	2061661
<b>Type Of Submission:</b>	Followup
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-23 17:25:12 EST
<b>Initial Report Date:</b>	08/15/2018
<b>Parent ICSR:</b>	2053786
<b>Follow-up Report to FDA Request:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Diagnosed with mild dilated cardiomyopathy, sinus bradycardia, first degree AV block; found to have taurine deficiency based on analysis of whole blood: <b>B6</b> nmol/mL). Update 10/22/18: Recheck whole blood taurine after diet change and oral supplementation: <b>B6</b> nmol/mL Update 1/8/19: Unremarkable echocardiogram; DCM resolved
	<b>Date Problem Started:</b>	07/11/2018
	<b>Date of Recovery:</b>	01/08/2019
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	Other medical history includes: eosinophilic bronchopneumopathy, overweight, suspected atopic dermatitis
	<b>Outcome to Date:</b>	Recovered Completely

<b>Product Information:</b>	<b>Product Name:</b>	TruDog FEED ME Crunchy Munchy Beef Bonanza		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Product Use Information:</b>	<b>Description:</b>	Fed in combination with Honest Kitchen vegetarian premix	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
		<b>Adverse Event Abate After Product Stop:</b>	Unknown	
		<b>Product Use Started Again:</b>	Unknown	
		<b>Perceived Relatedness to Adverse Event:</b>	Possibly related	
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes	
		<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>			
<b>Product Name:</b>	Honest Kitchen Dehydrated Grain Free Veggie, Nut & Seed Base Mix (Kindly)			
<b>Product Type:</b>	Pet Food			

<b>Lot Number:</b>		
<b>Package Type:</b>	BOX	
<b>Possess Unopened Product:</b>	No	
<b>Possess Opened Product:</b>	No	
<b>Product Use Information:</b>	<b>Description:</b>	Rehydrated and fed as main diet in rotation with other foods; fed in combination with 85% lean ground beef or Trudog raw beef diet
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
	<b>Adverse Event Abate After Product Stop:</b>	Unknown
	<b>Product Use Started Again:</b>	Unknown
	<b>Perceived Relatedness to Adverse Event:</b>	Probably related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>		
<b>Product Name:</b>	Honest Kitchen Grain Free Turkey Recipe (Embark)	
<b>Product Type:</b>	Pet Food	
<b>Lot Number:</b>		
<b>Package Type:</b>	BOX	
<b>Possess Unopened Product:</b>	No	
<b>Possess Opened Product:</b>	No	
<b>Product Use Information:</b>	<b>Description:</b>	Rehydrated and fed as main diet in rotation with other foods
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
	<b>Adverse Event Abate After Product Stop:</b>	Unknown
	<b>Product Use Started Again:</b>	No
	<b>Perceived Relatedness to Adverse Event:</b>	Probably related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location</b>		

	<b>Information:</b>															
	<b>Product Name:</b>	Honest Kitchen Grain Free Beef Recipe (Love)														
	<b>Product Type:</b>	Pet Food														
	<b>Lot Number:</b>															
	<b>Package Type:</b>	BOX														
	<b>Possess Unopened Product:</b>	No														
	<b>Possess Opened Product:</b>	No														
	<b>Storage Conditions:</b>	Unsure. Owner still has product at home but I do not have any samples of the product.														
	<b>Product Use Information:</b>	<table border="1"> <tr> <td><b>Description:</b></td> <td>Rehydrated and fed as part of main diet (in rotation with other products)</td> </tr> <tr> <td><b>Product Use Stopped After the Onset of the Adverse Event:</b></td> <td>Yes</td> </tr> <tr> <td><b>Adverse Event Abate After Product Stop:</b></td> <td>Unknown</td> </tr> <tr> <td><b>Product Use Started Again:</b></td> <td>No</td> </tr> <tr> <td><b>Perceived Relatedness to Adverse Event:</b></td> <td>Probably related</td> </tr> <tr> <td><b>Other Foods or Products Given to the Animal During This Time Period:</b></td> <td>Yes</td> </tr> </table>	<b>Description:</b>	Rehydrated and fed as part of main diet (in rotation with other products)	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	<b>Adverse Event Abate After Product Stop:</b>	Unknown	<b>Product Use Started Again:</b>	No	<b>Perceived Relatedness to Adverse Event:</b>	Probably related	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes		
<b>Description:</b>	Rehydrated and fed as part of main diet (in rotation with other products)															
<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes															
<b>Adverse Event Abate After Product Stop:</b>	Unknown															
<b>Product Use Started Again:</b>	No															
<b>Perceived Relatedness to Adverse Event:</b>	Probably related															
<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes															
	<b>Manufacturer /Distributor Information:</b>															
	<b>Purchase Location Information:</b>															
<b>Animal Information:</b>	<b>Name:</b>	B6														
	<b>Type Of Species:</b>	Dog														
	<b>Type Of Breed:</b>	Pointing Dog - Hungarian Short-haired (Vizsla)														
	<b>Gender:</b>	Male														
	<b>Reproductive Status:</b>	Neutered														
	<b>Age:</b>	5 Years														
	<b>Assessment of Prior Health:</b>	Unknown														
	<b>Number of Animals Given the Product:</b>	1														
	<b>Number of Animals Reacted:</b>	1														
	<b>Owner Information:</b>	<table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>Owner Information provided:</b>	Yes	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6	<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States
<b>Owner Information provided:</b>	Yes															
<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6									
<b>Name:</b>	B6															
<b>Phone:</b>	B6															
<b>Email:</b>	B6															
<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States													
B6																
United States																

<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6
	<b>Contact:</b>	<b>Name:</b> B6
		<b>Phone:</b> B6
		<b>Email:</b> B6
	<b>Address:</b>	B6 United States
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Date First Seen:</b>	08/08/2018
	<b>Permission to Release Records to FDA:</b>	Yes
	<b>Practice Name:</b>	B6
	<b>Contact:</b>	<b>Name:</b> B6
		<b>Phone:</b> B6
		<b>Email:</b> B6
	<b>Address:</b>	B6 United States
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Date First Seen:</b>	07/11/2018
<b>Permission to Release Records to FDA:</b>	Yes	
<b>Practice Name:</b>	B6	
<b>Contact:</b>	<b>Name:</b> B6	
	<b>Phone:</b> B6	
	<b>Address:</b>	B6 United States
<b>Type of Veterinarian:</b>	Primary/regular veterinarian	
<b>Sender Information:</b>	<b>Name:</b> B6	
	<b>Address:</b> B6 United States	
	<b>Contact:</b> <b>Phone:</b> B6 <b>Email:</b> B6	
	<b>Permission To Contact Sender:</b> Yes	
	<b>Preferred Method Of Contact:</b> Email	
	<b>Reported to Other Parties:</b> Other	
<b>Additional Documents:</b>		

<b>Attachment:</b>	<b>B6</b>	Medical history 2018-10-10 to 2019-01-23.pdf
<b>Description:</b>	<b>B6</b>	medical records 10-2018 through 1-2019
<b>Type:</b>	Medical Records	
<b>Attachment:</b>	<b>B6</b>	_2019-01-23_ECG.pdf
<b>Description:</b>	1/2019 ECG	
<b>Type:</b>	Medical Records	
<b>Attachment:</b>	<b>B6</b>	_2019-01-23_ <b>B6</b> Recs 12-5-18-1-9-19.pdf
<b>Description:</b>	Additional primary care veterinarian records <b>B6</b>	
<b>Type:</b>	Medical Records	



B6

B6

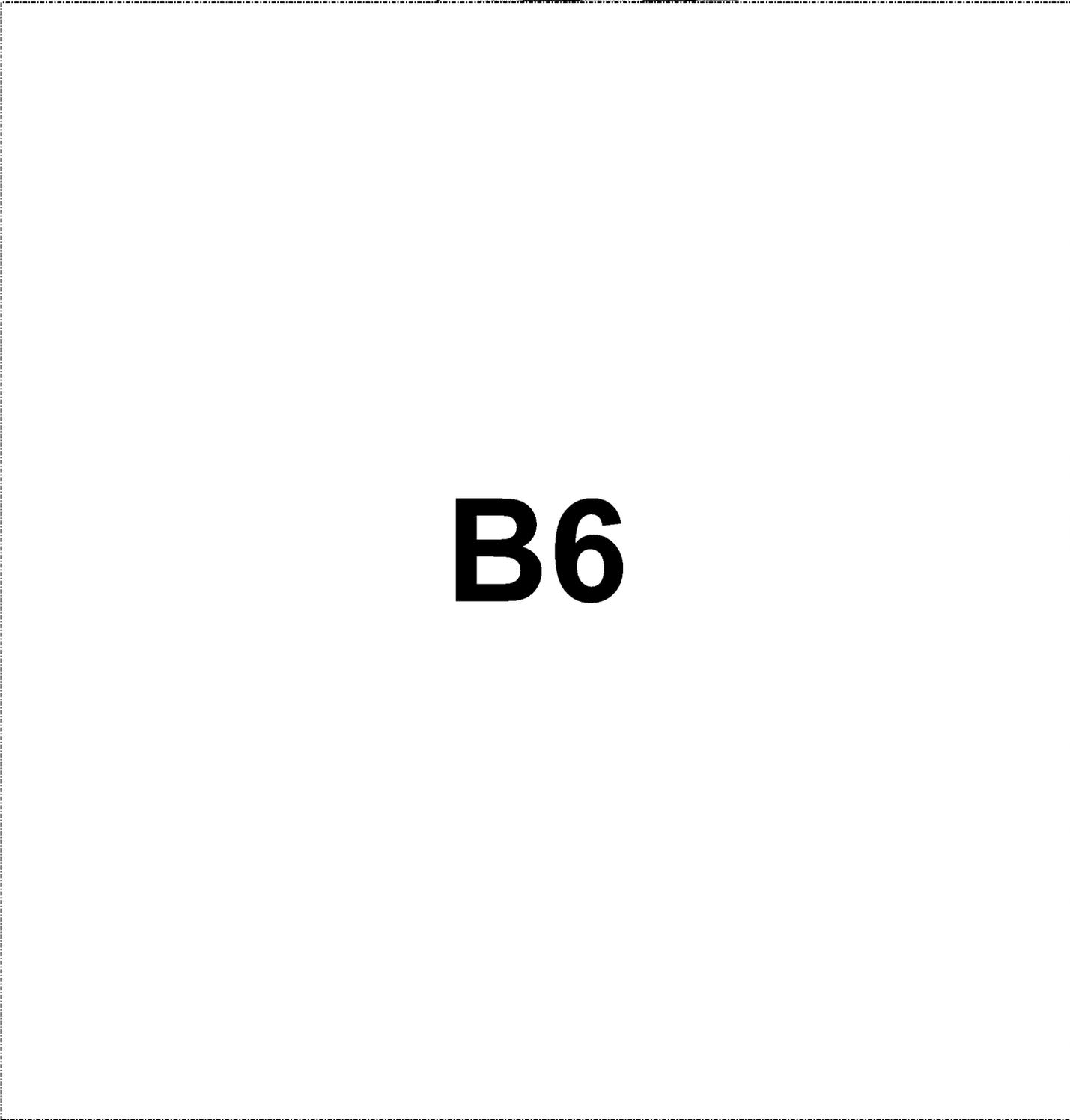
NAME  
NAME  
SPAYE

B6

ISS  
EEC

B6 (Canine)  
Breed: Vizsla Mix  
Color: Chocolate Wt: 69.4 pounds  
Sex: Neutered Male D.O.B. B6

AGE



B6

OWNER

PET'S NAME

TEMPERAMENT

B6

B6

B6

ADDRESS

BREED

B6

Canine)

Breed: Vizsla Mix

Color: Chocolate Wt: 69.4 pounds

Sex: Neutered Male

D.O.B.

B6

AGE

B6

B6

TEMPERAMENT

B6

TEMPERAMENT

B6

B6

NAME C

B6

NAME C

SPAYED

SS

B6 (Canine)

Breed: Vizsla Mix

ED

Color: Chocolate Wt: 80 pounds

Sex: Neutered Male

D.O.B.

B6

SE

B6

B6

MVC

B6

ADDRESS  
BREED

B6 (Canine)  
Breed: Vizsla Mix  
Color: Chocolate Wt: 60 pounds  
Sex: Neutered Male

D.O.B. B6

B6


OWNER

PET'S NAME

TEMPERAMENT

B6

B6

B6

ADDRESS

BREED

B6 (Canine)

Breed: Vizsla Mix

Color: Chocolate Wt: 60 pounds

Sex: Neutered Male

D.O.B.

B6

B6

PET'S NAME

B6

B6

### MEDICAL HISTORY

10-Oct-2018 to 23-Jan-2019

#### Client

**B6**  
Home: **B6**

#### Patient

**B6** **B6**  
Canine  
Mixed Breed; Vizsla  
Brown  
Male / Neutered - 65.1 lb (23-Jan-2019)

Most recent visit date: **B6**  
Microchip No.: n/a  
Rabies tag ID / date : n/a

Patient Alerts: n/a

Current medical overview: as of **B6**

#### Weight by Age

Wt.

Record date

**B6**

**B6**

23-Jan-2019  
08-Jan-2019  
10-Oct-2018

#### Active Concerns

Established

n/a

#### Inactive Concerns

Established

**B6**

#### Resolved Concerns (since 10-Oct-2018)

Established Resolved

Concern	Established	Resolved
Prednisone toxicity	10-Oct-2018	10-Oct-2018
Pruritus	10-Oct-2018	10-Oct-2018
Taurine deficiency	10-Oct-2018	22-Oct-2018
Dilated cardiomyopathy	10-Oct-2018	23-Jan-2019
First-degree AV heart block	10-Oct-2018	23-Jan-2019
Overweight	10-Oct-2018	23-Jan-2019

#### Medications (since 23-Jan-2018)

Amount Disp. Date

**B6** **Early Cardiac K9 7.7lb** 1.00 bag 19-Sep-2018  
Feed as directed.

**Outpatient visit (10-Oct-2018 to 10-Oct-2018)**

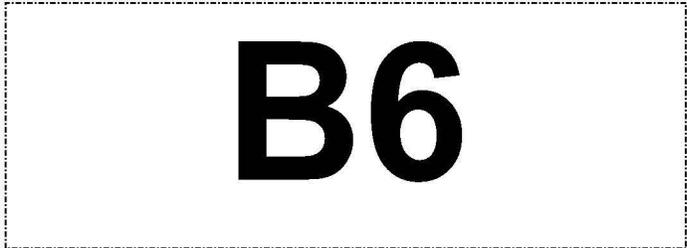
Appointment Type: **Recheck** Provider: **B6** **DVM, DACVN** Sex / age / weight: **Male - Neutered** / **B6** **31.5 kg** (10-Oct-2018)

**Concerns (Problem List)**

Active

- **Taurine deficiency** (10-Oct-2018)
- **Dilated cardiomyopathy** (10-Oct-2018)
- **Overweight** (10-Oct-2018)

Inactive



**B6** **Exam** **B6** **DVM, DACVN**

14:18

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain	BCS
14:18	101.5	100	28	--	< 2	Pink	0	6

CLIENT INTERVIEW

- Presenting concerns
- Medication history
- Diet history

**DCM, overweight - progress evaluation** - Initial consult 8/15/18, last recheck 9/5/18

**Flovent** - Q24h; Prednisone - absent - History of adverse reaction to prednisone

**Diet history** -

Current Diet: Royal Canin Veterinary Diet Early Cardiac dry (309 kcal/cup) - 1.5 cups 2x/day = 927 kcal/day. 50 mg Na/100 kcal = 464 mg Na/day

Previous Diets:

- Rotation between various flavors: Honest Kitchen Grain Free Beef, 1.5 cups 2x/day. 514 kcal/cup (rehydrated; kcal/cup for dry measure not provided) // Honest Kitchen Grain Free Turkey, 1.5 cups 2x/day. 488 kcal/cup // Honest Kitchen Grain Free Vegetarian premix, 1.5 cups 2x/day; 370 kcal/cup, WITH added 85% lean ground beef or TruDog raw beef diet (3/4 cup 2x/day)
- Taste of the Wild Salmon. Has avoided chicken/duck-based diets.

Treats:

- Zuke's Mini Naturals (3 kcal/treat) 2/day = 6 kcal/day
- VeggieDent chews, 102 kcal/treat, 4-5/week = ~68 kcal/day
- Cooked egg, 80 kcal/egg, 2-3/week = ~29 kcal/day
- Imagine pumpkin soup, 1/2 cup diluted with water/day. 60 kcal/cup, 590 mg Na/cup = 983 mg/100 kcal. 30 kcal/day, ~300 mg Na/day (total diet: 50 --> 74 mg Na/100 kcal)
- egg (1/week), Newman's Own chicken flavor treats 3/day, vegetable soup, bully stick, carrot, pear.
- Hx taco cheese (1/4 handful 2x/day), salmon skin treats, raw or cooked egg (1-2/week), peanut butter (1/tsp/pill), pumpkin

Supplements:

- Now Foods taurine 1000 mg PO q12h
- Hx Fortiflora 1 packet/day - stool quality fine without probiotic
- Hx Nutritional yeast - discontinued

Daily Calorie Intake: 1057 kcal/day (1.24\*RERideal), with 927 kcal/day from main diet + ~130 kcal/day from treats

Diagnostic history

**Summary of prior diagnostics** -

07/11/18: Echocardiogram: Mild DCM. Mild moderate myocardial failure of LV, no eccentric hypertrophy on LV. No LAE. No MR. Right heart normal in size. No pleural effusion, pericardial effusion, or ascites. ECG: HR 70 bpm, sinus bradycardia, first degree AV block. BP #3 RPL 160, 145, 145 mmHg (HR 80).

07/11/18: Whole blood taurine: 148 nmol/ml (200-350)

History

**General history** - Hx eosinophilic bronchopneumopathy - in remission. Bradycardia, first degree AV block. Mild DCM, taurine deficiency. Owner reports **B6** is doing well; has had fewer walks lately (owner was caring for friend in hospice). Owner had detailed phone interview with

\*Documents are available as separate attachments or files.

10-Oct-2018 Exam

**B6**

DVM, DACVN

14:18

FDA investigator to confirm history and provide additional information.

Weight history

**B6**

EXAM FINDINGS

**B6**

ASSESSMENTS

**B6**

**Dilated cardiomyopathy**

Mild

**Taurine deficiency**

07/11/18: Whole blood, **B6** mol/mL

**B6**

\*Documents are available as separate attachments or files.

**10-Oct-2018 Exam**

**B6**

**DVM, DACVN**

**14:18 Prednisone toxicity**

PLANS

**Taurine deficiency, Dilated cardiomyopathy, Overweight**

- Happy with weight progress! Losing weight within goal range. Can either continue with current diet plan, or consider transition to lower-calorie options from initial plan if volume of food seems too low. Make sure to track treat allowance adherence - currently slightly over.
- Submitted recheck whole blood taurine to UC Davis to assess progress.
- Scheduled for recheck echo in 1/08/19 at 10:15 am.
- Plan to email taurine update and discharge instructions within the next week.

**10-Oct-2018 Order items**

- Nutrition Reassessment [3.50]: 1.00 each
- Taurine Level UCD [127.27]: 1.00 test
  - Shipping/Handling \$20 [44.93]: 1.00 each

**Non-visit note**

Provider: **B6** **DVM, DACVN** Sex / age / weight: **Male - Neutered** / **B6** / **29.4 kg** (08-Jan-2019)

**Concerns (Problem List)**

- |  |  |
|--|--|
| Active                                 | Resolved   |
| • Dilated cardiomyopathy (10-Oct-2018) | • <b>Taurine deficiency</b> (10-Oct-2018 to 22-Oct-2018) |
| • Overweight (10-Oct-2018)             |  |

**22-Oct-2018 Progress note**

**B6**

**DVM, DACVN**

**17:40**

ASSESSMENTS

**Taurine deficiency**

Resolved  
 Initial whole blood taurine level (07/11/18): **B6** mol/ml  
 Recheck whole blood taurine after diet change and oral supplementation (10/22/18): **B6** mol/mL  
 Normal whole blood taurine >250 nmol/L

**Documents\***

22-Oct-2018 **B6** 2019-01-23\_Taurine Results from Amino Acid Lab .pdf

**Echocardiogram report**

**08-Jan-2019 Echocardiogram**

**B6**

**DVM, DACVIM, PhD Cardiology**

**10:00** Order item: Echocardiogram Recheck [23.39]

Findings

**B6**

\*Documents are available as separate attachments or files.



**Echocardiographic diagnosis:** unremarkable echocardiogram

**Electrocardiogram report**

**08-Jan-2019 Electrocardiogram** **B6** **DVM, DACVIM, PhD Cardiology**

**10:00** Order item: ECG Complete [39.58]

Report 6 lead Electrocardiogram:  
Heart rate: 92 bpm  
Rhythm: sinus arrhythmia

**Outpatient visit (08-Jan-2019 to 08-Jan-2019)**

Appointment Type: **Exam Consultation** **B6** Provider: **B6**, **DVM, DACVIM, PhD Cardiology** Sex / age / weight: **Male - Neutered** **B6** / **29.4 kg** (08-Jan-2019)

**Concerns (Problem List)**

- Active
• Dilated cardiomyopathy (10-Oct-2018)
• Overweight (10-Oct-2018)

**08-Jan-2019 Exam** **B6** **DVM, DACVIM, PhD Cardiology**

**10:08** Assisted by **B6** **B6**

VITALS table with columns: Temp (F), HR, RR, SBP, CRT, MM color, Pain, BCS. Values: 100.8, 98, 30, --, < 2, Pink, --, 5.

**CLIENT INTERVIEW**

Presenting concerns Recheck
Diet history Prescription diet - Royal Canine veterinary diet early cardiac dry with cooked eggs
Medication history Prescription medications - Taurine 1,000 mg - BID
Respiratory history B6 SID
No cough; Respiratory effort - Normal; Sleeping respiratory rate - Not doing RR

\*Documents are available as separate attachments or files.

**08-Jan-2019 Exam**

**B6**

**DVM, DACVIM, PhD Cardiology**

**10:08**

Assisted by: B6

B6

Activity and exercise history No exercise intolerance; No syncope  
 Digestive history No vomiting/diarrhea  
 Appetite history Normal appetite

EXAM FINDINGS

B6

ASSESSMENTS

**Dilated cardiomyopathy**

Resolved myocardial failure after switching diet to diet with grains and taurine supplementation. Recommend life long taurine supplementation. Prognosis is good at this time, but it is possible myocardial failure could re-emerge, so recommend rechecking echocardiogram in 1 year. Discussed that may not require such a low salt cardiac diet as currently feeding, recommend general adult diet with grains.

PLANS

**Dilated cardiomyopathy**

Continue taurine 1 G PO BID  
 echocardiogram 1 year

**08-Jan-2019 Order items**

- Cardiology Reassessment [3.22]: 1.00 each
- Echocardiogram Recheck [23.39]: 1.00 proc
  - Specialty Interpretation of US Study Limited [23.139]: 1.00 proc
- ECG Complete [39.58]: 1.00 proc

**Documents\***

- 08-Jan-2019 • B6 2019-01-23\_ECG.pdf
- B6 2019-01-23\_Recs 12-5-18-1-9-19.pdf
- B6 2019-01-23\_Echo Report 7-11-18.pdf

**Communication logs**

	Source	From	To	Created by/date
<b>16-Jan-2019</b> 19:10	Email	<span style="border: 1px dashed black; padding: 2px;">B6</span> DVM, DACVN	<span style="border: 1px dashed black; padding: 2px;">B6</span>	<span style="border: 1px dashed black; padding: 2px;">B6</span> /16-Jan-2019
		<p><b>Recommend continuing taurine supplementation as per <span style="border: 1px dashed black; padding: 2px;">B6</span> instructions</b></p> <p>From: <span style="border: 1px dashed black; padding: 2px;">B6</span></p>		

\*Documents are available as separate attachments or files.

B6 | B6

**MEDICAL HISTORY:** 10-Oct-2018 to 23-Jan-2019

Source	From	To	Created by/date
	Sent: Wednesday, January 16, 2019 7:09 PM		
	To: <b>B6</b>		
	Subject: Update on: <b>B6</b>		

Hi **B6**

I'm glad to hear that we saw great results at **B6** most recent recheck with **B6** and that both his heart and weight have improved. I agree with **B6** recommendations regarding continued taurine supplementation. You can continue with his current main diet long-term if desired; if you'd like additional options or further dietary recommendations, I'd be happy to see you and **B6** for another recheck.

Best,

**B6** DVM, DACVN  
**B6**  
**B6**

**Outpatient visit** (23-Jan-2019 to 23-Jan-2019)

Appointment Type: **Recheck** Provider: **B6** **DVM, DACVN** Sex / age / weight: **Male - Neutered** **B6** / **65.1 lb** (23-Jan-2019)

**Concerns** (Problem List)

Resolved

- **First-degree AV heart block** (10-Oct-2018 to 23-Jan-2019)
- **Overweight** (10-Oct-2018 to 23-Jan-2019)
- **Taurine deficiency** (10-Oct-2018 to 22-Oct-2018)
- **Dilated cardiomyopathy** (10-Oct-2018 to 23-Jan-2019)

**23-Jan-2019 Exam** **B6** **DVM, DACVN**

10:27

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain	BCS
10:27	101.8	<b>150</b>	30	--	< 2	Pink	0	5

CLIENT INTERVIEW

Diet history

**Diet history** -

Current Diet:

- Royal Canin Veterinary Diet Early Cardiac dry (309 kcal/cup) - 1.5 cups 2x/day = 927 kcal/day. 50 mg Na/100 kcal = 464 mg Na/day.
- Transitioning to Royal Canin Large Adult dry (OTC) but unsure how much to feed.
- Taste of the Wild lamb/turkey canned ~1 tbsp with meals

Previous Diets:

- Rotation between various flavors: Honest Kitchen Grain Free Beef, 1.5 cups 2x/day. 514 kcal/cup (rehydrated; kcal/cup for dry measure not provided) // Honest Kitchen Grain Free Turkey, 1.5 cups 2x/day. 488 kcal/cup // Honest Kitchen Grain Free Vegetarian premix, 1.5 cups 2x/day; 370 kcal/cup, WITH added 85% lean ground beef or TruDog raw beef diet (3/4 cup 2x/day)
- Taste of the Wild Salmon. Has avoided chicken/duck-based diets.

Treats:

- Zuke's Mini Naturals (3 kcal/treat) 2/day = 6 kcal/day
- VeggieDent chews, 102 kcal/treat, 4-5/week = ~68 kcal/day
- Cooked egg, 80 kcal/egg, 1/2 egg 1-2/week = ~9 kcal/day
- Discontinued treats: Imagine pumpkin soup, 1/2 cup diluted with water/day. 60 kcal/cup, 590 mg Na/cup = 983 mg/100 kcal. 30 kcal/day, ~300 mg Na/day (total diet: 50 --> 74 mg Na/100

\*Documents are available as separate attachments or files.

**B6**  
**B6** | **B6**

23-Jan-2019 Exam

**B6**

DVM, DACVN

10:27

kcal); Newman's Own chicken flavor treats 3/day, vegetable soup, bully stick, carrot, pear, Hx taco cheese (1/4 handful 2x/day), salmon skin treats, raw or cooked egg (1-2/week), peanut butter (1/tsp/pill), pumpkin

Supplements:

- Now Foods taurine 1000 mg PO q12h
- Hx Fortiflora 1 packet/day - stool quality fine without probiotic
- Hx Nutritional yeast - discontinued

Daily Calorie Intake: 1010 kcal/day (1.1\*REIdeal), with 927 kcal/day from main diet + ~83 kcal/day from treats

Diagnostic history

**Summary of prior diagnostics -**

07/11/18: Echocardiogram: Mild DCM. Mild moderate myocardial failure of LV, no eccentric hypertrophy on LV. No LAE. No MR. Right heart normal in size. No pleural effusion, pericardial effusion, or ascites. ECG: HR 70 bpm, sinus bradycardia, first degree AV block. BP #3 RPL 160, 145, 145 mmHg (HR 80).

07/11/18: Whole blood taurine: **B6** nmol/ml (200-350)

10/22/18: Whole blood taurine: **B6** nmol/mL (normal range >250)

01/08/19: Echocardiogram - unremarkable; no DCM noted. ECG - sinus arrhythmia.

History

Weight history

**B6**

Medication history

Presenting concerns

**DCM, overweight - progress evaluation** - Initial consult 8/15/18, last recheck 10/10/18

EXAM FINDINGS

**B6**

\*Documents are available as separate attachments or files.

23-Jan-2019 Exam

**B6**

DVM, DACVN

10:27

**B6**

ASSESSMENTS

**Overweight**

Weight 29.6 kg = 65.1 lbs, BCS 5.5/9  
RER for current weight = 888 kcal/day

**Dilated cardiomyopathy, First-degree AV heart block, Taurine deficiency**

FDA Individual Case Safety Report Number (ICSR) of 2053786

PLANS

**Overweight, Dilated cardiomyopathy, Taurine deficiency**

- Discussed happy with weight loss progress; okay to lose a few more pounds (initial estimated ideal weight was ~62 lbs) but okay to maintain at current weight given past history of cardiac changes; would not recommend weight gain.
- Agree with **B6** recommendation to continue long-term taurine supplementation.
- Current OTC dry diet sounds like a good choice; can also offer additional OTC options meeting our goals: low calorie, avoid very high salt (but restriction to very low salt diets is unnecessary), conventional ingredients, reputable manufacturer. Can look at both canned and dry diets. Ok to use current treats as long as we remain within a ~10% treat allowance. Discussed that continued fish oil supplementation is optional.
- If doing well and maintaining weight, continue monitoring and follow up per **B6** instructions. Additional nutrition rechecks can be scheduled if there are any questions/concerns/changes in medical status, but otherwise ok to continue care with primary care veterinarian and **B6**.
- Will follow up with FDA to ask about sample submission, paying for echo, etc. Discussed possible delay in response due to gov't shutdown.
- Suggested changing to softer harness if collar/leash may be rubbing against **B6** neck; if hypotrichosis persists/worsens or if **B6** is pruritic, recommend following up with primary care veterinarian and/or dermatologist.
- Discharges to follow by email.

**23-Jan-2019 Order items**

- Nutrition Reassessment [3.50]: 1.00 each

\*Documents are available as separate attachments or files.

**Report Details - EON-375244**

ICSR:	2060788
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:	2019-01-02 20:15:15 EST

<b>Reported Problem:</b>	<b>Problem Description:</b>	Initially presented to the [B6] Service for a 4 to 5 day history of lethargy, increased RR and ADP. Had been fed a grain-free diet for an extended period of time. Was evaluated by the Cardiology Service and diagnosed with decreased systolic function and secondary heart enlargement. Chest x-rays from the rDVM raised suspicion for congestive heart failure. However, repeat chest x-rays at [B6] showed no evidence of CHF. During his hospitalization [B6] experienced a syncopal episode secondary due to a run of ventricular tachycardia. He was started on heart failure therapy (pimobendan, furosemide, spironolcatone, enalapril) as well as taurine supplementation and an anti-arrhythmic (sotalol). He was initially started on L-carnitine as well, but this medication caused GI side effects and was discontinued.
	<b>Date Problem Started:</b>	08/12/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Stable

<b>Product Information:</b>	<b>Product Name:</b>	Horizon Pulsar Chicken Flavor Dog Kibble		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Purchase Date:</b>	06/01/2018		
	<b>Possess Unopened Product:</b>	Unknown		
	<b>Possess Opened Product:</b>	Unknown		
	<b>Product Use Information:</b>	<b>Description:</b>	Fed to the pet for approximately 6 years	
		<b>Time Interval between Product Use and Adverse Event:</b>	6 Years	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
		<b>Adverse Event Abate After Product Stop:</b>	Unknown	
		<b>Product Use Started Again:</b>	No	
<b>Perceived Relatedness to Adverse Event:</b>		Probably related		
<b>Manufacturer /Distributor Information:</b>				
<b>Purchase Location Information:</b>				

<b>Animal Information:</b>	<b>Name:</b>	[B6]
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Mixed (Dog)
	<b>Gender:</b>	Male

	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	21 Kilogram	
	<b>Age:</b>	8 Years	
	<b>Assessment of Prior Health:</b>	Excellent	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b>	Yes
		<b>Contact:</b>	<b>Name:</b> B6
			<b>Phone:</b> B6
			<b>Other Phone:</b> B6
			<b>Email:</b> B6
<b>Address:</b>	B6 United States		
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6	
	<b>Contact:</b>	<b>Name:</b> B6	
		<b>Phone:</b> B6	
		<b>Email:</b> B6	
	<b>Address:</b>	B6 United States	
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6 United States	
	<b>Contact:</b>	<b>Phone:</b>	B6
		<b>Email:</b>	B6
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
	<b>Reported to Other Parties:</b>	None	
<b>Additional Documents:</b>	<b>Attachment:</b>	B6 Troponin and Taurine Levels.pdf	
	<b>Description:</b>	Lab results (taurine and troponin)	
	<b>Type:</b>	Laboratory Report	
	<b>Attachment:</b>	B6 Most Recent Discharge.pdf	
	<b>Description:</b>	Recheck discharge instructions	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	B6 Initial Discharge.pdf	
	<b>Description:</b>	Initial discharge instructions	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	B6 Echo Report.pdf	

**Description:** Echocardiogram report

**Type:** Echocardiogram

B6

B6

Name: B6	MRN: B6	Visit Number: 01
Study Date: B6 09:17 AM	Breed: MIXB	Ordering Physician: B6 DVM, Dipl. ACVIM (Cardiology)
DOB: B6	Species: Canine	Weight: 21.2 kg Referring Physician: B6
Age: 7 yrs	Gender: Male	

**Chief Concerns/Major History**

Patient presented to the Emergency service for evaluation of a 4-5 day history of lethargy, increased respiratory rate, and being ADR. Evaluated by his primary care veterinarian last night, at which time heart murmur was noted, and thoracic radiographs and blood work were performed. Reportedly, blood work showed elevated liver values and an increased hematocrit. He was started on B6 mg PO BID last night. Upon presentation to the Emergency service, he was tachycardic and tachypneic, and a systolic heart murmur was detected. He has been fed a grain free diet.

**Physical Examination**

QAR, nervous. MMs light pink, moist, CRT 2.5 s. HR = 160 bpm, regularly irregular rhythm with suspected premature beats. Grade V/VI right apical systolic heart murmur, grade IV/VI left apical systolic heart murmur. Focal extra heart sound (possibly gallop) at left apex. Weak femoral pulses with frequent pulse deficits. RR = 60 breaths per minute in between panting with mildly increased respiratory effort with mild abdominal component. No crackles or wheezes on auscultation. Some referred upper respiratory sounds heard while panting. Abdomen soft and non-painful, no fluid wave detected.

**ECG**

Six-lead ECG shows an underlying sinus tachycardia with occasional polymorphic single VPCs along with ventricular couplets and triplets. Average HR = Tall R wave in lead II. Normal mean electrical axis.

**MMode/2D Measurements & Calculations**

B6

B6

**Time Measurements**

B6

**B6****Doppler Measurements & Calculations****B6****2-D Study****B6****Cardiac Diagnosis**

- 1) Severe left ventricular dilation and poor systolic function - r/o nutritional cardiomyopathy (taurine deficiency, related to grain-free diet, other) vs. myocarditis vs. dilated cardiomyopathy (DCM)
- 2) Severe mitral and tricuspid regurgitation - degenerative valve disease + atrioventricular annulus dilation
- 3) Polymorphic ventricular premature complexes (VPCs) - singlets, couplets, triplets, non-sustained runs of ventricular tachycardia
- 4) Moderate pulmonary hypertension.

**Assessment/Prognosis**

The patient's severe left ventricular dilation and poor systolic function could be due to nutritional cardiomyopathy (taurine deficiency, related to grain free diet, other), myocarditis, or primary dilated cardiomyopathy (DCM). Plasma or whole blood taurine level and cTnI level are recommended. The significant mitral and tricuspid regurgitation are likely due to both degenerative valve changes plus valve annulus stretch/dilation secondary to poor systolic function and left ventricular dilation. Thoracic radiographs obtained by his primary care veterinarian yesterday showed severe cardiomegaly and a mild diffuse bronchointerstitial pulmonary pattern (increased interstitial component in perihilar and caudodorsal lung fields). The rhythm diagnosis is sinus tachycardia with frequent polymorphic VPCs that occur in singlets, couplets, triplets, and few non-sustained runs of ventricular tachycardia. Initiation of CHF therapy and ant-arrhythmic therapy (sotalol) is recommended as outlined below. Prognosis depends on the underlying cause, however currently he is at increased risk for CHF, worsening arrhythmias, which could result in sudden death, and progressive signs of poor cardiac output.

**B6**

Follow up with the Cardiology service is recommended in 5-7 days for recheck renal panel, ECG, +/- Holter monitor, +/- thoracic radiographs.

**Addendum**

The patient had a syncopal episode in the emergency room, during which time, continuous ECG showed a run of ventricular tachycardia which converted to sinus tachycardia prior to ant-arrhythmic therapy. Patient was admitted to the hospital for continuous ECG monitoring and care.

Performed By:

B6

B6	DVM, MSCE, ACVIM (Cardiology)
B6	Dr med vet, PhD, ACVIM (Cardiology), ECVIM-CA (Cardiology)
B6	DVM, ACVIM (Cardiology, Internal Medicine), ECVIM-CA (Cardiology)

B6	VMD, Resident
B6	VMD, Resident
B6	DVM, Resident

**B6**

Case Number: B6  
Patient: B6  
CANINE, MIXED CANINE Born: B6, MALE, Castrated  
Owner: B6  
Primary Vet: B6  
Primary Clinician: B6  
Supervising Clinician: B6  
Service: CARDIOLOGY  
Admission Date: B6  
Weight: 21.200 kg(s)

B6  
B6  
Appointments: B6 • Emergency: B6 • Pharmacy: B6

Diagnoses:	Diagnosis 1 ( <i>Confirmed</i> ): Severe left ventricular dilation and poor systolic function Diagnosis 2 ( <i>Confirmed</i> ): Severe mitral and tricuspid regurgitation Diagnosis 3 ( <i>Confirmed</i> ): Polymorphic ventricular premature complexes Diagnosis 4 ( <i>Confirmed</i> ): Moderate pulmonary hypertension
Presenting Complaint:	B6 presented to the B6 on B6 for a 5 day history of lethargy, increased respiratory rate, and decreased appetite.
Discussion:	<p>On presentation, B6 had an elevated heart rate and elevated respiratory rate. His physical exam revealed a loud heart murmur and weak femoral pulses with occasional dropped beats.</p> <p>B6 echocardiogram revealed severe dilation of his heart and a decreased ability of his heart to effectively pump blood. This may be secondary to a nutritional deficiency, inflammation of the heart, or primary heart disease (dilated cardiomyopathy). B6 electrocardiogram (ECG) also showed abnormal beats and periods of an abnormal heart rhythm called ventricular tachycardia.</p> <p>While in the emergency room, B6 experienced a syncopal episode during which his heart was beating abnormally and he collapsed. His heart converted back to a normal rhythm on its own before anti-arrhythmic medications were administered.</p> <p>He was maintained overnight on his cardiac medications and a continuous ECG to monitor his heart rate and rhythm. Throughout the night he still showed occasional abnormal beats but had no more prolonged arrhythmias and had no additional syncopal episodes. When he was resting his heart rate came back down into the normal range. B6 breathing has improved compared to when he first came in although his breathing rate remains mildly increased. He is able to oxygenate his blood appropriately, and his chest x-rays showed no evidence of heart failure.</p> <p>Blood was drawn and submitted to test his taurine level. Taurine is a specific nutrient that is required for normal heart function. Blood was also run to test his cardiac troponin which is a marker associated with damage to the heart muscle. The cardiology department will follow up with you regarding the results of these tests.</p>
Procedures:	Procedure 1: SpO2 Procedure 2: NIBP Procedure 3: NOVA Procedure 4: ECG Procedure 5: Echocardiogram Procedure 6: Chest x-rays

Recommendations:

MONITORING

1. Respiratory Rate: It is important to become familiar with your dog's normal resting respiratory rate and effort. An increase in either of these is one of the first signs of fluid in the lungs and should be monitored regularly. When your dog is at rest, watch their sides rise and fall as they breathe normally. One rise and fall cycle is equal to one breath. Count the number of breaths they take in 15 seconds, then multiply this number by 4 to get total breaths per minute. For example, if you count 8 breaths in 15 seconds, that is equal to 32 (8 x 4) breaths per minute. A normal dog at rest should have a respiratory rate less than 40. If you notice this number increasing consistently, or notice an increase in the effort it takes to breathe, please contact [B6] or your local veterinarian.

2. General: Monitor for any lethargy, exercise intolerance, coughing or decreased appetite. Contact Dr. [B6] or your local veterinarian if you notice any of these signs. If you observe any episodes of weakness, pale gums, or collapse, [B6] should be taken to the nearest emergency room.

DIET CHANGE

The changes seen in [B6] heart may be caused by a nutritional deficiency that may be associated with his grain free diet. We recommend switching him to a non-grain free diet. Any balanced commercial diet that is not grain free is appropriate.

DIET SUPPLEMENTATION

You may consider supplementing [B6] diet with taurine and L-carnitine according to the instructions below. These supplements can be purchased from most health food stores and/or grocery stores. Depending on the results of the taurine test, long-term supplementation with taurine may not be required.

- 1. Taurine - 1 g by mouth twice daily with food
- 2. L-carnitine - 1 g by mouth twice daily with food

Follow Up:

Please schedule an appointment with the Cardiology Department in 5-7 days for recheck bloodwork (renal panel), ECG, and possibly Holter monitor placement.

Please contact our Cardiology Nurse [B6] ([B6]) to arrange a Nurse Practitioner appointment.

Please do not hesitate to contact us sooner with any questions or concerns.

**B6**

In compliance with state and risk management guidelines, all Pharmacy items, including drugs, fluid therapy, nutritional products and food are non-returnable. This policy is to protect your pet from receiving items that may have been tampered with or improperly used. The exception to this policy is pet foods that display a manufacturer's warranty.

For drug related questions please call the pharmacy at

Drug	Quantity Dispensed	Unit Strength	Instructions
------	--------------------	---------------	--------------

Drugs:

**B6**

Discharge  
Instructions:  
Clinician and  
Finalize Date:

VMD   
Cardiology Resident

Client picking up  
animal:  
(sign)

Date: \_\_\_\_\_

Please help us help dogs. Please complete our survey at:   
All dogs, whether diabetic or not, are encouraged to participate.

# CONGESTIVE HEART FAILURE

## What is Congestive Heart Failure (CHF)?

Heart failure, a clinical syndrome that is the end result of severe heart disease, describes the inability of the heart to pump blood with normal efficiency and keep up with the body's demands. Heart failure may be due to failure of the right, left, or both ventricles (chambers) of the heart to pump adequately.

Congestive heart failure, or CHF, is the final stage of heart failure when the body starts to 'leak' fluid into the lungs (pulmonary edema), the abdomen (ascites), or into the chest cavity (pleural effusion). The different stages of heart failure, mild to life-threatening, will dictate the symptoms in your pet

Causes include, but are not limited to:

- Decreased myocardial (heart muscle) contractility, which is commonly seen with dilated cardiomyopathy, a disease caused by weak heart muscle contractions.
- Valvular regurgitation as seen with mitral and tricuspid regurgitation, a disease that causes leaks in the heart valves.
- Increased myocardial stiffness impairing the heart's ability to fill with blood, as seen in feline hypertrophic cardiomyopathy, a disease caused by thickened heart muscle walls.

## What is the difference between right-sided and left-sided CHF?

Right-sided CHF occurs when blood returning from the body is impeded while draining into the right atrium and right ventricle. This 'back up' of blood creates excessive fluid in the abdomen (ascites), or fluid around the lungs (pleural effusion). Common clinical signs are distention of the abdomen, loss of appetite, and exercise intolerance.

Left-sided CHF occurs when blood from the lungs has difficulty returning to the left atrium and left ventricle. This leads to fluid accumulation within the lungs (pulmonary edema). Common clinical signs are increased respiratory rate, coughing, fainting, exercise intolerance, and loss of appetite.

## What are the goals of CHF treatment?

The primary goal of treating CHF is to manage the symptoms by reducing fluid accumulation in or around the lungs and abdomen. A variety of therapies are available and can be tailored to meet your pet's needs.

Treatment varies depending on the cause of the heart failure. The majority of patients with CHF will be on a combination of drugs to help alleviate the symptoms.

- A diuretic (water pill) is often the first medication prescribed. This medication will help alleviate fluid accumulation, and cause your pet to urinate and drink more frequently.
- Pimobendan and/or digoxin is medication to increase the 'pumping' ability of the heart.
- ACE inhibitors are drugs that help blood vessels dilate.
- A sodium-restricted diet may be recommended, along with restricted exercise.

Since diuretics increase the workload on the kidneys, your veterinarian may discuss performing periodic blood work exams to monitor kidney function. Depending on the nature of your dog's symptoms, additional drugs may be prescribed to help control fluid accumulation or abnormal heart rhythms. Please keep in mind that heart-failure therapy is a dynamic process and will require regular checkups with your veterinarian to ensure your pet's needs are being met.

## What should I monitor at home?

It is important that you monitor your pet's overall attitude and any change in appearance.

Count respiratory rates at home. Your pet's respiratory rate should typically be less than 40 breaths per minute. If the respiratory rate increases above its normal rate or is above 40 breaths per minute, contact your veterinarian.

If you notice any of the following, call your veterinarian:

- heavy or labored breathing
- coughing
- reduction in appetite
- fainting spells
- restlessness

# B6

# DILATED CARDIOMYOPATHY

## What is dilated cardiomyopathy (DCM)?

Dilated cardiomyopathy (DCM) is a disease of the heart characterized by poor contractions of the heart muscle. The weakened heart muscle results in a decrease in the amount of blood pumped out to the body and lungs.

As the heart fails to pump effectively, a backup of blood can result in congestive heart failure. If the left side of the heart fails, fluid backs up into the lungs, causing coughing and/or difficulty breathing. If the right side of the heart fails, fluid backs up into the abdomen, causing abdominal distension or fluid in the space surrounding the lungs. DCM also can cause abnormal heart rhythms, which can result in weakness or fainting episodes.

## What dogs are commonly affected by DCM?

DCM is most common in large-breed dogs such as the Doberman Pinscher, Boxer, Newfoundland, Great Dane, and the Irish Wolfhound. Most cases of DCM occur in middle-aged to older dogs. In certain breeds of dogs, such as the American Cocker Spaniel, DCM can be related to a dietary deficiency of taurine and/ or L-carnitine, which are protein building blocks.

## What is the long-term prognosis for DCM?

Long-term prognosis for dogs with DCM varies considerably. Some dogs with early DCM remain free of symptoms for years. In dogs with severe DCM, signs of congestive heart failure, fainting, or intolerance to activity can occur. Once symptoms of DCM occur, medical therapy is usually prescribed to help improve heart muscle function.

## Is there treatment available for dogs that have symptoms of DCM?

Dogs with DCM can develop congestive heart failure, which typically causes difficulty breathing or distension of the abdomen. The most common medications for dogs with congestive heart failure due to DCM include diuretics (water pills), such as furosemide and spironolactone, which help remove fluid that has accumulated in the abdomen or lungs; and ACE inhibitors, which dilate blood vessels; and pimobendan, which increases the strength of the heart muscle.

Side effects of diuretics and ACE inhibitors include increased thirst and urination. Since diuretics increase the workload on the kidneys, your veterinarian may discuss performing periodic blood work exams to monitor kidney function. Depending on the nature of your dog's symptoms, additional drugs may be prescribed to help control fluid accumulation or abnormal heart rhythms.

## Is there treatment available for dogs that are in the 'asymptomatic' or early phase of DCM?

Researchers have a great interest in therapy that slows disease while dogs are still symptom-free. One trial documented success of pimobendan to delay onset of symptoms in certain Doberman Pinschers with early DCM. Whether the success extends to other dog breeds is unknown. Other studies have suggested that a type of drug known as ACE inhibitors can also be of benefit in the early stages of DCM. Please consult your veterinarian to discuss the options if your dog has early DCM.

## What should I monitor at home?

It is important that you monitor your dog's overall attitude and any change in activity. Count respiratory rates at home. Your pet's respiratory rate should typically be less than 40 breaths per minute. If the respiratory rate increases above its normal rate or is above 40 breaths per minute, call your veterinarian.

If you notice any of the following, contact your veterinarian immediately:

- heavy or labored breathing
- coughing
- reduction in appetite
- fainting spells
- restlessness
- profound lethargy

# B6



# Measuring Respiratory Rate

My pet's next recheck: \_\_\_\_\_

## Why is respiratory rate important?

- Respiratory rate acquired at home can help predict the presence of congestive heart failure in the form of excess fluid in your pet's lungs or chest cavity.

## How do I measure my pet's respiratory rate?

- Watch your pet's chest move in-and-out. Each in-and-out cycle is one breath.
- While your pet is resting or sleeping, count how many breaths your pet takes in either 30 seconds or 1 minute.
- If you count the number of breaths in 30 seconds, multiply this number by 2, which will provide breaths per minute.

## What is a normal resting or sleeping respiratory rate?

- A normal resting or sleeping respiratory rate is usually between 10-30 breaths per minute.
- Most cats and dogs will have a respiratory rate that is consistently less than 25 breaths per minute.

## When should I be concerned about my pet's respiratory rate?

- If your pet's resting or sleeping respiratory rate is more than 40 breaths per minute, this could be a sign of congestive heart failure and you should contact your veterinarian.
- If your pet's respiratory rate has been consistent over time but then unexpectedly increases over several days in a row, this could be a sign of congestive heart failure and you should call your veterinarian.

## What are some tips to help me measure an accurate respiratory rate?

- Make sure your pet is calm and resting or sleeping when you take the rate
- Make sure your pet has not exercised prior to you taking the rate.
- Measure the rate at the same time each day, perhaps in the evening or at night when your pet is sleeping soundly.
- There are free iPhone and Android smartphone apps that can help you acquire your pet's respiratory rate. Search the appropriate app store on your phone. Two popular apps are "Cardalis" and "Resting Respiratory Rate".

Date	Respiratory Rate						

# B6

Report Details - EON-388960		
ICSR:	2067506	
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:	2019-05-28 15:31:05 EDT	
Reported Problem:	<b>Problem Description:</b> Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermittent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.	
	<b>Date Problem Started:</b> 05/17/2019	
	<b>Concurrent Medical Problem:</b> Yes	
	<b>Pre Existing Conditions:</b> Previously diagnosed (Jan 2019) with with a 1-2/6 heart murmur - asymptomatic, rDVM rec rechecking in 1 year.	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b>	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Spaniel - Cocker American	
	<b>Gender:</b> Female	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 14 Kilogram	
	<b>Age:</b> B6 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 1	
	<b>Number of Animals Reacted:</b> 1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b> Name: B6 Phone: B6
		<b>Address:</b> B6 United States
	<b>Healthcare Professional</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine

	<b>Information:</b>	<b>Contact:</b>	<b>Name:</b>	B6	
			<b>Phone:</b>		
			<b>Email:</b>	B6	
		<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States		
		<b>Practice Name:</b>	Tufts University Cummings School of Veterinary Medicine		
		<b>Contact:</b>	<b>Name:</b>	Lisa Freeman	
			<b>Phone:</b>	508 887 4696	
	<b>Type of Veterinarian:</b>	Referred veterinarian			
	<b>Permission to Release Records to FDA:</b>	Yes			
<b>Sender Information:</b>	<b>Name:</b>	B6			
	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States			
	<b>Contact:</b>	<b>Phone:</b>	B6		
		<b>Email:</b>	B6		
	<b>Permission To Contact Sender:</b>	Yes			
	<b>Preferred Method Of Contact:</b>	Email			
<b>Reported to Other Parties:</b>	None				
<b>Additional Documents:</b>	<b>Attachment:</b>	Med Rec pt 1.pdf			
	<b>Description:</b>	Medical Records			
	<b>Type:</b>	Medical Records			
	<b>Attachment:</b>	Med Rec pt 2.pdf			
	<b>Description:</b>	Medical Records			
	<b>Type:</b>	Medical Records			

**B6**

Case Number: **B6**  
Patient: **B6**  
CANINE, MIXED CANINE Born **B6** MALE, Castrated  
Owner: **B6**  
Primary Vet: **B6**  
Primary Clinician: **B6**  
Supervising Clinician: **B6**  
Service: CARDIOLOGY  
Admission Date: **B6**  
Discharge Date: **B6**  
Weight: 21.700 kg(s)

**B6**  
**B6**  
Appointments **B6** · Emergency **B6** · Pharmacy **B6**

Diagnoses:	Diagnosis 1 ( <i>Confirmed</i> ): Severe left ventricular dilation and poor systolic function Diagnosis 2 ( <i>Confirmed</i> ): Severe mitral and tricuspid regurgitation Diagnosis 3 ( <i>Confirmed</i> ): Polymorphic ventricular premature complexes Diagnosis 4 ( <i>Confirmed</i> ): Moderate pulmonary hypertension
Presenting Complaint:	<b>B6</b> a 7 year old male, castrated mixed breed was presented to the <b>B6</b> Cardiology Service for a Nurse Practitioner appointment for a recheck ECG, TFAST, and repeat Holter placement.
Discussion:	<p style="text-align: center;"><b>B6</b></p> <p>Respiration: Panting with slight increased effort - slightly harsh lungs sounds bilaterally, no crackles or wheezes - loud heart murmur with palpable thrill</p> <p>DIAGNOSTICS Blood pressure 130mmHg Doppler cuff #5 right front leg</p> <p>ECG An electrocardiogram was performed to assess <b>B6</b> heart rate and rhythm. His heart rate was still elevated, most likely due to his anxiety in the hospital. There were intermittent/occasional single and couplet ventricular premature contractions. These findings are subjectively similar to possibly mildly improved compared to his most recent results.</p>

	<p><b>Holter</b>  We are sending [B6] home again with a Holter monitor for further evaluation of his arrhythmia. These monitors are small devices kept in a pocket on the vest that are connected to three electrodes attached to the skin. It allows us to record extended ECG data. This will let us know more information regarding how often abnormal beats are occurring at home. This information will allow us to make a more informed decision as far as a diagnosis and possible need for treatment. It will also serve as data to compare to later on if the underlying rhythm deteriorates.</p> <p><b>TFast</b>  The heart ultrasound showed:  - No pericardial or pleural effusion  - Similar decrease in systolic function  - Significant mitral and tricuspid regurgitation  - No other significant abnormalities</p> <p><b>ASSESSMENT</b>  We are so happy that [B6] is doing well at home. The results from today's nurse practitioner recheck appointment will be communicated to [B6] and we will contact you to discuss results and additional recommendations.</p>
<p><b>Procedures:</b></p>	<p>Procedure 1: NIBP  Procedure 2: ECG  Procedure 3: Holter monitor placement  Procedure 4: TFast</p>
<p><b>Recommendations:</b></p>	<p><b>HOLTER MONITOR</b>  While the Holter monitor is on, please use the activity log provided to make note of any activities throughout the day (sleeping, barking at mailman, eating, medications given) making special note of any episodes of weakness or collapse. Please call or e-mail [B6] if you have any questions about this.</p> <p>Please remove the Holter monitor in 48 hours (at noon on Friday). Please do NOT use scissors to cut the tape, as this might damage the monitor equipment (cables). We are providing you with some moist wipes (Preppies) that you can use to make the ECG pads easier to remove. Please return the Holter monitor as soon as it is removed via the prepaid package we provided you with and we will contact you once we have analyzed the information (generally 1-2 days after it is received). Based on our results we will determine whether any further treatment is appropriate.</p> <p><b>MONITORING</b>  1. Respiratory Rate: It is important to become familiar with your dog's normal resting respiratory rate and effort. An increase in either of these is one of the first signs of fluid in the lungs and should be monitored regularly. When your dog is at rest, watch their sides rise and fall as they breathe normally. One rise and fall cycle is equal to one breath. Count the number of breaths they take in 15 seconds, then multiply this number by 4 to get total breaths per minute. For example, if you count 8 breaths in 15 seconds, that is equal to 32 (8 x 4) breaths per minute. A normal dog at rest should have a respiratory rate less than 40. If you notice this number increasing consistently, or notice an increase in the effort it takes to breathe, please contact [B6] or your local veterinarian.</p> <p>2. General: Monitor for any lethargy, exercise intolerance, coughing or decreased appetite. Contact Dr. [B6] or your local veterinarian if you notice any of these signs. If you observe any episodes of weakness, pale gums, or collapse, [B6] should be taken to the nearest emergency room.</p>
<p><b>Follow Up:</b></p>	<p>We will contact you with the Holter monitor results as soon as they are available (typically in 7 to 10 days). We will discuss a follow-up plan at that time.</p> <p>As always, [B6] is a terrific patient!</p> <p>[B6] CVT, VTS (ECC) - Cardiology Nursing Coordinator</p>

Medications:

Please continue all medications (including taurine supplementation) as previously prescribed.

**B6** has approved the addition of L-Carnitine (see dosing instructions below) & Omega 3 fatty acids (a liquid formulation called OmegaBenefits can be purchased online -- give as directed).

Drugs:

**In compliance with state and risk management guidelines, all Pharmacy items, including drugs, fluid therapy, nutritional products and food are non-returnable. This policy is to protect your pet from receiving items that may have been tampered with or improperly used. The exception to this policy is pet foods that display a manufacturer's warranty.**  
**For drug related questions please call the pharmacy at **B6****

Drug	Quantity Dispensed	Unit Strength	Instructions
------	--------------------	---------------	--------------

**B6**

Discharge Instructions: Clinician and Finalize Date:

**B6**

**B6** VMD **B6**  
Cardiology Resident

**B6**

Client picking up animal: (sign)

**B6** \_\_\_\_\_ Date: \_\_\_\_\_

Please help us help dogs. Please complete our survey at: **B6**  
All dogs, whether diabetic or not, are encouraged to participate.

**Report Details - EON-375409**

<b>ICSR:</b>	2060866		
<b>Type Of Submission:</b>	Initial		
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1		
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)		
<b>Reporting Type:</b>	Voluntary		
<b>Report Submission Date:</b>	2019-01-04 10:19:11 EST		
<b>Reporter is the Animal Owner:</b>	Yes		
<b>Reported Problem:</b>	<b>Problem Description:</b>	In April 2016, [B6] developed pancreatitis and her breathing was worsening. We brought her in for an ultrasound when we discovered she had fluid in her chest. The pleural effusion persisted from April 14, 2016 until her death on [B6]. On April 23, 2016, we brought her to [B6] in [B6] and implanted pleural ports. Prior to the surgery, a cardiac consult was performed which revealed the start of mitral valve disease. In May 2016, we switched from Natures Variety Grain Free food to Royal Canin Prescription Low Fat Kibble. The pleural effusion persisted with no known cause, we tested for everything. In July 2018, she went into congestive heart failure and had an enlarged heart. Her fluid from the pleural effusion increased exponentially from 100 ml's every 2-3 weeks to 500-600 ml's every 1-2 days. She was euthanized on [B6] due to fluid buildup in her lungs not responding to IV Lasix or Torsemide treatment.	
	<b>Date Problem Started:</b>	04/14/2016	
	<b>Concurrent Medical Problem:</b>	No	
	<b>Outcome to Date:</b>	Died Euthanized	
	<b>Date of Death:</b>	[B6]	
<b>Product Information:</b>	<b>Product Name:</b>	Instinct by Nature's Variety Original Grain-Free Recipe with Real Chicken Dry Dog Food, Instinct by Nature's Variety Raw Boost Grain-Free Recipe with Real Chicken Dry Dog Food	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	22.5 Pound	
	<b>Purchase Date:</b>	04/01/2016	
	<b>Number Purchased:</b>	1	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	No	
	<b>Storage Conditions:</b>	It was stored in its bag and sealed after each use.	
	<b>Product Use Information:</b>	<b>Description:</b>	Kibble was fed to both dogs. The raw boost would be added to the food or the raw meat mixed in the last few years. Both dogs were fed Natures Variety Grain Free Instinct food for 8 years. Chicken or lamb flavored kibble plus the frozen raw veal and chicken medallions.
		<b>First Exposure Date:</b>	04/01/2016
		<b>Last Exposure Date:</b>	04/23/2016
<b>Time Interval between Product Use and Adverse Event:</b>		8 Years	
<b>Product Use Stopped After the Onset of the Adverse Event:</b>		Yes	

		<b>Adverse Event Abate After Product Stop:</b>	No
		<b>Product Use Started Again:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Definitely related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>	<b>Name:</b>	Chewy
		<b>Address:</b>	United States
<b>Animal Information:</b>	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Sheepdog - Shetland	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	29 Pound	
	<b>Age:</b>	8 Years	
	<b>Assessment of Prior Health:</b>	Excellent	
	<b>Number of Animals Given the Product:</b>	2	
	<b>Number of Animals Reacted:</b>	2	
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6
		<b>Contact:</b>	<b>Name:</b> B6
			<b>Phone:</b> B6
		<b>Address:</b>	B6 United States
		<b>Type of Veterinarian:</b>	Referred veterinarian
		<b>Date First Seen:</b>	04/23/2016
		<b>Permission to Release Records to FDA:</b>	Yes
		<b>Practice Name:</b>	B6
		<b>Contact:</b>	<b>Name:</b> B6
			<b>Phone:</b> B6
			<b>Email:</b> B6
		<b>Address:</b>	B6 United States
		<b>Type of Veterinarian:</b>	Referred veterinarian

		<b>Date First Seen:</b> 04/23/2016	
		<b>Permission to Release Records to FDA:</b> Yes	
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6 United States	
	<b>Contact:</b>	<b>Phone:</b>	B6
		<b>Email:</b>	B6
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
	<b>Reported to Other Parties:</b>	None	
<b>Additional Documents:</b>	<b>Attachment:</b>	B6 medical history.pdf	
	<b>Description:</b>	Full medical history up to August 2018. Does not include x-rays, CT scans or echocardiogram files. Those can be sent upon request or requested from B6	
	<b>Type:</b>	Medical Records	

**Report Details - EON-376709**

<b>ICSR:</b>	2061375			
<b>Type Of Submission:</b>	Initial			
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1			
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)			
<b>Reporting Type:</b>	Voluntary			
<b>Report Submission Date:</b>	2019-01-17 15:51:20 EST			
<b>Reported Problem:</b>	<b>Problem Description:</b>	Diagnosed with dilated cardiomyopathy. Diet: Merrick's Good Earth Grain Free Pork Beef and Lamb kibble		
	<b>Date Problem Started:</b>	12/05/2018		
	<b>Concurrent Medical Problem:</b>	No		
	<b>Outcome to Date:</b>	Worse/Declining/Deteriorating		
<b>Product Information:</b>	<b>Product Name:</b>	Merrick Good Earth Grain Free Pork Beef and Lamb Kibble		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Storage Conditions:</b>	in owners home		
	<b>Product Use Information:</b>	<b>Description:</b>	fed as directed	
		<b>First Exposure Date:</b>	01/01/2018	
		<b>Last Exposure Date:</b>	12/05/2018	
		<b>Time Interval between Product Use and Adverse Event:</b>	1 Years	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
		<b>Adverse Event Abate After Product Stop:</b>	No	
		<b>Product Use Started Again:</b>	No	
		<b>Perceived Relatedness to Adverse Event:</b>	Probably related	
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Unknown	
<b>Manufacturer /Distributor Information:</b>				
<b>Purchase Location Information:</b>	<b>Name:</b>	B6		
	<b>Address:</b>	United States		
<b>Animal Information:</b>	<b>Name:</b>	B6		
	<b>Type Of Species:</b>	Dog		
	<b>Type Of Breed:</b>	Shepherd Dog - Australian		
	<b>Gender:</b>	Male		
	<b>Reproductive Status:</b>	Neutered		
<b>Weight:</b>	54 Pound			

	<b>Age:</b>	2 Years
	<b>Assessment of Prior Health:</b>	Excellent
	<b>Number of Animals Given the Product:</b>	2
	<b>Number of Animals Reacted:</b>	1
	<b>Owner Information:</b>	<b>Owner Information provided:</b> No
	<b>Healthcare Professional Information:</b>	
<b>Sender Information:</b>	<b>Name:</b>	B6
	<b>Address:</b>	B6 United States
	<b>Contact: Phone:</b>	B6
	<b>Reporter Wants to Remain Anonymous:</b>	No
	<b>Permission To Contact Sender:</b>	Yes
	<b>Preferred Method Of Contact:</b>	Phone
	<b>Reported to Other Parties:</b>	Other
<b>Additional Documents:</b>		

Report Details - EON-375900		
ICSR:	2061013	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-09 09:45:19 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> Critically Low Taurine Levels in both dogs <b>B6</b> for one and <b>B6</b> for the other on this diet, Merrick Grain-Free Chicken and Sweet Potato	
	<b>Date Problem Started:</b> 08/21/2018	
	<b>Date of Recovery:</b> 10/18/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Recovered Completely	
Product Information:	<b>Product Name:</b> Merrick Grain-Free Chicken and Sweet Potato	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 25 Pound	
	<b>Purchase Date:</b> 08/31/2018	
	<b>Number Purchased:</b> 1	
	<b>Possess Unopened Product:</b> No	
	<b>Possess Opened Product:</b> No	
	<b>Storage Conditions:</b> Air tight container	
	<b>Product Use Information:</b>	<b>Description:</b> One cup BID per dog
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes
		<b>Adverse Event Abate After Product Stop:</b> Yes
		<b>Product Use Started Again:</b> No
<b>Perceived Relatedness to Adverse Event:</b> Definitely related		
<b>Other Foods or Products Given to the Animal During This Time Period:</b> No		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>		
Animal Information:	<b>Name:</b> <b>B6</b>	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Retriever - Golden	
	<b>Gender:</b> Male	

	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 95 Pound
	<b>Age:</b> 3 Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 2
	<b>Number of Animals Reacted:</b> 2
	<b>Owner Information:</b>
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> B6
	<b>Contact:</b> <b>Name:</b> B6
	<b>Phone:</b> B6
	<b>Address:</b> B6 United States
	<b>Type of Veterinarian:</b> Referred veterinarian
	<b>Date First Seen:</b> 10/18/2018
	<b>Permission to Release Records to FDA:</b> Yes
<b>Sender Information:</b>	<b>Name:</b> B6
	<b>Address:</b> B6 United States
	<b>Contact:</b> <b>Phone:</b> B6
	<b>Email:</b> B6
	<b>Permission To Contact Sender:</b> Yes
	<b>Preferred Method Of Contact:</b> Phone
	<b>Reported to Other Parties:</b> Other
<b>Additional Documents:</b>	<b>Attachment:</b> fda4.JPG
	<b>Description:</b> echo result
	<b>Type:</b> Echocardiogram
	<b>Attachment:</b> fda3.JPG
	<b>Description:</b> echo result
	<b>Type:</b> Echocardiogram
	<b>Attachment:</b> fda1.JPG
	<b>Description:</b> initial lab
	<b>Type:</b> Laboratory Report
	<b>Attachment:</b> fda2.JPG
	<b>Description:</b> initial lab
	<b>Type:</b> Laboratory Report

Patient History Report: **B6** - 9/26/2018

Clinic:

**B6**

Client:

**B6**

Patient: **B6**

ID: **B6**  
Tag: **B6** Chip: **B6**  
Species: Canine, Golden Retriever  
Sex: male/neutered  
Age: **B6** mo, DOB: **B6**  
Weight: 87.6 Lbs  
Color: White  
Last visit: 9/14/2018

Referred By:

Home Phone: **B6**

Work Phone2: **B6** xhome

ID: **B6** File # **B6**

Tel: / Fax:

Medical Record Entries:

8/24/2018

<b>B6</b>	Lab Result -	Accession No.	Doctor	Owner	Pet Name
Received					
<b>B6</b>	8		<b>B6</b>	<b>B6</b>	<b>B6</b>
Species	Breed	Sex	Pet Age	Reported	
Canine		CM	2Y		

Test Requested	Results	Reference Range	Units
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Taurine	<b>B6</b>
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Normal Values (nmols/ml)		Critical Level
Normal Range		
Cat Plasma	60-120	Less than 40
Whole Blood	300-600	Less than 200
Dog Plasma	60-120	Less than 40
Whole Blood	200-350	Less than 150

TEST PERFORMED AT **B6**  
LABORATORY

**B6**

**B6**

Name: **B6** K9 GOLDEN RETRIEVER

MRN: **B6**

Study Date: 10/18/2018 01:16 PM

DOB: **B6**

Age: 3 yrs

Gender: Male

Exam: Transthoracic Echocardiogram

Performed By: **B6** VMD, DACVIM (Cardiology)

Weight: 91 lb

**B6**

Time Measurements

**B6**

**B6**

Pediatric Measurements & Calculations

**B6**

Presenting concern/Case History

Healthy dog. Was fed Merrick Grain Free Sweet Potato and chicken diet until Aug 2018. Owner had taurine testing performed at that time, low (whole blood). Changed to Chicken Soup for the Soul x 6 weeks, then changed to Royal Canin Golden Retriever 1 week ago. Began taurine testing in August, total dose of taurine administered 1000 mg PO q 12h. Recheck taurine 10/2 WNL **B6**

Cardiovascular Examination

Att: BAR. Respiratory rate (panting) breaths/minute. Respiratory effort normal. Mucous membrane color is pink. Mucous membranes are moist. CRT is 1-2 seconds in duration. Femoral pulse quality is strong. Femoral pulses are synchronous with heart beat. The heart rate is 144 beats per minute. The rhythm is regular. No murmurs or additional heart sounds noted. Lungs: clear. Body condition score: 5/9.

Electrocardiography

A sinus rhythm was present during echocardiogram.

Two-dimensional study

The left atrial size is normal. Right atrial size is normal. The left ventricle is normal in size. There is normal left ventricular wall thickness. Left ventricular systolic function is normal. The right ventricle is normal size. The morphology and motion of the aortic, pulmonic, mitral, and tricuspid valves is normal. No masses, thrombi, or effusions noted.

M-mode Calculations

The following measurements are based upon the 2D study. All M-Mode/2D values reported above are within normal limits for a patient of this size.

Color Doppler Study

Color flow interrogation of aortic, pulmonic, mitral, tricuspid valves is within normal limits.

Spectral Doppler Study

Normal diastolic function for age. Aortic and pulmonic flows are laminar and of normal peak velocity.

**B6**

**B6**

Name: **B6** K9 GOLDEN RETRIEVER  
MRN: **B6**  
Study Date: 10/18/2018 01:50 PM

DOB: **B6**  
Age: 31 mos  
Gender: Male

Exam: Transthoracic Echocardiogram  
Performed By: **B6** VMD, DACVIM (Cardiology)

Weight: 80 lb

**B6**

**Presenting concern/Case History**

Recheck examination. Hx of physiologic flow murmur, normal echo August 2017. Owner was previously feeding Merrick Grain Free Sweet Potato/Chicken, patient tested for taurine deficiency in August 2018, 106 (whole blood). Changed diet to Chicken Soup for the Soul x 6 weeks, then changed to Royal Canin Golden Retriever 1 week ago. Also began Vetriscience cardio strength caps, 4 caps PO q 12h (total taurine dose 1000 mg PO q 12h). Recheck taurine level 10/2 WNL **B6**. Asymptomatic.

**Cardiovascular Examination**

Att: BAR. Rectal temperature is 100.8 deg F. Respiratory rate (panting) breaths/minute. Respiratory effort normal. Mucous membrane color is pink. Mucous membranes are moist. CRT is 1-2 seconds in duration. Femoral pulse quality is strong. Femoral pulses are synchronous with heart beat. The heart rate is 144 beats per minute. The rhythm is regular. A holosystolic heart murmur is present. Grade I/VI. Point of maximal intensity: left base. Crescendo-decrescendo. Lungs: clear. Body condition score: 4/9.

**Electrocardiography**

A sinus rhythm was present during echocardiogram.

**Two-dimensional study**

The left atrial size is normal. Right atrial size is normal. The left ventricle is normal in size. There is normal left ventricular wall thickness. The left ventricle is hyperdynamic. The right ventricle is normal size. The morphology and motion of the aortic, pulmonic, mitral, and tricuspid valves is normal. No masses, thrombi, or effusions noted.

**M-mode Calculations**

The following measurements are based upon the 2D study. All M-Mode/2D values reported above are within normal limits for a patient of this size.

**Color Doppler Study**

Color flow interrogation of aortic, pulmonic, mitral, tricuspid valves is within normal limits.

**Report Details - EON-376853**

ICSR:	2061474
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:	2019-01-18 18:42:24 EST
Reporter is the Animal Owner:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	<p><b>B6</b> had just turned 9 years old and was fine. She still played with toys, had lots of energy, took long daily walks, and was in good health. She was a happy rambunctious dog. Overnight she became ill with an enlarged heart. She was coughing, had trouble breathing, lost her appetite and had no energy. I took her to her vet and was told she needed to be seen by the cardiologist at <b>B6</b> immediately. She had an enlarged heart, fluid on her lungs, and a leaky valve. Although she was on a heavy regimen of prescription drugs (increased in frequency and strength over time), and had frequent follow up visits with the cardiologists at <b>B6</b>, she grew weaker over time and her heart eventually gave out after a 1<sup>st</sup> month battle with DCM.</p>	
	<b>Date Problem Started:</b>	09/20/2017	
	<b>Concurrent Medical Problem:</b>	Yes	
	<b>Pre Existing Conditions:</b>	She took 1/2 of an Apoquel daily for allergies, which i expect is unrelated. But because of allergies, she ate grain free dog food daily for years which i suspect caused her sudden onset of DCM.	
	<b>Outcome to Date:</b>	Died Naturally	
	<b>Date of Death:</b>	<b>B6</b>	

<b>Product Information:</b>	<b>Product Name:</b>	Nature's Variety Instinct Limited Ingredient Diet Lamb Meal & Peas given ~2014 through 03/15/2016		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Package Size:</b>	25.3 Pound		
	<b>Purchase Date:</b>	03/15/2016		
	<b>Number Purchased:</b>	1		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Storage Conditions:</b>	put into a plastic pet food container (vault) as soon as it arrived		
	<b>Product Use Information:</b>	<b>Description:</b>	Dry dog food, fed 2x daily, given plain	
		<b>Time Interval between Product Use and Adverse Event:</b>	18 Months	
		<b>Perceived Relatedness to Adverse Event:</b>	Probably related	
<b>Other Foods or Products Given to the Animal During This Time Period:</b>		No		
<b>Manufacturer /Distributor Information:</b>				
<b>Purchase Location Information:</b>	<b>Name:</b>	Amazon.com and Chewy.com		

	<b>Address:</b>	United States	
<b>Product Name:</b>	Merrick Limited Ingredient Diet Grain-Free Real Lamb & Sweet Potatoes Recipe Dry Dog Food, 22 I		
<b>Product Type:</b>	Pet Food		
<b>Lot Number:</b>			
<b>Package Type:</b>	BAG		
<b>Package Size:</b>	22 Pound		
<b>Number Purchased:</b>	1		
<b>Possess Unopened Product:</b>	No		
<b>Possess Opened Product:</b>	No		
<b>Storage Conditions:</b>	It was put into a plastic pet food container (vault) as soon as it arrived		
<b>Product Use Information:</b>	<b>Description:</b>	Dry food fed 2x daily. Mixed with a small amount (~1 1/2 tsp) of chopped broccoli	
	<b>First Exposure Date:</b>	01/19/2017	
	<b>Last Exposure Date:</b>	<b>B6</b>	
	<b>Time Interval between Product Use and Adverse Event:</b>	5 Years	
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	No	
	<b>Perceived Relatedness to Adverse Event:</b>	Probably related	
	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes	
	<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>	<b>Name:</b>	Chewy.com (purchased online)	
	<b>Address:</b>	United States	
<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b>	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Mixed (Dog)	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	40 Pound	
	<b>Age:</b>	9 Years	
	<b>Assessment of Prior Health:</b>	Good	
	<b>Number of Animals Given the Product:</b>	2	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	<b>B6</b>
<b>Contact: Name:</b>		<b>B6</b>	

		Phone:	B6
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	09/20/2017	
	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:	Email		
Reported to Other Parties:	None			

Additional Documents:

Empty area for additional documents.

**Report Details - EON-375818**

<b>ICSR:</b>	2060968		
<b>Type Of Submission:</b>	Initial		
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1		
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)		
<b>Reporting Type:</b>	Voluntary		
<b>Report Submission Date:</b>	2019-01-08 13:27:41 EST		
<b>Reporter is the Animal Owner:</b>	Yes		
<b>Reported Problem:</b>	<b>Problem Description:</b>	Our dog has been eating a grain-free food (Natural Balance) since she was a puppy. She was recently diagnosed with a heart murmur and enlarged heart. This is unusual in her breed, and has been associated with grain free foods by the FDA. If possible, I would like assistance with testing expenses.	
	<b>Date Problem Started:</b>	05/01/2018	
	<b>Concurrent Medical Problem:</b>	No	
	<b>Outcome to Date:</b>	Unknown	
<b>Product Information:</b>	<b>Product Name:</b>	Natural Balance L.I.D. Limited Ingredient Diets® Sweet Potato & Fish Dry Dog Formula	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	Yes	
	<b>Storage Conditions:</b>	Stored in a sealed plastic tub	
	<b>Product Use Information:</b>	<b>Description:</b>	Food
		<b>First Exposure Date:</b>	01/01/2012
		<b>Last Exposure Date:</b>	01/04/2019
		<b>Time Interval between Product Use and Adverse Event:</b>	7 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
		<b>Adverse Event Abate After Product Stop:</b>	Unknown
		<b>Product Use Started Again:</b>	No
<b>Perceived Relatedness to Adverse Event:</b>		Probably related	
<b>Manufacturer /Distributor Information:</b>			
<b>Purchase Location Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6	
		United States	

<b>Animal Information:</b>	<b>Name:</b>	B6		
	<b>Type Of Species:</b>	Dog		
	<b>Type Of Breed:</b>	Terrier - Boston		
	<b>Gender:</b>	Female		
	<b>Reproductive Status:</b>	Neutered		
	<b>Weight:</b>	22 Pound		
	<b>Age:</b>	8 Years		
	<b>Assessment of Prior Health:</b>	Excellent		
	<b>Number of Animals Given the Product:</b>	1		
	<b>Number of Animals Reacted:</b>	1		
	<b>Owner Information:</b>			
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6	
		<b>Contact:</b>	<b>Name:</b>	B6
			<b>Phone:</b>	B6
			<b>Email:</b>	B6
		<b>Address:</b>	B6	
			United States	
<b>Type of Veterinarian:</b>		Primary/regular veterinarian		
<b>Date First Seen:</b>		05/01/2018		
<b>Permission to Release Records to FDA:</b>		Yes		
<b>Sender Information:</b>		<b>Name:</b>	B6	
	<b>Address:</b>	B6		
		United States		
	<b>Contact:</b>	<b>Phone:</b>	B6	
		<b>Email:</b>	B6	
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
	<b>Reported to Other Parties:</b>	None		
<b>Additional Documents:</b>				

**Report Details - EON-376360**

ICSR: 2061170  
 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: 2019-01-14 16:46:57 EST

**Reported Problem:**  
**Problem 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  
**Date Problem Started:** 12/21/2017  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Worse/Declining/Deteriorating

**Product Information:**  
**Product Name:** Annamaet chicken and rice dry + Honest kitchen beef, chicken, or turkey  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** See diet history  
**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:** 34.6 Kilogram  
**Age:** B6 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 3  
**Number of Animals Reacted:** 3  
**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

		<b>Address:</b> 200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
	<b>Contact:</b>	<b>Phone:</b> 5088874523 <b>Email:</b> lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes
	<b>Preferred Method Of Contact:</b>	Email
<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b> rpt_medical_record_preview.pdf
	<b>Description:</b>	Records
	<b>Type:</b>	Medical Records

**Report Details - EON-375110**

ICSR: 2060739  
 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: 2019-01-01 16:15:01 EST

**Reported Problem:**  
**Problem Description:** Diagnosed with degenerative mitral valve disease in Aug 2017. Progressed to CHF. On pimobendan, furosemide, enalapril. At regular re-evaluation on 12/19/18, reduced contractile function was noted on echo. Dog was noted to be eating BEG diet. Taurine pending Will recheck in 3 months Will evaluate other dog in household also eating same diet (asymptomatic). Owner is ok to provide further info.  
**Date Problem Started:** 12/19/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Degenerative mitral valve disease  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Orijen Adult Original dry (until Aug 2018)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** See diet history for additional details/diets  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Terrier - Border  
**Gender:** Male  
**Reproductive Status:** Intact  
**Weight:** 20.6 Kilogram  
**Age:** B6 Years  
**Assessment of Prior Health:** Good  
**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

		<b>Contact:</b>	<b>Name:</b> Lisa Freeman
			<b>Phone:</b> (508) 887-4523
			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States

<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		

<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b> medical record.pdf
	<b>Description:</b>	<b>B6</b> records
	<b>Type:</b>	Medical Records

Report Details - EON-375114		
ICSR:	2060741	
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:	2019-01-01 16:41:40 EST	
Reported Problem:	<b>Problem Description:</b> DCM and CHF diagnosed [B6] at emergency clinic. Started on furosemide, diltiazem, digoxin, pimobendan Seen by Tufts cardiology [B6] Eating Orijen grain free original dry so unclear if just genetically associated DCM or if diet associated.	
	<b>Date Problem Started:</b> [B6]	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Orijen grain free original dry	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> [B6]	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Doberman Pinscher	
	<b>Gender:</b> Male	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 32.6 Kilogram	
	<b>Age:</b> 9 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 1	
	<b>Number of Animals Reacted:</b> 1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b>
		<b>Name:</b> [B6]
		<b>Phone:</b> [B6]
<b>Email:</b> [B6]		
<b>Address:</b> [B6]		
<b>United States</b>		
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine	
	<b>Contact:</b>	
	<b>Name:</b> Lisa Freeman	
	<b>Phone:</b> (508) 887-4523	
<b>Email:</b> lisa.freeman@tufts.edu		

		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview	<b>B6</b> .pdf
	<b>Description:</b>	<b>B6</b> records	
	<b>Type:</b>	Medical Records	

**Report Details - EON-374783**

ICSR: 2060598  
 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: 2018-12-27 09:51:12 EST

**Reported Problem:**  
**Problem Description:** DCM diagnosed 10/2017. We saw July 2018 Originally feeding Orijen original dry since he was a puppy. Started taurine at time of diagnosis (10/2017). Heart improved significantly between echoes. Changed to Purina Proplan Adult 7+ July 2018. Will be rechecking soon.  
**Date Problem Started:** 10/05/2017  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Better/Improved/Recovering

**Product Information:**  
**Product Name:** Orijen Original dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** Fed Orijen puppy then Orijen Original (chicken) adult. Then changed to Orijen Senior in Oct 2017 after diagnosis  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Mixed (Dog)  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Weight:** 30.1 Kilogram  
**Age:** 8.4 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:** B6  
 United States  
**Healthcare Professional Information:** **Practice Name:** Tufts Cummings School of Veterinary Medicine  
**Contact:** **Name:** Lisa Freeman  
**Phone:** (508) 887-4523

			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b>	medical records.pdf
	<b>Description:</b>	Medical records	
	<b>Type:</b>	Medical Records	

**Report Details - EON-376361**

ICSR: 2061171  
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: **B6** 16:58:04 EST

Reported Problem: **Problem Description:** Eating Taste of the Wild Sierra Mountain since June 2018 (Acana Heritage Poultry before that). This diet was fed to multiple dogs - have not screened other dogs yet so unknown whether they are also affected. Echo showed reduced contractility and mild left atrial enlargement. BNP and troponin mildly elevated, troponin =0.547. Taurine WNL (88 and 250) Changing to Pro Plan Sensitive Skin /Stomach dry and will recheck in 3 months  
**Date Problem Started:** 01/02/2019  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Stable

Product Information: **Product Name:** Taste of the Wild Sierra Mountain dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** See diet history for more details. TOTW fed June, 2018 to present; Acana Heritage Free Run Poultry before that  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

Animal Information: **Name:** **B6**  
**Type Of Species:** Dog  
**Type Of Breed:** Retriever - Golden  
**Gender:** Female  
**Reproductive Status:** Intact  
**Pregnancy Status:** Not Pregnant  
**Lactation Status:** Not lactating  
**Weight:** 30.4 Kilogram  
**Age:** 3 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 7  
**Number of Animals Reacted:** 1  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** **B6**  
**Phone:** **B6**  
**Email:** **B6**  
**Address:** **B6**  
United States

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

Report Details - EON-376446			
ICSR:	2061214		
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:	2019-01-15 15:49:52 EST		
Reported Problem:	<b>Problem Description:</b> 2 syncopal episodes in summer got echo in October 2018 and arrhythmia identified Feeding BEG diets all of her life (Zignature) DCM and VPCs identified 1/9/19 Owner changing to Purina EN Fiber and we will recheck in 3 months BNP elevated, troponin and taurine pending		
	<b>Date Problem Started:</b> 01/09/2019		
	<b>Concurrent Medical Problem:</b> Yes		
	<b>Pre Existing Conditions:</b> Boxer colitis as young dog. Successfully treated		
	<b>Outcome to Date:</b> Stable		
Product Information:	<b>Product Name:</b> Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)		
	<b>Product Type:</b> Pet Food		
	<b>Lot Number:</b>		
	<b>Product Use Information:</b> <b>Description:</b> Rotated proteins/flavors of Zignature for past 8-9 years		
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>		
Animal Information:	<b>Name:</b> B6		
	<b>Type Of Species:</b> Dog		
	<b>Type Of Breed:</b> Boxer (German Boxer)		
	<b>Gender:</b> Female		
	<b>Reproductive Status:</b> Neutered		
	<b>Weight:</b> 21 Kilogram		
	<b>Age:</b> B6 Years		
	<b>Assessment of Prior Health:</b> Good		
	<b>Number of Animals Given the Product:</b> 1		
	<b>Number of Animals Reacted:</b> 1		
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes	
		<b>Contact:</b>	<b>Name:</b> B6
			<b>Phone:</b> B6
			<b>Email:</b> B6
<b>Address:</b> B6			
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine		
	<b>Contact:</b>	<b>Name:</b> Lisa Freeman	
		<b>Phone:</b> (508) 887-4523	

			<b>Email:</b> lisa.freeman@tufts.edu	
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			
<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview	<b>B6</b> pdf	
	<b>Description:</b>	Records		
	<b>Type:</b>	Medical Records		

**Report Details - EON-376363**

ICSR: 2061172  
 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: 2019-01-14 17:14:59 EST

**Reported Problem:**  
**Problem Description:** Eating BEG diet; developed DCM and CHF 4/11/18 Owner changed diet to Royal Canin Early Cardiac and dog has improved significantly. Will recheck again in 3 months. Have not gotten approval for you to contact owner but sent an email today  
**Date Problem Started:** 04/11/2018  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Better/Improved/Recovering

**Product Information:**  
**Product Name:** Zignature kangaroo dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** See diet history for more details. Zignature Sept 2017-April 2017 Acana Pork/Squash before that  
**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:** 26.3 Kilogram  
**Age:** B6 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1  
**Owner Information:** Owner Information provided: Yes  
**Contact:** 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

		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview	<b>B6</b> .pdf
	<b>Description:</b>	Records	
	<b>Type:</b>	Medical Records	

**Report Details - EON-375466**

<b>ICSR:</b>	2060874		
<b>Type Of Submission:</b>	Initial		
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1		
<b>Type Of Report:</b>	Both		
<b>Reporting Type:</b>	Voluntary		
<b>Report Submission Date:</b>	2019-01-04 14:35:25 EST		
<b>Reporter is the Animal Owner:</b>	Yes		
<b>Reported Problem:</b>	<b>Problem Description:</b>	Since my dog was about a year or so old, he has been eating the Tractor Supply Co. brand of Dog Food, 4Health grain-free and Untamed. Starting in December 2018, my dog developed a cough, stopped eating, and experienced difficulty breathing. He was seen by a veterinarian December 20th. He had blood work done which was unremarkable, his radiograph of his chest showed an enlarged heart with pulmonary edema. He was then started on cardiac medications, and sent to a cardiologist for an echocardiogram. The echo confirmed the diagnosis of Dilated Cardiomyopathy. This is when the topic of grain-free diet associated DCM came up. My Vet recommended supplementing Taurine into his diet, switching to a mainstream brand of dog food that has participated in nutritional research, and limiting his physical activity. We are hoping for the best but he is in rough shape. We will recheck the echocardiogram in 3 months to see if there have been any improvements. I hope this will help with any research ongoing with this issue. Please let me know if there is any more info I can provide or any additional research that has been done. Thank you. <span style="border: 1px solid black; padding: 2px;">B6</span>	
	<b>Date Problem Started:</b>	12/08/2018	
	<b>Concurrent Medical Problem:</b>	No	
	<b>Outcome to Date:</b>	Worse/Declining/Deteriorating	
<b>Product Information:</b>	<b>Product Name:</b>	4 Health Untamed	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Purchase Date:</b>	12/01/2018	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	No	
	<b>Storage Conditions:</b>	stored in a Tupperware tote	
	<b>Product Use Information:</b>	<b>Description:</b>	fed 2-4 cups per day
		<b>Time Interval between Product Use and Adverse Event:</b>	6 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
<b>Adverse Event Abate After Product Stop:</b>		Unknown	
<b>Product Use Started Again:</b>		No	
<b>Perceived Relatedness to Adverse Event:</b>	Possibly related		
<b>Other Foods or Products Given</b>	Unknown		

to the Animal  
During This Time  
Period:

Manufacturer  
/Distributor Information:

Purchase Location  
Information:

Name:

Tractor Supply Co.

Address:

B6

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Shepherd Dog - German

Gender: Male

Reproductive Status: Neutered

Weight: 79 Pound

Age: 6 Years

Assessment of Prior  
Health: Excellent

Number of Animals  
Reacted: 1

Owner Information:

Healthcare Professional  
Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

B6

Type of  
Veterinarian: Primary/regular veterinarian

Date First Seen: 01/03/2019

Permission to  
Release Records  
to FDA: Yes

Sender Information:

Name:

B6

Address:

B6

Contact:

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-377272**

<b>ICSR:</b>	2061634
<b>Type Of Submission:</b>	Followup
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-23 14:01:46 EST
<b>Initial Report Date:</b>	09/10/2018
<b>Parent ICSR:</b>	2054795
<b>Follow-up Report to FDA Request:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Presented for increased respiratory rate and effort at rest and exercise intolerance; was diagnosed with DCM and ventricular premature complexes of left bundle branch block morphology, was started on Pimobendan, enalapril, furosemide, and Taurine supplementation. 09/17/2018: <b>B6</b> was changed to NutriSource Chicken and Rice - developed diarrhea. 10/6/2018: <b>B6</b> was changed to Instinct - developed diarrhea. 11/7 - 11/11/2018: <b>B6</b> was transitioned to Royal Canin KP Hydrolyzed Protein.
	<b>Date Problem Started:</b>	08/13/2014
	<b>Date of Recovery:</b>	11/03/2014
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	Zignature Fish		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Product Use Information:</b>	<b>First Exposure Date:</b>	08/10/2014	
		<b>Last Exposure Date:</b>	12/19/2014	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	No	
		<b>Perceived Relatedness to Adverse Event:</b>	Possibly related	
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No	
	<b>Manufacturer /Distributor Information:</b>			
	<b>Purchase Location Information:</b>			
	<b>Product Name:</b>	Merrick Lamb, Peas, and Ancient Grains		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
<b>Product Use Information:</b>	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes		

		<b>Adverse Event Abate After Product Stop:</b>	Unknown
		<b>Product Use Started Again:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Possibly related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>		
	<b>Product Name:</b>	Natural Balance Lamb and Brown Rice	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Product Use Information:</b>	<b>Time Interval between Product Use and Adverse Event:</b>	5 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
		<b>Adverse Event Abate After Product Stop:</b>	Unknown
		<b>Product Use Started Again:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Possibly related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
		<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>		
<b>Animal Information:</b>	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Retriever - Golden	
	<b>Gender:</b>	Male	
	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	35.1 Kilogram	
	<b>Age:</b>	10 Years	
	<b>Assessment of Prior Health:</b>	Good	
	<b>Number of Animals Given the Product:</b>	1	
	<b>Number of Animals</b>	1	

	<b>Reacted:</b>																		
	<b>Owner Information:</b>	<table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>Owner Information provided:</b>	Yes	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6	<b>Address:</b>	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States			
<b>Owner Information provided:</b>	Yes																		
<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6												
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<b>Name:</b>	B6																		
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<b>Phone:</b>	B6																		
<b>Email:</b>	B6																		
<b>Permission To Contact Sender:</b>	Yes																		
<b>Preferred Method Of Contact:</b>	Email																		
<b>Reported to Other Parties:</b>	None																		
<b>Additional Documents:</b>	<table border="1"> <tr> <td><b>Attachment:</b></td> <td>B6</td> <td>01232019 SOAP.pdf</td> </tr> <tr> <td><b>Description:</b></td> <td colspan="2">Most Recent Cardiac Recheck showing improvement after transition away from grain-free diet</td> </tr> <tr> <td><b>Type:</b></td> <td colspan="2">Medical Records</td> </tr> </table>	<b>Attachment:</b>	B6	01232019 SOAP.pdf	<b>Description:</b>	Most Recent Cardiac Recheck showing improvement after transition away from grain-free diet		<b>Type:</b>	Medical Records										
<b>Attachment:</b>	B6	01232019 SOAP.pdf																	
<b>Description:</b>	Most Recent Cardiac Recheck showing improvement after transition away from grain-free diet																		
<b>Type:</b>	Medical Records																		

Report Details - EON-376311		
ICSR:	2061163	
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:	2019-01-14 12:02:07 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> After about a year on Balanced Diet Grain Free Dog Food - Salmon and Sweet Potato formula - Dog started having coughing symptoms. Upon evaluation at the vet it was determined she was heart worm free with an enlarged hear upon Xray. Dog was put on two hear medications and referred for ultrasound. Ultrasound determined mitral valve disease and congestive heart failure	
	<b>Date Problem Started:</b> 11/15/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Worse/Declining/Deteriorating	
Product Information:	<b>Product Name:</b> Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 26 Pound	
	<b>Purchase Date:</b> 12/07/2018	
	<b>Number Purchased:</b> 1	
	<b>Possess Unopened Product:</b> Yes	
	<b>Possess Opened Product:</b> Yes	
	<b>Storage Conditions:</b> stored in sealed container in pantry after bag is opened	
	<b>Product Use Information:</b>	<b>Description:</b> one cup of food twice daily
		<b>Last Exposure Date:</b> 01/01/2019
		<b>Time Interval between Product Use and Adverse Event:</b> 1 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> No
<b>Perceived Relatedness to Adverse Event:</b> Probably related		
<b>Other Foods or Products Given to the Animal During This Time Period:</b> No		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>	<b>Name:</b> Amazon	
	<b>Address:</b> United States	
Animal Information:	<b>Name:</b> B6	

	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> Mixed (Dog)
	<b>Gender:</b> Female
	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 65 Pound
	<b>Age:</b> 7 Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 2
	<b>Number of Animals Reacted:</b> 1
	<b>Owner Information:</b>
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> B6
	<b>Contact:</b> <b>Name:</b> B6
	<b>Phone:</b> B6
	<b>Address:</b> B6 United States
	<b>Type of Veterinarian:</b> Primary/regular veterinarian
	<b>Date First Seen:</b> 11/30/2018
	<b>Permission to Release Records to FDA:</b> Yes
<b>Sender Information:</b>	<b>Name:</b> B6
	<b>Address:</b> B6 United States
	<b>Contact:</b> <b>Phone:</b> B6
	<b>Email:</b> B6
	<b>Permission To Contact Sender:</b> Yes
	<b>Preferred Method Of Contact:</b> Email
	<b>Reported to Other Parties:</b> Store/Place of Purchase
<b>Additional Documents:</b>	

**Report Details - EON-376136**

<b>ICSR:</b>	2061092
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-11 12:02:43 EST

<b>Reported Problem:</b>	<b>Problem Description:</b>	Patient has been on Now Fresh Grain Free adult dog food/puppy dog food since purchased from breeder at approximately 16 weeks of age. P has developed, and confirmed by echocardiogram by boarded veterinary cardiologist, changes consistent with Nutritional Cardiomyopathy. P is currently on taurine supplementation and food has been changed to non grain-free diet, recheck echo planned for March/April 2019.
	<b>Date Problem Started:</b>	12/03/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Stable

<b>Product Information:</b>	<b>Product Name:</b>	Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>Package Type:</b>	BAG		
	<b>Purchase Date:</b>	08/01/2018		
	<b>Number Purchased:</b>	1		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	No		
	<b>Storage Conditions:</b>	Stored in cool dry place (garage)		
	<b>Product Use Information:</b>	<b>Description:</b>	Patient fed this food twice daily since obtained as puppy.	
		<b>First Exposure Date:</b>	09/01/2018	
		<b>Last Exposure Date:</b>	11/30/2018	
		<b>Time Interval between Product Use and Adverse Event:</b>	9 Years	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	
		<b>Adverse Event Abate After Product Stop:</b>	Unknown	
<b>Product Use Started Again:</b>		No		
<b>Perceived Relatedness to Adverse Event:</b>		Probably related		
<b>Other Foods or Products Given to the Animal During This Time Period:</b>		Unknown		
<b>Manufacturer /Distributor Information:</b>				

	<b>Purchase Location Information:</b>	<b>Name:</b>	Chewy.com	
		<b>Address:</b>	n/a n/a <b>B6</b> United States	
<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b>		
	<b>Type Of Species:</b>	Dog		
	<b>Type Of Breed:</b>	Retriever - Labrador		
	<b>Gender:</b>	Male		
	<b>Reproductive Status:</b>	Neutered		
	<b>Weight:</b>	72.8 Pound		
	<b>Age:</b>	<b>B6</b> Years		
	<b>Assessment of Prior Health:</b>	Unknown		
	<b>Number of Animals Given the Product:</b>	1		
	<b>Number of Animals Reacted:</b>	1		
<b>Owner Information:</b>	<b>Owner Information provided:</b>	No		
<b>Healthcare Professional Information:</b>				
<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>		
	<b>Address:</b>	<b>B6</b> United States		
	<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>	
		<b>Email:</b>	<b>B6</b>	
	<b>Reporter Wants to Remain Anonymous:</b>	No		
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
	<b>Reported to Other Parties:</b>	Other		
<b>Additional Documents:</b>				

**Report Details - EON-375242**

**ICSR:** 2060786  
**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:** 2019-01-02 19:46:49 EST  
**Reporter is the Animal Owner:** Yes

**Reported Problem:**  
**Problem Description:** B6 9 month old labradoodle, has been fed Nutrisource grain free small/medium breed puppy food since weaning. For the past 4-5 months it had been noticed that B6 was often short of breath and had a rapid heart rate. After being taken to the vet, a grade 2 murmur was found leading to the finding of cardiomyopathy. Awaiting echocardiogram. Advised by veterinarian to switch dog food to researched and approved brand because adverse health effects related to foods with lentils, such as the one B6 was on.  
**Date Problem Started:** 01/02/2019  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Unknown

**Product Information:**  
**Product Name:** Nutrisource Small and Medium Breed Puppy Grain Free Dog Food  
**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:** Mixed (Dog)  
**Gender:** Female  
**Reproductive Status:** Intact  
**Pregnancy Status:** Not Pregnant  
**Lactation Status:** Not lactating  
**Weight:** 42 Pound  
**Age:** 9 Months  
**Assessment of Prior Health:** Unknown  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1  
**Owner Information:**  
**Healthcare Professional Information:**  
**Contact:** **Name:** B6  
**Phone:** B6  
**Contact:** **Name:** B6  
**Phone:** B6

**Sender Information:**  
**Name:** B6  
**Address:** B6

**B6**

United States

**Contact:**

**Phone:**

**B6**

**Email:**

**B6**

**Permission To Contact  
Sender:** Yes

**Preferred Method Of  
Contact:** Email

**Additional Documents:**

Report Details - EON-374952	
ICSR:	2060676
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:	2018-12-29 04:20:02 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	<b>Problem Description:</b> Dog is a mixed breed: golden retriever and poodle hybrid (goldendoodle). He has developed heart disease (DCM) on the diet. Was told it is most likely related to taurine deficiency. Have put him on heart medication and a taurine supplement. Have already seen marked improvement in his demeanor. EKG to see if taurine supplement has reversed heart disease in 3-6 months.
	<b>Date Problem Started:</b> 12/17/2018
	<b>Date of Recovery:</b> 12/27/2018
	<b>Concurrent Medical Problem:</b> No
	<b>Outcome to Date:</b> Better/Improved/Recovering
Product Information:	<b>Product Name:</b> NutriSource Super Premium Pet Foods
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Package Type:</b> BAG
	<b>Package Size:</b> 30 Pound
	<b>Purchase Date:</b> 12/06/2018
	<b>Number Purchased:</b> 1
	<b>Possess Unopened Product:</b> No
	<b>Possess Opened Product:</b> No
	<b>Storage Conditions:</b> I only ever kept a 3-week supply. It was stored in one of those locked pet food bins at room temperature.
<b>Product Use Information:</b>	<b>Description:</b> Fed daily to dog, per package instructions, for almost exactly 4 years (originally purchased on approximately December 15, 2014).
	<b>First Exposure Date:</b> 12/06/2018
	<b>Last Exposure Date:</b> 12/27/2018
	<b>Time Interval between Product Use and Adverse Event:</b> 4 Years
	<b>Product Use Stopped After the Onset of the Adverse Event:</b> No
	<b>Perceived Relatedness to Adverse Event:</b> Probably related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes
	<b>Manufacturer:</b>

	<b>/Distributor Information:</b> <b>Purchase Location Information:</b>	<b>Name:</b> B6 <b>Address:</b> B6 United States
<b>Animal Information:</b>	<b>Name:</b> B6 <b>Type Of Species:</b> Dog <b>Type Of Breed:</b> Retriever - Golden <b>Gender:</b> Male <b>Reproductive Status:</b> Neutered <b>Weight:</b> 55 Pound <b>Age:</b> 11 Years <b>Assessment of Prior Health:</b> Excellent <b>Number of Animals Given the Product:</b> 1 <b>Number of Animals Reacted:</b> 1 <b>Owner Information:</b>	<b>Healthcare Professional Information:</b> <b>Practice Name:</b> B6 <b>Contact:</b> <b>Name:</b> B6 <b>Phone:</b> B6 <b>Email:</b> B6 <b>Address:</b> B6 United States <b>Type of Veterinarian:</b> Primary/regular veterinarian <b>Date First Seen:</b> 12/20/2018 <b>Permission to Release Records to FDA:</b> Yes <b>Practice Name:</b> B6 <b>Contact:</b> <b>Name:</b> B6 <b>Phone:</b> B6 <b>Email:</b> B6 <b>Address:</b> B6 United States <b>Type of Veterinarian:</b> Referred veterinarian <b>Date First Seen:</b> 12/26/2018 <b>Permission to Release Records to FDA:</b> Yes
<b>Sender Information:</b>	<b>Name:</b> B6 <b>Address:</b> B6	

**B6**

United States

**Contact:**

**Phone:**

**B6**

**Email:**

**B6**

**Permission To Contact Sender:** Yes

**Preferred Method Of Contact:** Phone

**Reported to Other Parties:** None

**Additional Documents:**

Report Details - EON-375869		
ICSR:	2060992	
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:	2019-01-08 17:50:04 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> Whole Blood Taurine was 224 Plasma Taurine was 90	
	<b>Date Problem Started:</b> 11/14/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Unknown	
Product Information:	<b>Product Name:</b> NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>UPC:</b> (01)18101625NWBARF	
	<b>Package Type:</b> BOX	
	<b>Package Size:</b> 25 Pound	
	<b>Possess Unopened Product:</b> Yes	
	<b>Possess Opened Product:</b> Yes	
	<b>Storage Conditions:</b> Always in the freezer	
	<b>Product Use Information:</b>	<b>Description:</b> Defrosted in refrigerator for 12 hours prior to feeding
		<b>First Exposure Date:</b> 01/01/2018
		<b>Time Interval between Product Use and Adverse Event:</b> 1 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> No
		<b>Perceived Relatedness to Adverse Event:</b> Possibly related
<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>		
Animal Information:	<b>Name:</b> B6	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Retriever - Golden	
	<b>Gender:</b> Female	
	<b>Reproductive Status:</b> Neutered	

	<b>Weight:</b>	54 Pound	
	<b>Age:</b>	8 Years	
	<b>Assessment of Prior Health:</b>	Excellent	
	<b>Number of Animals Given the Product:</b>	2	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>		
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6 United States	
	<b>Contact:</b>	<b>Phone:</b>	B6
		<b>Other Phone:</b>	B6
		<b>Email:</b>	B6
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
	<b>Reported to Other Parties:</b>	Other	
<b>Additional Documents:</b>			

**Report Details - EON-375393**

ICSR:	2060845
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:	2019-01-04 07:45:14 EST
Initial Report Date:	11/08/2018
Reporter is the Animal Owner:	Yes
Parent ICSR:	2058584
Follow-up Report to FDA Request:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	<p>This submission is in furtherance of your nutritionally-mediated DCM investigation. My young, energetic and very healthy Golden Retriever male had his second echocardiogram on Thursday, October 25, 2018. His first was approximately one year ago in September 2017. The 2017 echo was normal. The one from last week was not. It showed a subjective increase in sphericity of his heart, as well as mild systolic dysfunction compared with last year. ACK!!! His whole blood taurine level at U.C. Davis was 226 in September 2018. I had scheduled echocardiograms for [ B6 ] and my other two Golden retrievers out of an abundance of caution after two [ B6 ] (and his littermate brother) tested below 250 nmol/ml for taurine in whole blood. I'm glad I did. My veterinary cardiologist is [ B6 ] DVM ACVIM (Cardiology) of [ B6 ]. At last week's echocardiogram, he drew blood for CBC, chemistry, a repeat of the taurine test with paired samples, a full tick-borne disease panel, and thyroid tests. All test results are in except for the repeat taurine test from U.C. Davis. All [ B6 ] results were unremarkable or normal, except for a slightly low globulin level. That test will be repeated this week. I never purposely fed a "grain-free" food or an "exotic protein" food. I'm a physicist and I believe in science and common sense. HOWEVER, after FDA's investigation was announced, I noted that some of the commercial food I was feeding [ B6 ] (which I thought was perfectly conventional) met the FDA's description of "suspect diets". In addition, I had been giving my three Golden Retrievers a probiotic from Purina -- their Fortiflora product -- as a routine part of feeding after a period in which all three dogs had loose stool and diarrhea. I added the Fortiflora to their food for a period of over a year. I think the current thinking on this issue is that it's multifactorial, I wanted to mention first that I had added the Fortiflora and that while I didn't purposely choose a grain-free food (high in legumes), I've also found that the food itself has added "probiotics". I was surprised to see that. Now, I wonder if my accidental food choice for him, plus my "probiotic" supplement, changed something in how his body processed the taurine precursors and dietary taurine. In addition, he's definitely an "easy-keeper", eating nowhere near the amount of food advised on the bag. After his "equivocal" taurine level in mid-September 2018, I stopped feeding Fortiflora to all three Golden Retrievers. Their stool is perfectly fine, perhaps even better. I changed [ B6 ] diet from Fromm to Purina ProPlan Sport 30/20 at the same time. Please do get in touch if there's any further information you require or that you might provide me. Obviously, I hope this is diet-related and can be reversed. FOLLOW UP -- JANUARY 3, 2019 ECHOCARDIOGRAM Hey, good news. After 90 days of diet change, 8 weeks of taurine supplementation, and 6 weeks of l-carnitine supplementation, [ B6 ] echocardiographic findings are either within normal limits or are improving. I will attach his cardiologist's detailed report. I'm delighted, of course.</p>
	<b>Date Problem Started:</b>	10/25/2018
	<b>Date of Recovery:</b>	01/03/2019
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering
<b>Product Information:</b>	<b>Product Name:</b>	Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora
	<b>Product Type:</b>	Pet Food

	<b>Lot Number:</b>																	
	<b>Package Type:</b>	BAG																
	<b>Package Size:</b>	13 Pound																
	<b>Possess Unopened Product:</b>	Yes																
	<b>Possess Opened Product:</b>	No																
	<b>Product Use Information:</b>	<table border="1"> <tr> <td><b>Description:</b></td> <td>I can provide a description of how I mixed this food with two others for part of <b>B6</b> diet. Please let me know if you'd like me to send that. He was also fed scrambled eggs, yogurt, cottage cheese, and meats.</td> </tr> <tr> <td><b>First Exposure Date:</b></td> <td>12/03/2017</td> </tr> <tr> <td><b>Last Exposure Date:</b></td> <td>09/15/2018</td> </tr> <tr> <td><b>Product Use Stopped After the Onset of the Adverse Event:</b></td> <td>Yes</td> </tr> <tr> <td><b>Adverse Event Abate After Product Stop:</b></td> <td>Unknown</td> </tr> <tr> <td><b>Product Use Started Again:</b></td> <td>No</td> </tr> <tr> <td><b>Perceived Relatedness to Adverse Event:</b></td> <td>Possibly related</td> </tr> <tr> <td><b>Other Foods or Products Given to the Animal During This Time Period:</b></td> <td>Yes</td> </tr> </table>	<b>Description:</b>	I can provide a description of how I mixed this food with two others for part of <b>B6</b> diet. Please let me know if you'd like me to send that. He was also fed scrambled eggs, yogurt, cottage cheese, and meats.	<b>First Exposure Date:</b>	12/03/2017	<b>Last Exposure Date:</b>	09/15/2018	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	<b>Adverse Event Abate After Product Stop:</b>	Unknown	<b>Product Use Started Again:</b>	No	<b>Perceived Relatedness to Adverse Event:</b>	Possibly related	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
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<b>First Exposure Date:</b>	12/03/2017																	
<b>Last Exposure Date:</b>	09/15/2018																	
<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes																	
<b>Adverse Event Abate After Product Stop:</b>	Unknown																	
<b>Product Use Started Again:</b>	No																	
<b>Perceived Relatedness to Adverse Event:</b>	Possibly related																	
<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes																	
	<b>Manufacturer /Distributor Information:</b>																	
	<b>Purchase Location Information:</b>	<b>Name:</b> Chewy.com																
<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b> - <b>B6</b>																
	<b>Type Of Species:</b>	Dog																
	<b>Type Of Breed:</b>	Retriever - Golden																
	<b>Gender:</b>	Male																
	<b>Reproductive Status:</b>	Neutered																
	<b>Weight:</b>	80 Pound																
	<b>Age:</b>	3 Years																
	<b>Assessment of Prior Health:</b>	Excellent																
	<b>Number of Animals Given the Product:</b>	2																
	<b>Number of Animals Reacted:</b>	1																
	<b>Owner Information:</b>																	
	<b>Healthcare Professional Information:</b>	<table border="1"> <tr> <td><b>Practice Name:</b></td> <td><b>B6</b></td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td><b>B6</b> DVM, ACVIM (Cardiology)</td> </tr> <tr> <td><b>Phone:</b></td> <td><b>B6</b></td> </tr> <tr> <td><b>Other Phone:</b></td> <td><b>B6</b></td> </tr> <tr> <td><b>Email:</b></td> <td><b>B6</b></td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td><b>B6</b></td> </tr> </table>	<b>Practice Name:</b>	<b>B6</b>	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td><b>B6</b> DVM, ACVIM (Cardiology)</td> </tr> <tr> <td><b>Phone:</b></td> <td><b>B6</b></td> </tr> <tr> <td><b>Other Phone:</b></td> <td><b>B6</b></td> </tr> <tr> <td><b>Email:</b></td> <td><b>B6</b></td> </tr> </table>	<b>Name:</b>	<b>B6</b> DVM, ACVIM (Cardiology)	<b>Phone:</b>	<b>B6</b>	<b>Other Phone:</b>	<b>B6</b>	<b>Email:</b>	<b>B6</b>	<b>Address:</b>	<b>B6</b>		
<b>Practice Name:</b>	<b>B6</b>																	
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<b>Phone:</b>	<b>B6</b>																	
<b>Other Phone:</b>	<b>B6</b>																	
<b>Email:</b>	<b>B6</b>																	
<b>Address:</b>	<b>B6</b>																	

			<b>B6</b> United States
		<b>Type of Veterinarian:</b>	Referred veterinarian
		<b>Date First Seen:</b>	10/31/2018
		<b>Permission to Release Records to FDA:</b>	Yes
		<b>Practice Name:</b>	<b>B6</b>
		<b>Contact:</b>	<b>Name:</b> <b>B6</b> DVM
			<b>Phone:</b> <b>B6</b>
			<b>Other Phone:</b> <b>B6</b>
			<b>Email:</b> <b>B6</b>
		<b>Address:</b>	<b>B6</b> United States
		<b>Type of Veterinarian:</b>	Primary/regular veterinarian
		<b>Date First Seen:</b>	11/08/2018
		<b>Permission to Release Records to FDA:</b>	Yes
<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>	
	<b>Address:</b>	<b>B6</b> United States	
	<b>Contact:</b>	<b>Phone:</b> <b>B6</b>	
		<b>Other Phone:</b> <b>B6</b>	
		<b>Email:</b> <b>B6</b>	
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
	<b>Reported to Other Parties:</b>	None	
<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b> 20190103 193001.pdf	
	<b>Description:</b>	This is <b>B6</b> follow-up echocardiogram report from yesterday, January 3, 2019.	
	<b>Type:</b>	Echocardiogram	

**Report Details - EON-376960**

<b>ICSR:</b>	2061494
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-20 10:10:37 EST
<b>Reporter is the Animal Owner:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	My 3 y/o German Shepard, was recently dx with dilated cardiomyopathy (DCM) and Congestive Heart Failure. I feel the dog food I fed her was Pedigree grain free, with main ingredients being, potatoes, peas and Legumes. She ate that food for about 2 years. During that time, she had a minor cough which progressed to a bad hacking cough. I took her to the vet and did a Chest x-ray which revealed an enlarged heart with fluid in her lungs. The first vet I took her to just prescribed an antibiotic and told me to follow up with a specialist in [B6] [B6] condition worsened to the point where I though I would have to put her down. I, immediately took her to another vet. She recognized [B6] condition, and administered Lasix immediately and observed [B6] for 4 hours. [B6] improved to the point I could take her home however, she will be on meds for DCM and CHF for the rest of her life. I feel the dog food I fed [B6]s responsible for her condition.
	<b>Date Problem Started:</b>	01/02/2019
	<b>Date of Recovery:</b>	01/20/2019
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	Ped	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	30 Pound	
	<b>Purchase Date:</b>	11/30/2018	
	<b>Number Purchased:</b>	1	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	No	
	<b>Storage Conditions:</b>	Air tight plastic container.	
	<b>Product Use Information:</b>	<b>Description:</b>	Dog food bowl full 2 times a day.
		<b>Last Exposure Date:</b>	01/01/2019
		<b>Time Interval between Product Use and Adverse Event:</b>	2 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
<b>Adverse Event Abate After Product Stop:</b>		No	
<b>Product Use Started Again:</b>		No	
<b>Perceived Relatedness to</b>		Definitely related	

		<b>Adverse Event:</b>	
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>	<b>Name:</b>	Petsmart
		<b>Address:</b>	<b>B6</b> United States
<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b>	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Shepherd Dog - German	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Intact	
	<b>Pregnancy Status:</b>	Not Pregnant	
	<b>Lactation Status:</b>	Not lactating	
	<b>Weight:</b>	50 Pound	
	<b>Age:</b>	3 Years	
	<b>Assessment of Prior Health:</b>	Excellent	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>		
<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>	
	<b>Address:</b>	<b>B6</b> United States	
	<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>
		<b>Email:</b>	<b>B6</b>
	<b>Reporter Wants to Remain Anonymous:</b>	No	
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Phone	
	<b>Reported to Other Parties:</b>	None	
<b>Additional Documents:</b>			

Report Details - EON-375203			
ICSR:	2060773		
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:	2019-01-02 15:05:36 EST		
Reported Problem:	<b>Problem Description:</b>	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).	
	<b>Date Problem Started:</b>	10/05/2018	
	<b>Concurrent Medical Problem:</b>	Yes	
	<b>Pre Existing Conditions:</b>	Past history of vomiting/diarrhea - IBD suspected but not confirmed. History of struvite crystalluria, dental calculus.	
	<b>Outcome to Date:</b>	Stable	
Product Information:	<b>Product Name:</b>	Whole Life Pet Just One Ingredient Pure Beef Liver Treat	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Possess Unopened Product:</b>	Unknown	
	<b>Possess Opened Product:</b>	Unknown	
	<b>Storage Conditions:</b>	Unknown	
	<b>Product Use Information:</b>	<b>Description:</b>	1 treat given monthly
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Unknown
		<b>Perceived Relatedness to Adverse Event:</b>	Unrelated
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>		
	<b>Product Name:</b>	Pure Vita Venison & Red Lentils Grain Free Entree	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Possess Unopened Product:</b>	Unknown	
<b>Possess Opened Product:</b>	Unknown		
<b>Storage Conditions:</b>	Unknown		
<b>Product Use Information:</b>	<b>Description:</b>	1.25 cup fed 2x/day since 9/2017	
	<b>First Exposure Date:</b>	09/01/2017	
	<b>Time Interval between Product Use and Adverse Event:</b>	2 Years	
	<b>Product Use Stopped After the</b>	Yes	

		<b>Onset of the Adverse Event:</b>	
		<b>Adverse Event Abate After Product Stop:</b>	Unknown
		<b>Product Use Started Again:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Possibly related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>		
<b>Animal Information:</b>	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Retriever - Golden	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	60 Pound	
	<b>Age:</b>	8 Years	
	<b>Assessment of Prior Health:</b>	Fair	
	<b>Number of Animals Given the Product:</b>	1	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b>	Yes
		<b>Contact:</b>	<b>Name:</b> B6
			<b>Phone:</b> B6
			<b>Other Phone:</b> B6
			<b>Email:</b> B6
		<b>Address:</b>	B6 United States
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6
		<b>Contact:</b>	<b>Name:</b> B6
			<b>Phone:</b> B6
			<b>Email:</b> B6
		<b>Address:</b>	B6 United States
		<b>Type of Veterinarian:</b>	Referred veterinarian
		<b>Permission to</b>	Yes

<b>Release Records to FDA:</b>	
<b>Practice Name:</b>	B6
<b>Contact:</b>	<b>Name:</b> B6 <b>Phone:</b> B6
<b>Address:</b>	B6 United States
<b>Type of Veterinarian:</b>	Referred veterinarian
<b>Date First Seen:</b>	10/06/2018
<b>Permission to Release Records to FDA:</b>	Yes
<b>Practice Name:</b>	B6
<b>Contact:</b>	<b>Name:</b> B6 <b>Phone:</b> B6
<b>Address:</b>	B6 United States
<b>Type of Veterinarian:</b>	Primary/regular veterinarian

<b>Sender Information:</b>	<b>Name:</b> B6
	<b>Address:</b> B6 United States
	<b>Contact:</b> <b>Phone:</b> B6 <b>Email:</b> B6
	<b>Permission To Contact Sender:</b> Yes
	<b>Preferred Method Of Contact:</b> Email
	<b>Reported to Other Parties:</b> None

<b>Additional Documents:</b>	<b>Attachment:</b> B6_2019-01-02_Converted medical history for B6.pdf
	<b>Description:</b> Older medical history
	<b>Type:</b> Medical Records
	<b>Attachment:</b> B6_2018-10-21_17.50_care instructions.pdf
	<b>Description:</b> Diet recommendations
	<b>Type:</b> Medical Records
	<b>Attachment:</b> B6_2019-01-02_Echo.pdf
	<b>Description:</b> Echocardiogram report
	<b>Type:</b> Echocardiogram
	<b>Attachment:</b> B6_2019-01-02_Ref Recs- B6 2) taurine results.pdf
	<b>Description:</b> Whole blood taurine results from B6
	<b>Type:</b> Laboratory Report

<b>Attachment:</b>	<b>B6</b>	Medical history 2018-09-09 to 2018-12-06.pdf
<b>Description:</b>	More recent medical history ( <b>B6</b> )	
<b>Type:</b>	Medical Records	

Client: B6  
Patient: B6

Doctor: B6  
Record Date: 12-Jun-2014 to 19-Oct-2016

Medical Records

Client: B6 Patient: B6  
B6 B6  
Canine Golden  
Phone: B6 Retriever, Golden Female Spayed 0 pounds

Diagnostic History

Date	Code	Diagnosis
------	------	-----------

Medical History

Visit Info Date Start: 2016-10-19 Date End: 2016-10-19 Notes:

Date	Type	Description	Qty	Resource
19-Oct-2016	Converted History	B6	1	B6

19-Oct-2016	Converted Rx	B6	5	B6
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Visit Info Date Start: 2016-10-18 Date End: 2016-10-18 Notes:

Date	Type	Description	Qty	Resource
18-Oct-2016	Converted History	• Entered: B6	1	B6

18-Oct-2016	Converted History	Syringe - 1cc x 25g (6)	6	B6
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18-Oct-2016	Converted History	Cyanocobalamine 1000mcg/ml for Rx (5)	5	B6
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Visit Info Date Start: 2016-10-17 Date End: 2016-10-17 Notes:

Date	Type	Description	Qty	Resource
17-Oct-2016	Converted History	Needle - 18g x 1"	1	B6

17-Oct-2016	Converted History	Vitamin B Complex Inj. (5)	5	B6
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17-Oct-2016	Converted History	* Entered: B6	1	B6
-------------	-------------------	---------------	---	----

17-Oct-2016	Converted Rx	B6	1	B6
17-Oct-2016	Converted Rx	B6	5	B6

Visit Info Date Start: 2016-09-28 Date End: 2016-09-28 Notes:

Date	Type	Description	Qty	Resource
------	------	-------------	-----	----------

B6

History:  
Client Communication

B6

B6

B6

B6

\* Entered:

B6

B6

B6

B6

B6

B6

Visit Info		Date Start:	2016-09-26	Date End:	2016-09-26	Notes:	Qty	Resource
Date	Type	Description						
26-Sep-2016	Converted History	B6				4	B6	
26-Sep-2016	Converted History					1	B6	
26-Sep-2016	Converted Rx					4	B6	

Visit Info		Date Start:	B6	Date End:	B6	Notes:	Qty	Resource
Date	Type	Description						

History:

B6

Physical Exam:

B6

Objective:  
Wt-30.9 kg, T-102 F, P-128 bpm, R-pant

Abdominal ultrasound

B6

No significant findings  
CBC: WBC 10.9 K/uL (6-17), HCT 53.5% (37-55) and platelets 265 K/uL (200-500)  
PCV/TP: 52%, 6.8 g/dL  
Chemistry panel: ALP <5 U/L (20-150), phosphorus 2.8 mg/dL (2.9-6.6)  
Fecal PCR: results pending  
Cobalamin/folate/PLI: results pending

Assessment:

B6

Body condition score:  
BCS 7/9

Pain Score:  
0/4

Prognosis:  
Undetermined

Follow-up with Primary Care Veterinarian:

Plan:

B6

History:

Ultrasound Findings:

B6

Conclusion:  
No significant findings

<b>B6</b>	Converted History	Mailing Fee - <b>B6</b>		1	Other, Doctor
<b>B6</b>	Converted History	<b>B6</b>		21	<b>B6</b>
<b>B6</b>	Converted History	<b>B6</b>		4	<b>B6</b>
<b>B6</b>	Converted History	<b>B6</b> to <b>B6</b>		1	<b>B6</b>
<b>B6</b>	Converted History	GI Profile FastPanel PCR Canine #T950		1	<b>B6</b>
<b>B6</b>	Converted History	* Entered: <b>B6</b>		1	<b>B6</b>
<b>B6</b>	Converted History	Consultation - Internal Medicine		1	<b>B6</b>
<b>B6</b>	Converted History	<b>B6</b> CBC STAT		1	<b>B6</b>
<b>B6</b>	Converted History	Ultrasound, Abdomen - CG		1	<b>B6</b>
<b>B6</b>	Converted History	<b>B6</b> (10.01)		10.01	<b>B6</b>

<b>B6</b>	Converted History	Consultation - Emergency		1	<b>B6</b>
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CHIEF COMPLAINT: Vomiting blood. To transfer to **B6**  
History:

**B6**

<b>B6</b>	Converted Rx	<b>B6</b>		4	<b>B6</b>
-----------	--------------	-----------	--	---	-----------

<b>B6</b>	Converted Rx	<b>B6</b>		21	<b>B6</b>
<b>B6</b>	Converted Rx	<b>B6</b>		4	<b>B6</b>
<b>B6</b>	Converted Rx	<b>B6</b>		21	<b>B6</b>

<b>Visit Info</b>	Date Start:	<b>B6</b>	Date End:	<b>B6</b>	Notes:
Date	Type	Description	Qty	Resource	

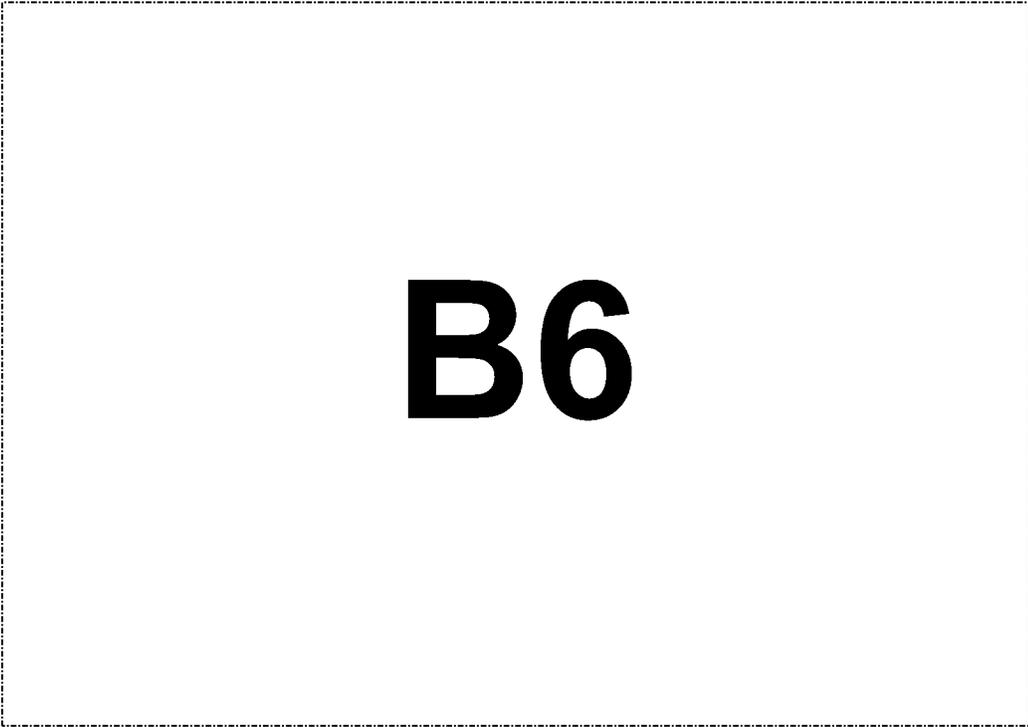
B6

Converted History Consultation - Emergency

1

B6

CHIEF COMPLAINT: Acute moist dermatitis



B6

B6

Converted History \* To Go Home

B6

1

B6

B6

Converted History \* Entered:

B6

1

B6

B6

Converted History Wound Care Level I

1

B6

B6

Converted History Consultation - Emergency

1

B6

B6

Converted History \* Entered:

B6

1

B6

B6

Converted History

10

B6

B6

Converted History

13.33

B6

B6

Converted Rx

10

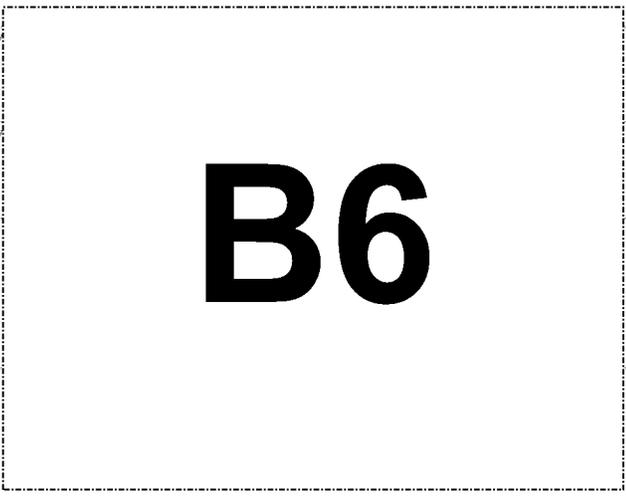
B6

B6

Converted Rx

10

B6



B6

Visit Info

Date Start:

2014-06-15

Date End:

2014-06-15

Notes:

Date	Type	Description	Qty	Resource
15-Jun-2014	Converted History	Client Communication (emergency serv)	1	B6

History: Hot spots  
Client Communication: 1445 - SW [B6], [B6] is doing very well and owner is happy.

Visit Info

Date Start:

2014-06-12

Date End:

B6

Notes:

Date	Type	Description	Qty	Resource
------	------	-------------	-----	----------

B6

Converted History Consultation - Emergency  
(10:54 PM)

1

B6

CHIEF COMPLAINT Has open wound behind left ear and rash on stomach

**B6**

B6

Converted History

10

B6

B6

Converted History

1

B6

B6

Converted History

1

B6

B6

Converted History

1

B6

B6

Converted History

10

B6

B6

Converted History

8

B6

**B6**

B6

Converted History

1

B6

B6

Converted History

1

B6

B6

Converted History

21.44

B6

B6

Converted Rx

1

B6

B6

Converted Rx

10

B6

B6

Converted Rx

8

B6

**B6**

B6

Converted Rx

10

B6

**B6**

**B6**

Name   
Patient Id   
Birthdate   
Age 8  
Sex/Breed FS GOLDEN RETRIEVER  
Weight 27.5 kg

Date 10/06/2018

Physician

**2D**  
Ao Diam  
LA Diam  
LA/Ao  
Ao/LA  
LVLd A4C  
LVEDV MOD  
A4C  
LVLs A4C  
LVESV MOD  
A4C  
LVEF MOD A4C  
SV MOD A4C

**B6**

**M-Mode**  
IVSd  
LVIDd  
LVPWd  
IVSs  
LVIDs  
LVPWs  
EDV(Teich)  
ESV(Teich)  
EF(Teich)  
%FS  
SV(Teich)

**B6**

**Doppler**  
MV E Vel  
MV A Vel  
MV E/A Ratio  
E/IVRT  
IVRT  
E/IVRT  
AV Vmax  
AV maxPG

**B6**

**Subjective Findings**

NORMAL CHAMBER DIMENSIONS, ALL VALVES COMPETENT, MILD DECREASE IN SYSTOLIC FUNCTION.

**B6**

Print Date: 10/06/2018

B6

B6

B6

### MEDICAL HISTORY

09-Sep-2018 to 06-Dec-2018

#### Client

B6

Home: B6

Most recent visit date: 10-Oct-2018

Microchip No.: n/a

Rabies tag ID / date : n/a

#### Patient

B6

Canine  
Retriever, Golden

B6

B6

Golden  
Female / Spayed - 60 lb (10-Oct-2018)

Patient Alerts: n/a

Current medical overview: as of B6

Weight by Age		Wt.	Record date
B6		27.22 kg	60 lb
		27.5 kg	60.63 lb

Active Concerns	Established
Urinary crystal, struvite	10-Oct-2018
Dental calculus	10-Oct-2018
Overweight	10-Oct-2018
Gastroenteritis	10-Oct-2018
Taurine deficiency	10-Oct-2018
Systolic dysfunction	06-Oct-2018

Inactive Concerns	Established
n/a	

Resolved Concerns (since 09-Sep-2018)	Established	Resolved
n/a		

Medications (since 06-Dec-2017)	Amount	Disp. Date
n/a		

**Documents\***

09-Sep-2018 • [B6] 2019-01-02\_Converted medical history for [B6].pdf

**Communication logs**

	Source	From	To	Created by/date
05-Oct-2018 17:54	Email	[B6]	[B6]	[B6]/05-Oct-2018
<p><b>Appointment Confirmation</b> for [B6] at [B6] [B6] Dear [B6]</p> <p>This email is to confirm your appointment at [B6] for [B6]. Please review the appointment details below for accuracy:</p> <p>Reason for Appointment: Medical Appointment Date: Saturday, October 6, 2018 Appointment Time: 10:30 AM If you have any questions or need to reschedule your appointment, please contact us at [B6]</p> <p>Thank you, [B6]</p> <p>Map &amp; Directions <i>Please use attached .ics file to add appointment to your calendar.</i> Please do not reply to this email as we do not receive mail sent to this address.</p>				

**Echocardiogram report**

06-Oct-2018 **Echocardiogram** [B6] DVM

10:30 Order item: Echocardiogram [23.38]

Findings	
	<p><b>Mitral Valve:</b> Unremarkable valve morphology Valve insufficiency: not present</p> <p><b>Tricuspid Valve:</b> anatomically unremarkable morphology Valve insufficiency: not present Pulmonary Hypertension is not present</p> <p><b>Aorta</b> Aortic valve: Unremarkable morphology Blood flow velocity is within normal limits Aortic insufficiency: is not present Heart base mass was not present</p> <p><b>Pulmonic valve:</b> Unremarkable morphology Blood flow velocity is within normal limits</p> <p><b>Left atrium:</b> Normal in size and not dilated</p> <p><b>Right atrium:</b> Normal in size and not dilated No mass was seen</p> <p><b>Left ventricle:</b> Diastolic diameter: Normal in size Systolic function: Mild systolic myocardial failure Wall thickness: Within normal limits</p> <p><b>Right ventricle</b> Diastolic diameter: Normal in size</p>

\*Documents are available as separate attachments or files.

Wall thickness: Subjectively normal

**Pericardium:** No pericardial effusion present

**Pleural space:** Unremarkable

**Abdomen/ hepatic veins:** Not visualized

Interpretation

Mild systolic dysfunction with normal chamber dimensions. All valves competent.

**Outpatient visit** (06-Oct-2018 to 06-Oct-2018)

Appointment Type: **New Consult Only** **B6** Provider: **B6**, **DVM** Sex / age / weight: **Female - Spayed** / **B6** / **27.5 kg**  
(06-Oct-2018)

**Concerns** (Problem List)

Active

- **Systolic dysfunction** (06-Oct-2018)

**06-Oct-2018 Exam**

**B6** **DVM**

10:35

Assisted by: **B6**

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain	BCS
10:35	not taken	100	pant	--	< 2	Pink	--	--

CLIENT INTERVIEW

General findings

**History** - **B6** presented for a cardiology consultation due to recently diagnosed taurine deficiency (135 whole blood), her breed and history of being fed a grain free diet raised concern for taurine deficiency DCM. **B6** is overall asymptomatic at this time. She does seem heat intolerant and tires easily on walks yet this is not new. **B6** has a history of severe IBD, which prompted the grain free diet.

Presenting concerns

**Taurine Deficiency**

Past medical history

**Referring DVM Diagnostics**

Medication history

**Digestive Enzymes Probiotic; Allertech - 1 T SID**

Diet history

**PurVita Venison and Lintels**

EXAM FINDINGS

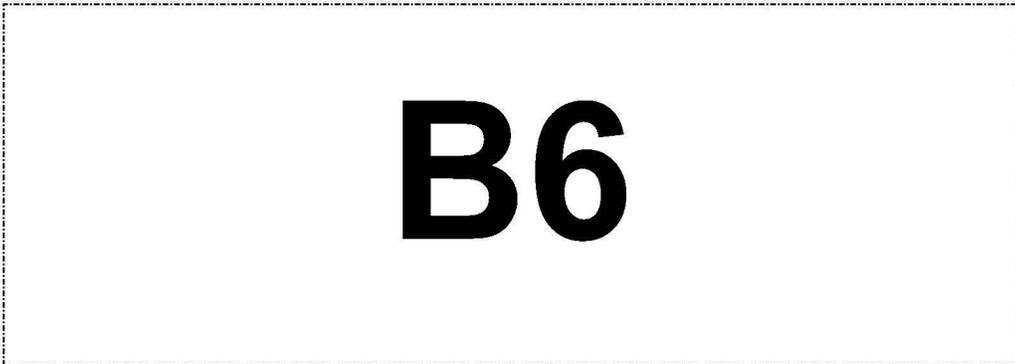
Whole body

Eyes

Thorax

Abdomen

Musculoskeletal



ASSESSMENTS

**Systolic dysfunction**

Suspect secondary to taurine deficiency give recent bloodwork. Systolic dysfunction is mild at this time with normal chamber dimensions.

Taurine deficiency DCM has been documented more commonly in Golden Retrievers and linked to diets containing novel proteins, grain-free, and/or boutique diets. The exact cause of taurine deficiency is unknown, given the over representation of GR dogs it is thought that they might have something in their genetic make-up that makes them less efficient at making taurine. It is also suspected that certain diets may have fewer building blocks for taurine or food components may inhibit

\*Documents are available as separate attachments or files.

**06-Oct-2018 Exam**

**B6** **DVM**

10:35

Assisted by: **B6**

synthesis. Given that the issue is not fully understood, the typically recommendation is to start taurine supplementation and alter diet (pending current diet profile). Pimobendan may be recommended in more severe cases.

Due to **B6** history of severe IBD, I recommend consulting your primary veterinarian regarding diet or our nutritionist Dr. **B6** here at **B6** I feel we need to be mindful in how we switch her diet to avoid causing a significant flare up of IBD.

PLANS

**Systolic dysfunction**

Recommend starting taurine supplementation 500mg PO q12h for 1-2 weeks, increase to 1000mg PO q12h if stools remain normal.

Recommend recheck taurine level 1 month after starting supplementation.

Recommend recheck echocardiogram in 4-6 months.

**06-Oct-2018 Order items**

- Exam/Consultation Cardiology [3.19]: 1.00 each
- Echocardiogram [23.38]: 1.00 proc
  - Specialty Interpretation of Ultrasound Study [23.134]: 1.00 proc

**Documents\***

- **B6** 2019-01-02\_Echo .pdf
- **B6** 2019-01-02\_Ref Recs- **B6** pdf
- 2019-01-02\_Ref Recs- **B6** pdf

**Outpatient visit (10-Oct-2018 to 10-Oct-2018)**

Appointment Type: **Consultation** Provider: **B6** **DVM, DACVN** Sex / age / weight: **Female - Spayed** / **B6** / **60 lb** (10-Oct-2018)

**Concerns (Problem List)**

Active

- **Urinary crystal, struvite** (10-Oct-2018)
- **Dental calculus** (10-Oct-2018)
- **Overweight** (10-Oct-2018)
- **Gastroenteritis** (10-Oct-2018)
- **Taurine deficiency** (10-Oct-2018)
- **Systolic dysfunction** (06-Oct-2018)

**10-Oct-2018 Exam**

**B6** **DVM, DACVN**

09:10

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain	BCS
09:10	<b>102.4</b>	110	phant	--	< 2	Pink	0	6

CLIENT INTERVIEW

General findings

**History** - Systolic dysfunction, taurine deficiency (135 whole blood). Generally asymptomatic; seems heat intolerant and tires easily on walks but this is not a new finding. Chronic history of sensitive stomach - owner reports suspected IBD but biopsies not performed; full elimination diet trial with challenge testing has not been performed to confirm or rule out food allergy. History of soft stool with mucus - resolved on current diet. Still has occasional episodes of bilious vomiting; possibly related to eating poop from feral cats. Seasonal allergies, well-managed with Allertec. Past history of calcium oxalate crystalluria per owner, recent struvite crystalluria with negative culture. No pollakiuria, hematuria, stranguria. Lifestyle: Indoor, moderate activity, no other pets at home. Fed 2x/day, finishing all food offered.

\*Documents are available as separate attachments or files.

10-Oct-2018 Exam

**B6** DVM, DACVN

09:10

Stable weight, no current nausea/vomiting. Good drinker.

Presenting concerns

**Taurine Deficiency**

Medication history

**Cetirizine** - (Aller-Tec) 10 mg PO q24h; **Heartgard** - Monthly

Diagnostic history

**Summary of prior diagnostics -**

09/19/16: ALP <10 u/L. PT wnl. Snap cPL wnl.  
09/20/16: AXR: No radiopaque GIFB, possible decreased serosal detail in mid/cranial abdomen  
06/23/16: CBC wnl. ALP <5 u/L, phos 2.8.  
09/23/16: AUS - no significant abnormalities noted.  
09/28/16: Fecal PCR negative. TAMU GI Panel: low B12; no abnormal folate/PLI results recorded.  
09/20/18: USG 1.030, pH 9, 2+ struvite crystalluria. UMIC negative.  
10/05/18: UC Davis whole blood taurine: 135 nmol/mL (200-350)  
10/06/18: Echo - Normal chamber dimensions, all valves competent, mild decrease in systolic function

Diet history

**Diet history -**

Current diet: Pure Vita Venison & Red Lentils Entrée Grain Free dry, 1.25 cup 2x/day fed since 9/2017. 429 kcal/cup = 1073 kcal/day. 6.8 g protein, 4 g fat, 77 mg sodium/100 kcal, 22.9 mg taurine/100 kcal. Contains venison, lentil, garbanzo beans, sunflower, alfalfa, pumpkin, chia seed, various fruits/vegetables

Previous diet:

- Wellness Complete Health Deboned Chicken & Oatmeal - d/c due to hematemesis, low B12. Contains chicken, oatmeal, barley, pea, rice, sweet potato, fruits/vegetables.
- Royal Canin Veterinary Diet Selected Protein Adult PV dry - started 12/2016; some vomiting, developed UTI; d/c due to venison shortage
- Royal Canin Veterinary Diet Selected Protein Adult PR dry - started 7/2017; diarrhea, fever, infection after change
- Home-cooked chicken and rice fed during recent GI upset - got better; chicken well-tolerated

Treats: Whole Life Pet Just One Ingredient Pure Beef Liver Treat (freeze dried), 1 treat/month; well-tolerated. Switch Pumpkin 1 tsp used when transitioning between diets.

Supplements:

- NaturVet Digestive Enzymes, 1/4 tsp q12h with meals.
- Country Life Taurine with B6 500 mg capsules sprinkled over food - gave twice; discontinued due to uncertainty about B6. Concerned about "fillers" in supplements
- Hx Henry Schein Omega Tri-V caps Large Dogs fish oil - discontinued.

Daily calorie intake: 1073 kcal/day

Prior ingredient exposures include: chicken, beef, venison, rabbit, oat, barley, pea, rice, sweet potato, lentil, garbanzo beans, pumpkin

Weight history

**Past weights -**

09/26/16: 30.9 kg = 68 lbs, BCS 7/9  
09/20/18: 28 kg = 61.9 lbs, BCS 4/9  
10/10/18: 27.2 kg = 60 lbs, BCS 6/9 (lots of motion)

**EXAM FINDINGS**

Whole body

Eyes

Ears

Mouth

Thorax

Abdomen

Pelvic region



\*Documents are available as separate attachments or files.

<b>B6</b>	<b>Exam</b>	<b>B6</b>	<b>DVM, DACVN</b>
09:10	Integument	<b>B6</b>	
	Lymphatic system		
	Musculoskeletal		
	Nervous system		

ASSESSMENTS

**Systolic dysfunction**

Mild decrease in systolic function noted on echo 10/06/18

**Taurine deficiency**

Low taurine while fed grain-free diet  
10/05/18: UC Davis whole blood taurine: 135 nmol/mL (200-350)

**B6**

PLANS

**Gastroenteritis, Taurine deficiency, Systolic dysfunction**

- Discussed nutritional management of DCM, current concerns about DCM/taurine deficiency/diet, nutritional management of chronic GI signs. Discussed elimination diet trial procedure including challenge testing.
- Recommend feeding limited ingredient diet from reputable manufacturer; can try more readily available protein sources (e.g., fish, hydrolyzed protein) and try products with higher fiber content to help with stool quality.
- Specific urinary diet not indicated at this time.
- Recommend reporting case to FDA to help with ongoing investigation.
- Nutrition plan to follow by email within 2 weeks.

**10-Oct-2018 Order items**

- Nutrition Consultation [3.48]: 1.00 each

**Documents\***

10-Oct-2018 **B6** 2019-01-02\_Nutrition intake form .pdf

**Communication logs**

	Source	From	To	Created by/date
<b>10-Oct-2018</b> 15:25	Phone	<b>B6</b> DVM, DACVN	<b>B6</b>	<b>B6</b>
		<b>FDA reporting</b> Spoke with <b>B6</b> by phone to discuss reporting to the FDA safety reporting portal. O had questions about privacy of data/information. Plan to email O with FDA links so she can investigate further and consider; O will email back to confirm whether she would like to move forward with FDA reporting or decline to participate.  Confirmed ok to do gradual introduction of taurine if <b>B6</b> seems to have an upset stomach.		

\*Documents are available as separate attachments or files.

	Source	From	To	Created by/date
15:29	Email	[B6] DVM, DACVN	[B6]	[B6] /10-Oct-2018

**Emailed FDA portal information**

From: [B6]  
Sent: Wednesday, October 10, 2018 3:25 PM  
To: [B6]  
Subject: FDA reporting portal

Hi [B6]

Here's the website with instructions for the FDA's safety reporting portal for reporting pet food complaints:  
[https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/\[B6\].htm](https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/[B6].htm)

FAQs on reporting a pet food complaint:  
[https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/\[B6\].htm](https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/[B6].htm)

Best,

[B6] DVM, DACVN  
**[B6]**

31-Oct-2018  
15:15

Email	[B6]	[B6] DVM, DACVN	[B6]	[B6] 31-Oct-2018
-------	------	-----------------	------	------------------

**O question about recommended diet**

From: [B6] <[B6]>  
Sent: Wednesday, October 31, 2018 3:05:14 PM  
To: [B6]  
Subject: [B6]-diet

Hi [B6]

Thank you for the list of authorized diets for [B6]

**[B6]**

Thank you very much,

[B6]

From: [B6]  
Sent: Wednesday, October 31, 2018 3:15 PM  
To: [B6]  
Subject: Re: [B6]-diet

\*Documents are available as separate attachments or files.

[B6] [B6]

Source	From	To	Created by/date
--------	------	----	-----------------

Hi [B6]

Yes, you have linked the correct product.

[B6] DVM, DACVN  
**[B6]**

06-Dec-2018  
20:08

Email	[B6]	[B6] DVM, DACVN	[B6] 06-Dec-2018
-------	------	-----------------	------------------

**O grants permission to report case to FDA**  
 From: [B6] [mailto:[B6]]  
 Sent: Wednesday, December 05, 2018 3:28 PM  
 To: [B6] <[B6]>  
 Subject: [B6] follow up

Hi [B6]

I just realized that I hadn't gotten back to you regarding reporting [B6] condition to the FDA.

Please feel free to share this info with them. I hope it helps in their investigation into this condition. I will be scheduling a follow up with you soon. I just completed the transition to the new food. Please feel free to contact me with any questions. Thank you for your time. [B6]

=====  
 From: [B6]  
 Sent: Thursday, December 06, 2018 8:10 PM  
 To: [B6] <[B6]>  
 Subject: RE: [B6] follow up

Hi [B6]

Thanks for the update. I'll be able to work on [B6] FDA case reporting when I'm back at [B6] next Wednesday.

Sincerely,

[B6], DVM, DACVN

B6

B6

B6

B6

Canine (Retriever, Golden) | Golden | F: S

B6

**B6** **Nutrition Plan** - October 21, 2018

**Medical Concerns:**

Systolic dysfunction - mild

Taurine deficiency

History of gastroenteritis, large bowel diarrhea - improved with limited-ingredient diet; chicken/beef allergy unlikely  
Struvite crystalluria - asymptomatic, urine culture negative. Owner reports past history of calcium oxalate crystalluria.

Overweight (27.3 kg = 60 lbs, BCS 6/9)

- Estimated ideal weight: 24.8 kg = 54.6 lbs

Seasonal allergies

Dental calculus

**Nutritional Goals:**

Complete and balanced diet

Taurine supplementation

Consider elimination diet trial to evaluate for food allergy

Consider fiber supplementation

Encourage moisture intake

Maintain body condition score (BCS) 5-6/9

A strict elimination diet trial is the only reliable way to diagnose food allergy in dogs. This procedure involves feeding a special diet using either novel ingredients (ones that have never been eaten before) or hydrolyzed proteins (ones where the proteins are very small and less likely to stimulate an immune system response). This special diet would need to be fed exclusively for at least 4 weeks for gastrointestinal signs or at least 8 weeks for skin signs. If signs improve, then challenge tests can be done to determine which food(s) may be causing a food allergy. If signs do not improve during the trial or do not return with a return to the previous diet, then food allergy is unlikely.

In **B6** case, she has been on a diet with unusual ingredients for quite some time. This diet may also differ from her past diets in other ways (e.g., digestibility, fiber content, etc.) rather than just its ingredients. Our plan is to transition her to a diet made by a well-established manufacturer, which should allow us to complete an elimination diet trial with less concern for issues related to DCM and taurine deficiency. Then, if her signs remain stable on the new diet, we can proceed with challenge testing to confirm or rule out food allergy.

**Daily calorie goal:** 1000 Calories per day, with 980 Calories/day from a balanced main diet and up to 20 Calories/day from treats.

**Commercial diets:** Veterinary therapeutic diets are available through a veterinarian or with a prescription. Daily feeding amounts can be divided into smaller meals as desired. You can mix and match diets as desired; adjust feeding amounts as needed to meet the daily calorie goal listed above.

- Royal Canin Veterinary Diet Selected Protein Adult PW Moderate Calorie dry (260 Calories/cup) - Feed 3 & 3/4

cups per day

- Royal Canin Veterinary Diet Hydrolyzed Protein Moderate Calorie dry (286 Calories/cup) - Feed 3 & 1/2 cups per day
- Hill's Prescription Diet i/d Sensitive dry (380 Calories/cup) - Feed 2 & 1/2 cups per day

**Water:** Fresh water should be available at all times. Water can be added to dry, canned, or home-cooked food to further increase water intake. Monitoring urine specific gravity (USG) will help determine whether more water should be added.

**Diet transitions:** A slow transition to a new diet plan may help with acceptance and tolerance. Gradually decrease the amount of old food while gradually increasing the amount of new food over about 7 days. Stop feeding a diet if it is not tolerated (refusal to eat, vomiting and/or diarrhea, etc.).

**Treats:** Treats should be limited to 20 Calories per day. The treats below are compatible with **B6** elimination diet trial.

- Royal Canin Veterinary Diet Hydrolyzed Protein treats: 6 Calories per treat
- Purina ProPlan Veterinary Diets Gentle Snackers: 15 Calories per treat

### Supplements:

- Taurine: Give 1000 mg orally twice daily. Suggested brands include NOW Foods, Solgar, and GNC.
- Fiber supplementation can be helpful for some pets with diarrhea. If soft stool is noted after transitioning to the new diet, you can try gradually adding about 1 teaspoon of ground psyllium husk to food 1-2 times daily; start low and increase as needed. You can mix psyllium with water or a small amount of canned pumpkin to help with consistency. One product without added flavors or sweeteners is NOW Foods Psyllium Husk Powder.
- Omega-3 fatty acids: There is some evidence that omega-3 fatty acid supplementation using fish oil can be helpful for animals with some types of heart disease. However, side effects can include stomach upset and soft stool. Please discontinue fish oil for now; we can consider gradual reintroduction of a concentrated fish oil supplement after determining the best main diet for **B6**.
- Probiotic supplementation can be helpful for some pets with soft stool. If needed, choose from the following recommended products and administer according to package directions.
  - Nutramax Provable DC: This product comes in a sprinkle capsule that can be opened so you can sprinkle the contents over food. Give one capsule per day.
  - Visbiome Vet: Give 2 capsules per day. Handling instructions: Visbiome Vet should be refrigerated. If stored under refrigeration, the product is guaranteed through "Best if used by" date. Visbiome can be stored at room temperature for up to one week without adversely affecting potency. Available online through [www.VetRxDirect.com](http://www.VetRxDirect.com).
- Digestive enzyme supplementation is not indicated for **B6** at this time.

B6

B6

B6

B6

Canine (Retriever, Golden) | Golden | F: S

B6

### Foods to avoid:

- Avoid any foods with ingredients that are not included in the selected elimination diet trial diet. This includes any treats, people foods, or flavored medications. Ask your regular veterinarian about topical or unflavored flea, tick, and heartworm medications.
- Avoid high salt foods including most dairy and bread products, potato chips, deli meats, fast food, and pizza.
- Avoid macadamia nuts, garlic, onions, grapes, raisins, and other foods that are toxic to dogs.
- Avoid xylitol, a sweetener found in some sugar-free gum, candy, and peanut butter.
- Avoid fresh, frozen, and freeze-dried raw foods and treat (including bully sticks, pig ears, and raw meaty bones) due to risk for bacterial contamination and other health concerns.
- Avoid bones, antlers, hooves, and other very hard chews; if a chew cannot be indented by your fingernail, it is too hard and can cause dental damage.

### Monitoring and Follow Up:

- **Tracking progress:** Please keep a journal or calendar of B6 diet, medications, supplements, and clinical signs (food intake, any vomiting, stool quality - please see fecal score chart handout). This will help us to monitor her response to changes in our treatment plan.
- **Weight:** Please weigh B6 every 1-2 weeks and contact us with an update if she is gaining or losing weight.
- **Urinary signs:** Monitor for lower urinary tract signs, including blood in the urine, urinating frequently in small amounts, or straining to urinate. If B6 is ever straining and unable to pass urine, please have her evaluated immediately; urinary obstruction is a medical emergency.
- **Cardiac:** Continue heart monitoring as directed by B6
- **Recheck:** A progress evaluation with B6 is recommended about 4 weeks after transitioning to the new diet plan. At this appointment, we will discuss whether calorie goals and diet recommendations need to be adjusted.
- **FDA reporting:** Reporting taurine-deficient DCM cases to the FDA is strongly recommended in order to help investigators learn more about this problem. Per your request, we have not yet initiated an FDA report for B6. If you would like to proceed with FDA reporting, please visit the following website: <https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm>. It is recommended that you keep B6 old food or packaging materials in case the FDA needs these for further investigation.
- Diet recommendations may require adjustment in the future if diets are not tolerated, if there are changes to B6 health, or if she will not eat any of the recommended foods.

Please contact us with any questions about B6 nutrition plan.

Sincerely,

**B6**

**B6**

**B6**

**B6**

| Canine (Retriever, Golden) | Golden | F: S

**B6**

**B6** DVM

Diplomate, American College of Veterinary Nutrition

**Report Details - EON-377164**

<b>ICSR:</b>	2061580
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Both
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-22 17:05:34 EST
<b>Reporter is the Animal Owner:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	dog began coughing at night. very did x-ray and listened; heart murmur which wasn't evident six months earlier, enlarged heart and connection which was also new. began feeding dog grain free food one year ago. dogs heart was healthy at that time at vet visit. have since been prescribed vetmedin and am switching back to mixed diet.
	<b>Date Problem Started:</b>	09/12/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Worse/Declining/Deteriorating

<b>Product Information:</b>	<b>Product Name:</b>	Rachel Ray's only six		
	<b>Product Type:</b>	Pet Food		
	<b>Lot Number:</b>			
	<b>UPC:</b>	unknown		
	<b>Package Type:</b>	BAG		
	<b>Package Size:</b>	15 Pound		
	<b>Purchase Date:</b>	08/01/2018		
	<b>Number Purchased:</b>	1		
	<b>Possess Unopened Product:</b>	No		
	<b>Possess Opened Product:</b>	Yes		
	<b>Storage Conditions:</b>	stored in a closed container.		
	<b>Product Use Information:</b>	<b>Description:</b>	free feeding	
		<b>Last Exposure Date:</b>	01/08/2019	
		<b>Time Interval between Product Use and Adverse Event:</b>	6 Months	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Unknown	
<b>Perceived Relatedness to Adverse Event:</b>		Definitely related		
<b>Other Foods or Products Given to the Animal During This Time Period:</b>		No		
<b>Manufacturer /Distributor Information:</b>				
<b>Purchase Location Information:</b>	<b>Name:</b>	petco		
	<b>Address:</b>	B6		

**B6**

United States

**Animal Information:**

**Name:** Chihuahua, dachshund  
**Type Of Species:** Dog  
**Type Of Breed:** Chihuahua  
**Gender:** Mixed Population of Female and Male  
**Reproductive Status:** Neutered  
**Weight:** 6 Pound  
**Age:** 10 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 2  
**Number of Animals Reacted:** 2  
**Owner Information:**  
**Healthcare Professional Information:**

**Sender Information:**

**Name:**  
**Address:** **B6**  
United States  
**Contact:**  
**Reporter Wants to Remain Anonymous:** Yes  
**Reported to Other Parties:** Other

**Additional Documents:**

Report Details - EON-375339		
ICSR:	2060822	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-03 15:48:03 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> There are 3 of my dogs that have been diagnosed with Enlarged heart. None of these 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.	
	<b>Date Problem Started:</b> B6	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Not Applicable	
Product Information:	<b>Product Name:</b> Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 12 Pound	
	<b>Purchase Date:</b> 12/03/2018	
	<b>Number Purchased:</b> 1	
	<b>Possess Unopened Product:</b> No	
	<b>Possess Opened Product:</b> No	
	<b>Storage Conditions:</b> Always removed from bag and put in a sterilite bin. Note date first given would actually be since )5/01/2001 It would not let me enter that year.	
	<b>Product Use Information:</b>	<b>Description:</b> I have fed this formula to my yorkies for 18 years. This not a specific bag instance. They were fed 1/4 cup twice a day dry.
		<b>Last Exposure Date:</b> 12/30/2018
		<b>Time Interval between Product Use and Adverse Event:</b> 18 Years
<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes		
<b>Adverse Event Abate After Product Stop:</b> No		
<b>Product Use Started Again:</b> No		
<b>Perceived Relatedness to Adverse Event:</b> Possibly related		
<b>Other Foods or Products Given</b> No		

to the Animal  
During This Time  
Period:

**Manufacturer  
/Distributor Information:**

**Purchase Location  
Information:**

Name:

B6

Address:

B6

United States

**Animal Information:**

Name:

B6

Type Of Species: Dog

Type Of Breed: Terrier - Yorkshire

Gender: Female

Reproductive Status: Neutered

Weight: 4.4 Pound

Age: 6 Years

Assessment of Prior  
Health: Excellent

Number of Animals  
Given the Product: 3

Number of Animals  
Reacted: 3

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: 04/12/2018

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

Preferred Method Of  
Contact: Phone

Reported to Other  
Parties: Manufacturer

Additional Documents:

Report Details - EON-375865		
ICSR:	2060990	
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:	2019-01-08 17:40:09 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> Whole Blood Taurine Level was 204 Plasma Taurine Level was 79	
	<b>Date Problem Started:</b> 11/14/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Not Applicable	
Product Information:	<b>Product Name:</b> Stella & Chewy's Frozen Raw Stella's Super Beef Dinner Patties	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 12 Pound	
	<b>Purchase Date:</b> 01/03/2019	
	<b>Number Purchased:</b> 1	
	<b>Possess Unopened Product:</b> Yes	
	<b>Possess Opened Product:</b> No	
	<b>Storage Conditions:</b> Always stored in the freezer	
	<b>Product Use Information:</b>	<b>Description:</b> Removed from freezer and put in refrigerator 12 hours prior to feeding
		<b>Time Interval between Product Use and Adverse Event:</b> 1 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> No
		<b>Perceived Relatedness to Adverse Event:</b> Possibly related
<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>	<b>Address:</b> United States	
Animal Information:	<b>Name:</b> B6	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Retriever - Golden	
	<b>Gender:</b> Female	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 44 Pound	

	<b>Age:</b>	3 Years
	<b>Assessment of Prior Health:</b>	Excellent
	<b>Number of Animals Given the Product:</b>	2
	<b>Number of Animals Reacted:</b>	1
	<b>Owner Information:</b>	
	<b>Healthcare Professional Information:</b>	
<b>Sender Information:</b>	<b>Name:</b>	B6
	<b>Address:</b>	B6 United States
	<b>Contact:</b>	<b>Phone:</b> B6
		<b>Other Phone:</b> B6
		<b>Email:</b> B6
	<b>Permission To Contact Sender:</b>	Yes
	<b>Preferred Method Of Contact:</b>	Email
	<b>Reported to Other Parties:</b>	Other
<b>Additional Documents:</b>		

**Report Details - EON-377564**

<b>ICSR:</b>	2061774		
<b>Type Of Submission:</b>	Initial		
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1		
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)		
<b>Reporting Type:</b>	Voluntary		
<b>Report Submission Date:</b>	2019-01-25 16:57:34 EST		
<b>Reporter is the Animal Owner:</b>	Yes		
<b>Reported Problem:</b>	<b>Problem Description:</b>	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.	
	<b>Date Problem Started:</b>	12/04/2018	
	<b>Concurrent Medical Problem:</b>	No	
	<b>Outcome to Date:</b>	Worse/Declining/Deteriorating	
<b>Product Information:</b>	<b>Product Name:</b>	4 health	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	No	
	<b>Storage Conditions:</b>	In original bag.	
	<b>Product Use Information:</b>	<b>Description:</b>	2 cups, twice a dsy
		<b>Time Interval between Product Use and Adverse Event:</b>	2 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
<b>Adverse Event Abate After Product Stop:</b>		No	
<b>Product Use Started Again:</b>		No	
<b>Perceived Relatedness to Adverse Event:</b>		Probably related	
<b>Other Foods or Products Given to the Animal During This Time Period:</b>		No	
<b>Manufacturer:</b>			

	<b>/Distributor Information:</b>	
	<b>Purchase Location Information:</b>	<b>Name:</b> Tractor Supply
		<b>Address:</b> United States
	<b>Product Name:</b>	Taste of the Wild
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Possess Unopened Product:</b>	No
	<b>Possess Opened Product:</b>	No
	<b>Storage Conditions:</b>	Stored in original bag. In the pantry.
	<b>Product Use Information:</b>	<b>Description:</b> 2 cups twice a day
		<b>Perceived Relatedness to Adverse Event:</b> Probably related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b> No
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
<b>Animal Information:</b>	<b>Name:</b>	B6
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Bulldog - American
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	56 Pound
	<b>Age:</b>	3 Years
	<b>Assessment of Prior Health:</b>	Excellent
	<b>Number of Animals Given the Product:</b>	1
	<b>Number of Animals Reacted:</b>	1
	<b>Owner Information:</b>	
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> B6
		<b>Contact:</b> <b>Name:</b> B6
		<b>Phone:</b> B6
	<b>Type of Veterinarian:</b>	Primary/regular veterinarian
	<b>Date First Seen:</b>	12/04/2018
	<b>Permission to Release Records to FDA:</b>	Yes
	<b>Practice Name:</b> B6	
		<b>Contact:</b> <b>Name:</b> B6
		<b>Phone:</b> B6
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Date First Seen:</b>	01/25/2019

Permission to Release Records to FDA: Yes

Sender Information:

Name:	
Address:	B6 United States
Contact:	
Reporter Wants to Remain Anonymous:	Yes
Reported to Other Parties:	None

Additional Documents:

**Report Details - EON-377278**

<b>ICSR:</b>	2061637		
<b>Type Of Submission:</b>	Initial		
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1		
<b>Type Of Report:</b>	Both		
<b>Reporting Type:</b>	Voluntary		
<b>Report Submission Date:</b>	2019-01-23 14:31:35 EST		
<b>Reporter is the Animal Owner:</b>	Yes		
<b>Reported Problem:</b>	<b>Problem Description:</b>	<b>B6</b> 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 UC Davis 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.	
	<b>Date Problem Started:</b>	08/22/2018	
	<b>Date of Recovery:</b>	01/10/2019	
	<b>Concurrent Medical Problem:</b>	No	
	<b>Outcome to Date:</b>	Recovered Completely	
<b>Product Information:</b>	<b>Product Name:</b>	Taste of the Wild (Pacific Stream formula)	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	28 Pound	
	<b>Purchase Date:</b>	08/06/2018	
	<b>Number Purchased:</b>	1	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	No	
	<b>Storage Conditions:</b>	It was stored in its original bag, in a closed plastic storage container in the basement.	
	<b>Product Use Information:</b>	<b>Description:</b>	It was kibble fed to <b>B6</b> twice a day, moistened with water.
		<b>Last Exposure Date:</b>	08/30/2018
		<b>Time Interval between Product Use and Adverse Event:</b>	3 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
<b>Adverse Event Abate After Product Stop:</b>		Yes	
<b>Product Use Started Again:</b>		No	
<b>Perceived Relatedness to Adverse Event:</b>		Definitely related	
<b>Other Foods or</b>		Yes	

		Products Given to the Animal During This Time Period:		
	Manufacturer /Distributor Information:			
	Purchase Location Information:	Name:	chewy.com	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	74 Pound		
	Age:	6 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	
Email:			B6	
Address:		B6		
		United States		
Type of Veterinarian:		Referred veterinarian		
Date First Seen:	09/06/2018			
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:	Email			
Reported to Other Parties:	None			
Additional Documents:	Attachment:	img088.jpg		
	Description:	follow-up echocardiogram		
	Type:	Echocardiogram		
	Attachment:	img076.jpg		
		initial echocardiogram		

**Description:**

**Type:** Echocardiogram

B6

B6

Name: B6  
Weight: 33.0 kg (72.8 lbs)  
Age: 6  
Sex: Male  
Breed: Canine

Date: 09/06/2018  
Cardiologist: B6 DVM, DACVIM (Cardiology)  
Ref. Hosp.: B6  
Patient ID: B6

B6

**History & Cardiovascular Examination:**

Indication: low blood taurine on recent exam. Screen for DCM. Diet was salmon based originally and changed to chicken based diet.

PE: panting; no murmur; regular

**Echocardiographic Findings:**

Comprehensive echocardiographic descriptions::

ECG: sinus rhythm

Left ventricle: moderate dilation in diastole and systole; adequate fractional shortening

Left atrium: normal size.

Right ventricle: normal size and function

Right atrium: normal size.

Mitral valve: normal appearance without regurgitation.

Tricuspid valve: normal appearance without regurgitation.

Aortic valve: normal appearance without regurgitation nor stenosis

Pulmonic valve: normal appearance without regurgitation nor stenosis.

Aorta: normal size and appearance.

Pulmonary arteries: normal size and appearance.

Pericardium: normal appearance without pericardial effusion.

Pleural space: no effusion noted

**Cardiac Diagnoses & Assessment:**

- 1) Left ventricular dilatation - r/o DCM vs nutritional/malabsorptive vs myocarditis
- 2) Low blood taurine

DCM is a rule out diagnosis and given the recent low taurine levels and diet changes, a nutritional cardiomyopathy seems more likely than primary DCM. Future exams will better prognosticate.

**Recommendations:**

- 1) Start pimobendan 10mg PO BID
- 2) Add taurine 1 gram PO BID
- 3) Add enalapril 15mg PO BID (check renal values in 5-7 days)
- 3b) 2 weeks recheck taurine, renal, tick panel and thyroid
- 4) Continue a commercial, non-novel protein based diet

Print Date: 9/6/2018

FDA-CVM-FOIA-2019-1704-003676

Report Details - EON-377174			
ICSR:	2061583		
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:	2019-01-22 17:58:32 EST		
Reported Problem:	<b>Problem Description:</b>	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,	
	<b>Date Problem Started:</b>	B6	
	<b>Concurrent Medical Problem:</b>	No	
	<b>Outcome to Date:</b>	Better/Improved/Recovering	
Product Information:	<b>Product Name:</b>	Taste of the Wild High Prairie grain-free with roasted bison and roasted venison	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Possess Unopened Product:</b>	Unknown	
	<b>Possess Opened Product:</b>	Unknown	
	<b>Product Use Information:</b>	<b>Description:</b>	Fed daily for 5-6 years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
		<b>Adverse Event Abate After Product Stop:</b>	Unknown
		<b>Product Use Started Again:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Possibly related
<b>Manufacturer /Distributor Information:</b>			
<b>Purchase Location Information:</b>			
Animal Information:	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Mixed (Dog)	
	<b>Gender:</b>	Male	
	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	27 Kilogram	
	<b>Age:</b>	11 Years	
	<b>Assessment of Prior Health:</b>	Good	
	<b>Number of Animals Given the Product:</b>	1	
	<b>Number of Animals Reacted:</b>	1	
<b>Owner Information:</b>	<b>Owner</b> Yes		

	<b>Information provided:</b>									
	<b>Contact:</b>	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> </table>	Name:	B6	Phone:	B6				
Name:	B6									
Phone:	B6									
	<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States						
B6										
United States										
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6								
	<b>Contact:</b>	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td>B6</td> </tr> </table>	Name:	B6	Phone:	B6	Other Phone:	B6	Email:	B6
Name:	B6									
Phone:	B6									
Other Phone:	B6									
Email:	B6									
	<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States						
B6										
United States										
<b>Sender Information:</b>	<b>Name:</b>	B6								
	<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States						
B6										
United States										
	<b>Contact:</b>	<table border="1"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td>B6</td> </tr> </table>	Phone:	B6	Other Phone:	B6	Email:	B6		
Phone:	B6									
Other Phone:	B6									
Email:	B6									
	<b>Permission To Contact Sender:</b>	Yes								
	<b>Preferred Method Of Contact:</b>	Email								
	<b>Reported to Other Parties:</b>	None								
<b>Additional Documents:</b>										

Report Details - EON-374547							
ICSR:	2060525						
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:	2018-12-22 17:18:45 EST						
Reported Problem:	<b>Problem Description:</b> Patient presented on <b>B6</b> with a 10 day history of reduced appetite and an episode of diarrhea 2 weeks prior. Prior to presentation he was found to be very lethargic with a distended abdomen. Patient was found to have changes consistent with dilated cardiomyopathy were severe pump dysfunction and biventricular congestive heart failure. Had been given a grain free diet for over a year (Tate of the Wild Prey). The abdomen was drained of about 2.6 L for comfort. The patient initially responded favorably but died suddenly the next morning with an acute onset of respiratory difficulty. Contacted Jennifer Jones, DVM who recommended a complaint be submitted and obtained tissue samples from the pet even though a full necropsy was unable to be performed.						
	<b>Date Problem Started:</b> <b>B6</b>						
	<b>Concurrent Medical Problem:</b> No						
	<b>Outcome to Date:</b> Died Naturally						
Product Information:	<b>Date of Death:</b> <b>B6</b>						
	<b>Product Name:</b> Taste of the Wild Prey						
	<b>Product Type:</b> Pet Food						
	<b>Lot Number:</b>						
	<b>Package Type:</b> BAG						
	<b>Product Use Information:</b> <table border="1"> <tr> <td><b>Description:</b></td> <td>Meal feeding</td> </tr> <tr> <td><b>Time Interval between Product Use and Adverse Event:</b></td> <td>1 Years</td> </tr> <tr> <td><b>Perceived Relatedness to Adverse Event:</b></td> <td>Probably related</td> </tr> </table>	<b>Description:</b>	Meal feeding	<b>Time Interval between Product Use and Adverse Event:</b>	1 Years	<b>Perceived Relatedness to Adverse Event:</b>	Probably related
	<b>Description:</b>	Meal feeding					
	<b>Time Interval between Product Use and Adverse Event:</b>	1 Years					
<b>Perceived Relatedness to Adverse Event:</b>	Probably related						
<b>Manufacturer /Distributor Information:</b>							
<b>Purchase Location Information:</b>							
Animal Information:	<b>Name:</b> <b>B6</b>						
	<b>Type Of Species:</b> Dog						
	<b>Type Of Breed:</b> Terrier - Bull - Staffordshire						
	<b>Gender:</b> Male						
	<b>Reproductive Status:</b> Intact						
	<b>Weight:</b> 26 Kilogram						
	<b>Age:</b> 2 Years						
	<b>Assessment of Prior Health:</b> Good						
	<b>Number of Animals Given the Product:</b> 1						
	<b>Number of Animals Reacted:</b> 1						
	<b>Owner Information:</b> <table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>No</td> </tr> </table>	<b>Owner Information provided:</b>	No				
	<b>Owner Information provided:</b>	No					
	<b>Healthcare Professional</b>						

	<b>Information:</b>		
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6 United States	
	<b>Contact:</b>	<b>Phone:</b>	B6
		<b>Other Phone:</b>	B6
		<b>Email:</b>	B6
	<b>Reporter Wants to Remain Anonymous:</b>	No	
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Reported to Other Parties:</b>	None		
<b>Additional Documents:</b>			

Report Details - EON-377360							
ICSR:	2061702						
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:	2019-01-24 11:22:19 EST						
Reporter is the Animal Owner:	Yes						
Reported Problem:	<b>Problem Description:</b> Diet for entire life consisted of grain free food. Started in July to have labored breathing with an occasional gag. Activity level had decreased. X-rays showed displacement of trachea. Vet treated for pneumonia due to white areas of lung. Finally got an echocardiogram and the diagnosis was Dilated Cardiomyopathy. Tests also showed his liver, spleen, and caudal vena cava were enlarged. The last week of life, he could not lay down but would just stand and pant. When it got so bad, I chose to let him be euthanized.						
	<b>Date Problem Started:</b> 07/01/2018						
	<b>Concurrent Medical Problem:</b> No						
	<b>Outcome to Date:</b> Died Euthanized						
	<b>Date of Death:</b> B6						
Product Information:	<b>Product Name:</b> Taste of the Wild Sierra Mountain						
	<b>Product Type:</b> Pet Food						
	<b>Lot Number:</b>						
	<b>Package Type:</b> BAG						
	<b>Possess Unopened Product:</b> No						
	<b>Possess Opened Product:</b> No						
	<b>Product Use Information:</b> <table border="1"> <tr> <td><b>Time Interval between Product Use and Adverse Event:</b></td> <td>4 Years</td> </tr> <tr> <td><b>Product Use Stopped After the Onset of the Adverse Event:</b></td> <td>No</td> </tr> <tr> <td><b>Perceived Relatedness to Adverse Event:</b></td> <td>Definitely related</td> </tr> </table>	<b>Time Interval between Product Use and Adverse Event:</b>	4 Years	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	No	<b>Perceived Relatedness to Adverse Event:</b>	Definitely related
	<b>Time Interval between Product Use and Adverse Event:</b>	4 Years					
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	No					
	<b>Perceived Relatedness to Adverse Event:</b>	Definitely related					
<b>Manufacturer /Distributor Information:</b>							
<b>Purchase Location Information:</b>							
Animal Information:	<b>Name:</b> B6						
	<b>Type Of Species:</b> Dog						
	<b>Type Of Breed:</b> Bulldog						
	<b>Gender:</b> Male						
	<b>Reproductive Status:</b> Intact						
	<b>Weight:</b> 56 Pound						
	<b>Age:</b> 10 Years						
	<b>Assessment of Prior Health:</b> Excellent						
<b>Number of Animals Given the Product:</b> 5							

	<b>Number of Animals Reacted:</b>	1
	<b>Owner Information:</b>	
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6
	<b>Contact:</b>	<b>Name:</b> B6 <b>Phone:</b> B6
	<b>Type of Veterinarian:</b>	Primary/regular veterinarian
	<b>Date First Seen:</b>	08/02/2018
	<b>Permission to Release Records to FDA:</b>	Yes
	<b>Practice Name:</b>	B6
	<b>Contact:</b>	<b>Name:</b> B6 <b>Phone:</b> B6
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Date First Seen:</b>	08/22/2018
	<b>Permission to Release Records to FDA:</b>	Yes
<b>Sender Information:</b>	<b>Name:</b>	B6
	<b>Address:</b>	B6 United States
	<b>Contact:</b>	<b>Phone:</b> B6 <b>Email:</b> B6
	<b>Permission To Contact Sender:</b>	Yes
	<b>Preferred Method Of Contact:</b>	Email
	<b>Reported to Other Parties:</b>	None
<b>Additional Documents:</b>		

**Report Details - EON-374534**

<b>ICSR:</b>	2060519		
<b>Type Of Submission:</b>	Initial		
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1		
<b>Type Of Report:</b>	Both		
<b>Reporting Type:</b>	Voluntary		
<b>Report Submission Date:</b>	2018-12-22 10:35:42 EST		
<b>Reporter is the Animal Owner:</b>	Yes		
<b>Reported Problem:</b>	<b>Problem Description:</b>	On third and final visit to vet due to heavy panting, difficulty breathing, and collapse the vet started an IV to hydrate her and found excessive fluid around the heart in x-ray. Sent us to emergency pet hospital which eventually asked us if we wanted to have them insert breathing tube to aid her struggle to breathe. Eventually, put her down because decided to discontinue breathing assistance.	
	<b>Date Problem Started:</b>	B6	
	<b>Concurrent Medical Problem:</b>	Yes	
	<b>Pre Existing Conditions:</b>	In and out of vet for past 3 months leading to event for various symptoms. First visit (Mar 2018) was for lethargy, weakness in hind legs. Vet prescribed Gabepentin and Carprofen and Dasuquin supplment. Secon visit was for puffy face, which we thought was allergies. Vet suggested Benadryl. Third visit was for excessive panting and difficulty breathing.	
	<b>Outcome to Date:</b>	Died Euthanized	
	<b>Date of Death:</b>	B6	
<b>Product Information:</b>	<b>Product Name:</b>	Taste of the Wild Wetlands Canine Formula with roasted Fowl	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	15 Pound	
	<b>Number Purchased:</b>	1	
	<b>Possess Unopened Product:</b>	No	
	<b>Storage Conditions:</b>	Stored in large tin with a lid	
	<b>Product Use Information:</b>	<b>Description:</b>	1/4 cup was given in bowl in combination with rice, a fruit or vegetable, and protein (typically cottage cheese, eggs, or meat).
		<b>First Exposure Date:</b>	04/01/2012
		<b>Last Exposure Date:</b>	B6
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Definitely related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
<b>Manufacturer /Distributor Information:</b>			
<b>Purchase Location Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6	

**B6**

United States

**Animal Information:**

<b>Name:</b>	
<b>Type Of Species:</b>	Dog
<b>Type Of Breed:</b>	Retriever - Golden
<b>Gender:</b>	Female
<b>Reproductive Status:</b>	Neutered
<b>Weight:</b>	65 Pound
<b>Age:</b>	6 Years
<b>Assessment of Prior Health:</b>	Excellent
<b>Number of Animals Given the Product:</b>	1
<b>Number of Animals Reacted:</b>	1
<b>Owner Information:</b>	
<b>Healthcare Professional Information:</b>	

**Sender Information:**

<b>Name:</b>	<b>B6</b>
<b>Contact:</b>	<b>Email:</b> <b>B6</b>
<b>Reporter Wants to Remain Anonymous:</b>	No
<b>Permission To Contact Sender:</b>	Yes
<b>Preferred Method Of Contact:</b>	Email

**Additional Documents:**

Report Details - EON-376466	
ICSR:	2061221
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:	2019-01-15 17:57:25 EST
Reported Problem:	<b>Problem Description:</b> B6 presented on emergency for lethargy, hyporexia, and tachypnea. Diagnostics testing (echocardiogram) revealed Dilated Cardiomyopathy. It was discovered that B6 had been on a grain free diet.
	<b>Date Problem Started:</b> B6
	<b>Date of Recovery:</b> 11/09/2018
	<b>Concurrent Medical Problem:</b> No
	<b>Outcome to Date:</b> Better/Improved/Recovering
Product Information:	<b>Product Name:</b> Taste of the Wild.
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Product Use Information:</b>
	<b>Description:</b> Taste of the Wild is a dry dog kibble. B6 has been on this diet and only this diet since he was a puppy.
	<b>First Exposure Date:</b> 01/01/2015
	<b>Time Interval between Product Use and Adverse Event:</b> 3 Years
	<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes
	<b>Adverse Event Abate After Product Stop:</b> Yes
	<b>Product Use Started Again:</b> No
<b>Perceived Relatedness to Adverse Event:</b> Probably related	
<b>Manufacturer /Distributor Information:</b>	
<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> B6
	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> Retriever - Golden
	<b>Gender:</b> Male
	<b>Reproductive Status:</b> Intact
	<b>Weight:</b> 79 Pound
	<b>Age:</b> 4 Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 1
	<b>Number of Animals Reacted:</b> 1

	<b>Owner Information:</b>	<b>Owner Information provided:</b>	Yes					
		<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>
<b>Name:</b>	B6							
<b>Phone:</b>	B6							
<b>Email:</b>	B6							
		<b>Address:</b>	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States			
<b>B6</b>								
United States								
	<b>Healthcare Professional Information:</b>							
<b>Sender Information:</b>	<b>Name:</b>	B6						
	<b>Address:</b>	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States				
	<b>B6</b>							
	United States							
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Phone:</b>	B6	<b>Email:</b>	B6		
	<b>Phone:</b>	B6						
	<b>Email:</b>	B6						
<b>Reporter Wants to Remain Anonymous:</b>	No							
<b>Permission To Contact Sender:</b>	Yes							
<b>Preferred Method Of Contact:</b>	Email							
<b>Reported to Other Parties:</b>	Other							
<b>Additional Documents:</b>	<b>Attachment:</b>	B6	Taurine T_22752.pdf					
	<b>Description:</b>	Taurine level from the diagnostic lab at UC Davis. They are investigating "grain free" diets and DCM, suspecting Taurine deficiency. The UC Davis lab considers B6 level low according to what they are seeing with grain free diets.						
	<b>Type:</b>	Laboratory Report						

Report Details - EON-374698		
ICSR:	2060561	
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:	2018-12-26 11:24:57 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> Started feeding him Taste of the Wild bison formula on 03/2016. On 11/2016 we started to notice a decrease in his activity level and his health in general. After undergoing several test on 05/2018 we were told that he had now an enlarged heart. Something that was not detected previously. We finally determined that it was the food we were feeding him that was causing all the problems. We change the food we were feeding him but the damage had already been done. Sadly he passed away on [ B6 ] while playing in the park.	
	<b>Date Problem Started:</b> 03/01/2016	
	<b>Concurrent Medical Problem:</b> Yes	
	<b>Pre Existing Conditions:</b> Had a slightly herniated disc and was taking 400 mg of Gabapentin 2 times a day while under going rehab. Also had 2 melanomas removed from his leg. The first in 2014. The second in the same location in 02/2018.	
	<b>Outcome to Date:</b> Died Other	
	<b>Date of Death:</b> [ B6 ]	
Product Information:	<b>Product Name:</b> Taste of the Wild	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>UPC:</b> NA	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 30 Pound	
	<b>Number Purchased:</b> 1	
	<b>Possess Unopened Product:</b> No	
	<b>Possess Opened Product:</b> No	
	<b>Storage Conditions:</b> Sealed plastic container.	
	<b>Product Use Information:</b>	<b>Description:</b> Feed 2 times a day.
		<b>First Exposure Date:</b> 03/01/2016
		<b>Last Exposure Date:</b> 05/18/2018
		<b>Time Interval between Product Use and Adverse Event:</b> 8 Months
<b>Product Use Stopped After the Onset of the Adverse Event:</b> No		
<b>Perceived Relatedness to Adverse Event:</b> Definitely related		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b> Name: Several locations		

<b>Animal Information:</b>	<b>Name:</b>	B6		
	<b>Type Of Species:</b>	Dog		
	<b>Type Of Breed:</b>	Boxer (German Boxer)		
	<b>Gender:</b>	Male		
	<b>Reproductive Status:</b>	Neutered		
	<b>Weight:</b>	90 Pound		
	<b>Age:</b>	B6 Years		
	<b>Assessment of Prior Health:</b>	Good		
	<b>Number of Animals Given the Product:</b>	1		
	<b>Number of Animals Reacted:</b>	1		
	<b>Owner Information:</b>			
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	B6	
		<b>Contact:</b>	<b>Name:</b>	Staff Vet
			<b>Phone:</b>	B6
			<b>Other Phone:</b>	B6
		<b>Address:</b>	B6	
			United States	
<b>Type of Veterinarian:</b>		Referred veterinarian		
<b>Date First Seen:</b>		05/18/2018		
<b>Permission to Release Records to FDA:</b>		Yes		
<b>Sender Information:</b>		<b>Name:</b>	B6	
	<b>Address:</b>	B6		
		United States		
	<b>Contact:</b>	<b>Phone:</b>	B6	
		<b>Other Phone:</b>	B6	
<b>Email:</b>		B6		
<b>Permission To Contact Sender:</b>	Yes			
<b>Preferred Method Of Contact:</b>	Email			
<b>Reported to Other Parties:</b>	None			
<b>Additional Documents:</b>				

**Report Details - EON-377156**

<b>ICSR:</b>	2061571
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-22 15:59:06 EST
<b>Reporter is the Animal Owner:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	<b>B6</b> has NEVER had a heart issue and has been fed a grain free diet for several years at least (two different brands, which I purchased from Chewy.com) - and she developed a heart murmur just recently (valve issue), and an irregular heartbeat just recently. This was first noticed in December 2018, at a mostly routine visit, and then the specialist told me that the grain free diets could be linked. We visited the specialist in January 2019.
	<b>Date Problem Started:</b>	12/26/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Unknown

<b>Product Information:</b>	<b>Product Name:</b>	Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food, 27-lb bag
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>UPC:</b>	unknown
	<b>Package Type:</b>	BAG
	<b>Package Size:</b>	27 Pound
	<b>Purchase Date:</b>	07/01/2014
	<b>Number Purchased:</b>	1
	<b>Possess Unopened Product:</b>	No
	<b>Possess Opened Product:</b>	No
<b>Storage Conditions:</b>	In an airtight container at room temperature in the house.	

<b>Product Use Information:</b>	<b>Description:</b>	Served as regular dog food morning and night.
	<b>First Exposure Date:</b>	07/24/2014
	<b>Last Exposure Date:</b>	02/01/2015
	<b>Time Interval between Product Use and Adverse Event:</b>	5 Years
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Unknown
	<b>Perceived Relatedness to Adverse Event:</b>	Possibly related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Unknown
	<b>Manufacturer /Distributor Information:</b>	
<b>Purchase Location</b>	<b>Name:</b>	Chewy.com

<b>Information:</b>	<b>Address:</b> unknown <b>B6</b> unknown United States	
<b>Product Name:</b>	Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food, 23.5-lb bag by CANIDAE	
<b>Product Type:</b>	Pet Food	
<b>Lot Number:</b>		
<b>UPC:</b>	unknown	
<b>Package Type:</b>	BAG	
<b>Package Size:</b>	23.5 Pound	
<b>Purchase Date:</b>	05/05/2017	
<b>Number Purchased:</b>	1	
<b>Possess Unopened Product:</b>	No	
<b>Possess Opened Product:</b>	Yes	
<b>Storage Conditions:</b>	Stored in an airtight container at room temperature in the house.	
<b>Product Use Information:</b>	<b>Description:</b>	Fed to my dog morning and night as her normal food.
	<b>First Exposure Date:</b>	05/05/2017
	<b>Last Exposure Date:</b>	01/16/2019
	<b>Time Interval between Product Use and Adverse Event:</b>	21 Months
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
	<b>Adverse Event Abate After Product Stop:</b>	Unknown
	<b>Product Use Started Again:</b>	No
	<b>Perceived Relatedness to Adverse Event:</b>	Probably related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Unknown
	<b>Manufacturer /Distributor Information:</b>	
<b>Purchase Location Information:</b>	<b>Name:</b>	Chewy.com
	<b>Address:</b> unknown <b>B6</b> unknown United States	
<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b>
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Shepherd Dog - Australian
	<b>Gender:</b>	Female

	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 55 Pound
	<b>Age:</b> 11 Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 1
	<b>Number of Animals Reacted:</b> 1
	<b>Owner Information:</b>
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> B6
	<b>Contact:</b> <b>Name:</b> B6
	<b>Phone:</b> B6
	<b>Address:</b> B6 United States
	<b>Type of Veterinarian:</b> Primary/regular veterinarian
	<b>Date First Seen:</b> 12/26/2018
	<b>Permission to Release Records to FDA:</b> Yes
	<b>Practice Name:</b> B6
	<b>Contact:</b> <b>Name:</b> B6
	<b>Phone:</b> B6
	<b>Address:</b> B6 United States
	<b>Type of Veterinarian:</b> Referred veterinarian
	<b>Date First Seen:</b> 01/17/2019
	<b>Permission to Release Records to FDA:</b> Yes
<b>Sender Information:</b>	<b>Name:</b> B6
	<b>Address:</b> B6 United States
	<b>Contact:</b> <b>Phone:</b> B6
	<b>Email:</b> B6
	<b>Permission To Contact Sender:</b> Yes
	<b>Preferred Method Of Contact:</b> Email
	<b>Reported to Other Parties:</b> Distributor
<b>Additional Documents:</b>	<b>Attachment:</b> Vet record 1-17-19; B6.pdf
	<b>Description:</b> Record of the visit to B6 (cardiac specialist) detailing her condition.



**Report Details - EON-377359**

<b>ICSR:</b>	2061700
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-01-24 11:11:03 EST
<b>Reporter is the Animal Owner:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	<b>B6</b> began vomiting once a day for a few days, then it progressed to a couple of times a day. Her energy seemed to dissipate too...she was lethargic, depressed. I was contacting the vet via email and inquiring on ideas of what was going on. We put her on a bland rice/egg diet for a week, but no change was noted...other than a new symptom occurred of her panting a lot. When <b>B6</b> started to noticeably lose weight, I immediately took her into the vet for a physical exam. She had dropped 9 lbs from the previous visit of two months earlier! The vet kept us there most of the day running blood work, etc. Everything came back fine. When xrays were performed, it was clear what the problem was. <b>B6</b> heart was clearly enlarged. Where it normally was supposed to be within 3 ribs, it was over 5 ribs and encroaching on her other organs! The vet immediately suspected it was the grain-free kibble (Wholesomes Food For Dogs Chickmeal and Chickpea formula: Grain-free/Gluten-free that I purchased at Tractor Supply) that I had her on...and she prescribed her heart meds, an antibiotic (going the remedial course as if peritonitis as a secondary diagnosis), and a medication to alleviate the nausea. We purchased Purina dogfood and immediately fed it to her...and she is still on it to this very day. <b>B6</b> is still throwing up occasionally, but the vet assured me that if her heart heals this will lessen.
	<b>Date Problem Started:</b>	12/23/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Stable

<b>Product Information:</b>	<b>Product Name:</b>	Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	BAG	
	<b>Package Size:</b>	35 Pound	
	<b>Number Purchased:</b>	1	
	<b>Possess Unopened Product:</b>	No	
	<b>Possess Opened Product:</b>	No	
	<b>Storage Conditions:</b>	I purchased it from Tractor Supply, took it home and put it in a dogfood container (plastic) and threw out the bag	
	<b>Product Use Information:</b>	<b>Description:</b>	I give 2 cups of food to <b>B6</b> in the morning and 2 cups of food at night.
	<b>First Exposure Date:</b>	11/26/2018	
	<b>Last Exposure Date:</b>	01/14/2019	
	<b>Time Interval between Product Use and Adverse Event:</b>	3 Weeks	
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes	

		Adverse Event Abate After Product Stop:	Yes
		Product Use Started Again:	No
		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:	Tractor Supply
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - German	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	64 Pound	
	Age:	3 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
		Email:	B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	01/14/2019
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6 United States	

	<b>Contact:</b>	<b>Phone:</b>	B6
		<b>Email:</b>	B6
	<b>Reporter Wants to Remain Anonymous:</b>	No	
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
<b>Reported to Other Parties:</b>	Other		

<b>Additional Documents:</b>	<b>Attachment:</b>	daily log on	B6	.jpg
	<b>Description:</b>	Daily log on B6		
	<b>Type:</b>	Photograph		
	<b>Attachment:</b>	meds that	B6	is on.jpg
	<b>Description:</b>	Meds that B6 is currently on		
	<b>Type:</b>	Photograph		
	<b>Attachment:</b>	B6	food.jpg	
	<b>Description:</b>	picture of dogfood purchased		
	<b>Type:</b>	Photograph		



# Determination of the prevalence of whole blood taurine in Irish wolfhound dogs with and without echocardiographic evidence of dilated cardiomyopathy<sup>☆</sup>

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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.

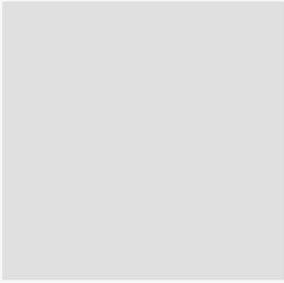
**Methods:** Whole blood taurine was measured in IW that received cardiovascular examination. Dietary history was recorded; crude protein and energy intake were estimated.

**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

<sup>☆</sup> 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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## Commentary

# Diet-associated dilated cardiomyopathy in dogs: what do we know?

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**D**iet-associated DCM first came to light in cats in the late 1980s<sup>1</sup> and in dogs in the mid-1990s.<sup>2</sup> The association between diet and DCM in dogs has generally not been much in the news since the early 2000s, but over the past few years, an increasing number of DCM cases involving dogs appear to have been related to diet. The extent of this issue is not clear, not all cases have been confirmed to be linked to diet, and a true association has not been proven to exist. However, when one of the authors (RF) recently surveyed veterinary cardiologists about cases of possible diet-associated DCM in dogs examined in the past 2 years, information for > 240 cases was obtained, with responses received from the United States, United Kingdom, Canada, Israel, and Austria (unpublished data). Dogs for which breed was specified consisted of mixed-breed dogs (n = 134), Golden Retrievers (23), Labrador Retrievers (9), German Shepherd Dogs (8), Cocker Spaniels (7), and between 1 and 5 dogs each of 25 other breeds. Further, possible diet-associated DCM represented 16% of all cases of DCM diagnosed by the respondents during this period.

The recent announcement from the US FDA<sup>3</sup> alerting pet owners and veterinarians about reports of DCM in dogs eating pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients has raised concerns among the pet-owning public. Therefore, we wanted to increase awareness of this issue among veterinarians, review what is currently known about the possible association between certain diets and DCM in dogs, and discuss what veterinarians can do to help identify underlying causes.

## DCM and Diet in Dogs and Cats

Dilated cardiomyopathy used to be one of the most common cardiac diseases in cats. In 1987, how-

### ABBREVIATIONS

BEG	Boutique, exotic-ingredient, and grain-free
CHF	Congestive heart failure
DCM	Dilated cardiomyopathy

ever, Pion et al<sup>1</sup> published a landmark paper reporting that DCM in cats was associated with taurine deficiency and could be reversed by providing supplemental taurine. On the basis of that report and substantial subsequent research, the requirement for taurine in cat foods was increased, and taurine deficiency-related DCM is now uncommon in cats. However, it can still be seen in cats eating home-prepared diets or commercial diets prepared with inadequate nutritional expertise or quality control.

In 1995, veterinary cardiologists investigating the role of taurine deficiency in dogs with DCM suggested that certain breeds (eg, Golden Retrievers and American Cocker Spaniels) may be predisposed to taurine deficiency,<sup>2</sup> and a study in Cocker Spaniels subsequently showed that supplementation with taurine and L-carnitine could partially or completely reverse the disease.<sup>4</sup> Additional dog breeds potentially predisposed to taurine deficiency-associated DCM were identified, including Newfoundlands, English Setters, Saint Bernards, and Irish Wolfhounds.<sup>5-10</sup> Later, certain types of diets, including lamb and rice, low-protein, and high-fiber diets were associated with taurine deficiency in some dogs.<sup>5,7,9,11-14</sup> Research suggested that other ingredients (eg, beet pulp) may also increase the risk of taurine deficiency,<sup>15</sup> although the exact role of these ingredients was still unclear. In addition, the apparent breed predispositions suggested that genetic factors, breed-specific metabolic abnormalities, or low metabolic rates may also have been playing a role.<sup>8,9,16</sup>

## Current Concerns About Diet and DCM in Dogs

Beginning in the early 2000s, the number of dogs with taurine deficiency and DCM subjectively appeared to decrease. Recently, however, we have heard from veterinary cardiologists who had an impression that they were diagnosing DCM in Golden Retrievers at higher rates than expected and in dogs of breeds

typically not thought to be prone to this condition. Subjectively, it also appeared that these dogs were frequently eating BEG diets containing foodstuffs such as kangaroo, duck, buffalo, salmon, lamb, bison, venison, lentils, peas, fava beans, tapioca, barley, or chickpeas as major ingredients. Some of the affected dogs had low plasma or whole blood taurine concentrations and improved with taurine supplementation and a diet change. On the other hand, some dogs that did not have low plasma or whole blood taurine concentrations also improved with a diet change and taurine supplementation. Cardiologists and other veterinarians have been reporting cases to the US FDA, which is investigating the issue.<sup>3</sup>

Currently, it seems that in addition to those dogs with DCM completely unrelated to diet (eg, breed-specific DCM), there may be 2 groups of dogs with diet-associated DCM: dogs with DCM specifically related to taurine deficiency and dogs with DCM associated with separate, but yet unknown, dietary factors. Identifying the potential dietary factors contributing to DCM in these latter 2 groups may be challenging. From our discussions with veterinary cardiologists, it appears that many dogs in both groups have been eating BEG diets; however, the true percentages are not known. The previously mentioned survey identified 23 types of BEG diets being fed to dogs with DCM, including home-prepared diets, and not all diets were grain-free diets. Importantly, BEG diets have increased in popularity in recent years, and many dogs with DCM unrelated to diet and many dogs without DCM are likely eating these diets.

Multiple factors play a role in the increased popularity of BEG diets.<sup>17</sup> Regardless, the apparent link between BEG diets and DCM may be due to the grain-free nature of these diets (ie, use of ingredients such as lentils, chickpeas, or potatoes to replace grains), other common ingredients in BEG diets (eg, exotic meats, flaxseed, fruits, or probiotics), possible nutritional imbalances, or inadvertent inclusion of toxic dietary components. Or, the apparent association may be spurious.

The complexity of pet food manufacturing is often underestimated. Pet foods must contain all required nutrients in the right amounts and right proportions. Nutrient standards (minimums and, for some nutrients, maximums) are established by the Association of American Feed Control Officials. However, the effects of processing (or not processing) the ingredients must also be considered, along with nutrient bioavailability and the effects of all other ingredients in the food. Unfortunately, this may not always be done. In addition, extensive testing is needed on an ongoing basis to ensure rigorous quality control. Inclusion of exotic ingredients, such as kangaroo, alligator, fava beans, and lentils, adds another level of complexity to ensuring the diet is nutritious and healthy. Exotic ingredients have different nutritional profiles and different digestibility than typical ingredients and have the potential to affect the metabolism of other nutrients. For example, the bioavailability of taurine is different when included in a lamb-based

diet, compared with a chicken-based diet, and can be affected by the amount and types of fiber in the diet.<sup>14,15</sup>

### **Diet-associated DCM in dogs with taurine deficiency**

Golden Retrievers have been reported, as a breed, to be susceptible to development of taurine deficiency-associated DCM,<sup>2,8</sup> leading some to suggest a breed-wide genetic propensity for diet-associated DCM. One of the authors (JAS) recently concluded a study evaluating 24 Golden Retrievers with echocardiographically confirmed DCM and low plasma or whole blood taurine concentrations that were followed up for 12 to 24 months after a diet change and the addition of supplemental taurine to their diet (unpublished data). Although the results are still preliminary, all but 1 dog for which follow-up data were available had substantial echocardiographic improvement. In addition, in all 9 dogs that initially had CHF, the heart failure resolved, and diuretic administration was substantially reduced or safely discontinued. All 24 of these Golden Retrievers were eating BEG diets at the time DCM was diagnosed.

Although taurine deficiency appears to be more common in Golden Retrievers than in dogs of other breeds, plasma and whole blood taurine concentrations should be measured in every dog with DCM because some dogs of other breeds with DCM have been found to have taurine deficiency. Even dogs of breeds that have previously been found to be genetically predisposed to developing DCM, such as Doberman Pinschers and Boxers, should be tested because taurine concentrations have been found to be low in some of these dogs also. In addition, taurine deficiency should be considered as a possibility not just in dogs eating BEG, very-low-protein, or high-fiber diets, but also in dogs eating vegetarian, vegan, or home-prepared diets.

The reasons for taurine deficiency in dogs are not completely understood but could be related to reduced synthesis of taurine resulting from an absolute dietary deficiency of the taurine precursors methionine and cystine; reduced bioavailability of taurine, methionine, or cystine in the diet; abnormal enterohepatic recycling of bile acids because of fiber content of the diet; increased urinary loss of taurine; or altered metabolism of taurine in the intestine as a result of interactions between certain dietary components and intestinal microbes.<sup>9,12-16</sup> In addition to the possibility of breed-related metabolic differences, there may be genetic factors that play a role in susceptibility to taurine deficiency, as appeared to be the case in cats with taurine deficiency.<sup>18</sup>

### **Diet-associated DCM in dogs without taurine deficiency**

Preliminary results of a study<sup>8</sup> performed by one of the authors (DBA) found that dogs with DCM that had been eating grain-free diets had more advanced cardiomyopathic changes than did dogs with DCM that had been eating grain-based diets. Unreported results of the study indicated that a subset of dogs

clinically and echocardiographically improved after a diet change. Notably, however, some dogs improved after a diet change from one grain-free diet to another, and this finding, along with the differences identified between dogs fed various BEG diets, suggested that DCM was not necessarily tied to the grain-free status of the diet. Taurine supplementation was prescribed for many of these dogs despite the lack of apparent deficiency, and it is unclear what role taurine may have played in their recovery.

Although DCM in some dogs without any apparent taurine deficiency appears to be reversible with a change in diet, with or without taurine supplementation, no cause has thus far been identified for non-aurine deficiency-associated DCM. Possible causes that are being investigated include absolute deficiencies of other nutrients, altered bioavailability of certain nutrients because of nutrient-nutrient interactions, and the inadvertent inclusion of toxic ingredients.

For example, BEG diets could possibly be more likely to have deficiencies of nutrients other than taurine, such as choline, copper, L-carnitine, magnesium, thiamine, or vitamin E and selenium, that have been associated with cardiomyopathies.<sup>19</sup> Although pet foods are required to be nutritionally complete and balanced (unless they have a label statement that they are for intermittent or supplemental use only), that does not always provide a guarantee,<sup>20</sup> and deficiencies could occur if diets do not contain appropriate amounts of all dietary nutrients. Further, a deficiency may occur even if a diet contains the required minimum amount of a nutrient because of reduced bioavailability or interaction with other ingredients in the diet. This may be a concern for diets based on exotic ingredients, whose nutritional properties may not be as well studied.

Researchers are also exploring whether diet-associated DCM in dogs without taurine deficiency may be related to inclusion of a cardiotoxic ingredient in the diet. This could be an adulterated ingredient, as with ingredients containing melamine-cyanuric acid that affected pet foods in 2007, resulting in extensive recalls<sup>21</sup>; a heavy metal; a chemical sprayed on 1 of the ingredients; or even a natural chemical compound in 1 of the ingredients that has toxic effects when fed in large amounts.

Of course, the cause may be even more complicated, such as an interaction between gut microbiota and a dietary factor (eg, trimethylamine *N*-oxide).<sup>22</sup> It is encouraging that some recovery of cardiac function has been observed in some dogs following a change in diet, with or without taurine supplementation. However, research is needed to identify the underlying cause.

## Diet History

For many years, veterinary nutritionists have emphasized the importance of nutritional assessment.<sup>23,24</sup> Nutritional assessment includes 4 key components: body weight, body condition score, muscle condition score, and diet history. Body weight and

body condition score are likely already a part of most clinicians' standard physical examination, and muscle condition scoring would be a valuable addition. Cardiac cachexia (muscle loss) occurs early in patients with CHF and should be detected at its mildest stages, when interventions are more likely to be successful.<sup>25</sup> Muscle condition scoring charts and training videos are available.<sup>26,27</sup>

The fourth component of nutritional assessment—diet history—may not be routinely collected but is equally important. A diet history, for example, can help identify issues that could be contributing to an underlying disease. For patients with recent-onset CHF, for example, the diet history may reveal that the owner changed to a new diet with a higher sodium content. Other diet-associated issues that can be identified from the diet history include anemia or thiamine deficiency caused by a nutritionally unbalanced home-prepared diet or diarrhea due to a contaminated raw meat diet. Veterinary cardiologists examining dogs with DCM were able to make an association with BEG diets because they were obtaining a diet history, and obtaining a diet history may help researchers identify patterns (eg, products made by the same manufacturer or by manufacturers using ingredients from the same supplier) that could eventually lead to determining the underlying cause.

A diet history can also identify an individual patient's food preferences, such as whether canned or dry food is preferred or whether specific flavors are preferred, that can be helpful for feeding when the patient is hospitalized. And, a diet history is useful in determining whether the patient's usual diet is appropriate after discharge or needs to be changed. For example, dietary modification will be required for dogs with cardiac disease that are eating high-sodium dog food or treats.

The diet history should include the main foods being fed. However, this is more than just "dry dog food" or "brand X dog food." It is critical to solicit information on brand, the exact product, and even the flavor, as these factors can make a big difference in the ingredients and nutrient profile. We recommend telling owners that their description of a product should be detailed enough that we could go to the store and buy the exact product they are feeding. If owners are feeding a home-prepared diet, the exact recipe should be provided.

Of course, pet food is often just the tip of the iceberg. The diet history should also include all treats; table food; rawhides, bully sticks, and other chews; dietary supplements; and foods used to administer medications. These other components of the diet can contribute large amounts of sodium and other nutrients to a patient's overall intake or unbalance the overall diet. In addition, these other components may contribute to adverse effects. For example, a Fanconi-like syndrome associated with jerky treats has been reported<sup>28</sup> but may not have been identified if complete diet histories had not been obtained for affected dogs. In addition, although diet-associated DCM is most likely related to pet food, it may possibly be a result of another dietary

component (eg, treats, chews, or supplements) commonly fed to dogs eating these diets.

Use of a standard form, such as the generic form recommended by the World Small Animal Veterinary Association,<sup>26</sup> or a cardiology-specific form (**Supplementary Appendix S1**, available at [avmajournals.avma.org/doi/suppl/10.2460/javma.253.11.1390](http://avmajournals.avma.org/doi/suppl/10.2460/javma.253.11.1390)) will facilitate obtaining a complete diet history. We recommend all clinicians collect a diet history for every dog and cat patient at every appointment. Because many owners are unable to recall specific diet details at the time of their appointment, we recommend having owners complete the diet history form at home prior to the appointment so that they can provide exact details on all components of the diet.

## Recommendations

If DCM is diagnosed in a dog that is eating a BEG, vegetarian, vegan, or home-prepared diet, we recommend measuring plasma and whole blood taurine concentrations.<sup>b</sup> It is still unclear whether plasma or whole blood taurine concentration more accurately reflects myocardial concentration in dogs, so measurement of both plasma and whole blood taurine concentrations is recommended. However, if cost is an issue, measurement of whole blood taurine concentration should be prioritized because it is thought to be a better indicator of long-term taurine status. Importantly, reference ranges for taurine concentrations in dogs should be interpreted cautiously. Dilated cardiomyopathy has been diagnosed in some dogs, particularly Golden Retrievers, with whole blood taurine concentrations between 200 and 250 nmol/L, which would generally be considered within reference limits, although at the low end of the reference range. At least some of these patients, however, have responded well to a diet change and taurine supplementation. Therefore, reference ranges for plasma and whole blood taurine concentrations may need to be breed specific. Research in Golden Retrievers with taurine deficiency-associated DCM is ongoing, but a whole blood taurine concentration of at least 250 nmol/L is recommended for this breed.

We also recommend that all other dogs in the household that are eating the same diet be screened for DCM. Further, we recommend that owners of dogs with possible diet-associated DCM be instructed to save samples of all dietary components they are currently feeding, including not only the main food itself but also all treats, chews, and supplements. Ideally, this would include not just samples of the dietary components but also product bags or labels. With complete diet information in hand, the veterinarian or owner should report the case to the FDA, which can be done either online or by telephone<sup>29</sup> because this will help the agency identify possible underlying causes as quickly as possible. A recently published article<sup>30</sup> provides an excellent summary of information for veterinarians on reporting suspected animal food issues. If the dog is a Golden Retriever, the veterinarian or owner may also consider reporting the case to the Josh Stern Cardiac Genetics Laboratory,<sup>31</sup> which

is currently evaluating possible genetic factors that may increase susceptibility to taurine deficiency.

For dogs in which possible diet-associated DCM is diagnosed, we recommend the owner change the diet to one made by a well-established manufacturer that contains standard ingredients (eg, chicken, beef, rice, corn, and wheat). In the authors' (LMF and JER) hospital, we recommend several specific products with a low sodium content that only contain standard ingredients.<sup>32</sup> We also emphasize that changing to a raw or home-prepared diet may not be sufficient to improve cardiac abnormalities and may increase the risk for other nutritional deficiencies or infectious diseases. For dogs that require a home-prepared diet or that have other medical conditions that require special dietary considerations, consultation with a board-certified veterinary nutritionist is recommended.

We also provide supplemental taurine for all dogs with possible diet-associated DCM. In dogs with a taurine deficiency, taurine supplementation is critical. In dogs with taurine concentrations within reference limits, it is unclear whether taurine supplementation is needed, and some patients have recovered with only a diet change. However, taurine supplementation may still have some benefits owing to other effects of taurine (eg, antioxidant and positive inotropic effects). Taurine supplements from manufacturers with a history of good quality control should be used. A 2009 study<sup>33</sup> identified certain brands with good quality control. In addition, ConsumerLab is expected to release a report in late 2018 on independent quality control testing of taurine supplements.

Although the optimal taurine dosage for dogs with taurine deficiency is not fully understood, we recommended 250 mg, PO, every 12 hours for dogs weighing < 10 kg (22 lb); 500 mg, PO, every 12 hours for dogs weighing 10 to 25 kg (55 lb); and 1,000 mg, PO, every 12 hours for dogs weighing > 25 kg.

Follow-up echocardiography should be performed in 3 to 6 months. In our experience, some improvements are typically evident in this time span. However, in certain dogs, it may take even longer for improvements to be apparent echocardiographically.

Finally, although an association between BEG diets and DCM in cats has not been recognized, we recommend collecting diet histories on all cats as well and especially in cats with DCM. If cats with DCM are eating a BEG, vegetarian, vegan, or home-prepared diet, we recommend following the same protocol as described for dogs.

## Summary

Pet food marketing has outpaced the science, and owners are not always making healthy, science-based decisions even though they want to do the best for their pets. The recent cases of possible diet-associated DCM are obviously concerning and warrant vigilance within the veterinary and research communities. Importantly, although there appears to be an association between DCM and feeding BEG, vegetarian, vegan, or home-prepared diets in dogs, a cause-and-effect rela-

tionship has not been proven, and other factors may be equally or more important. Assessing diet history in all patients can help to identify diet-related cardiac diseases as early as possible and can help identify the cause and, potentially, best treatment for diet-associated DCM in dogs.

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## **Vet-LIRN Update on Investigation into Dilated Cardiomyopathy – February 2019**

This update describes FDA and Vet-LIRN's investigative efforts through November 2018 at a level of technical detail geared toward veterinarians. For more general information, please visit FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy.

In July 2018, the FDA [alerted](#) the public about an investigation into reports of canine dilated cardiomyopathy (DCM) in dogs eating certain pet food. DCM itself is not considered rare in dogs, but these reports are unusual because many of the reported cases occurred in breeds of dogs not typically genetically predisposed to the disease and were reported to have been fed diets containing legumes like peas or lentils, other legume ingredients (pulses) or potatoes as main ingredients. Many of these products are labeled as "grain-free" or "zero-grain."

Since then, the FDA's Center for Veterinary Medicine (CVM) has taken a multi-pronged approach to the investigation. CVM veterinarians, nutritionists, pathologists and epidemiologists are collaborating with several sectors of the animal health world to collect and evaluate information about the DCM cases and the diets pets ate prior to becoming ill. A key partner in the investigation is the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), a collaboration of government and veterinary diagnostic laboratories.

### **Food Testing**

#### Minerals and Elements

Prior to FDA's July 2018 notice about the investigation, Vet-LIRN collected and tested case-related food samples and purchased store-bought products labelled "grain free" for:

- Calcium
- Phosphorous
- Magnesium
- Cobalt
- Copper
- Zinc
- Selenium
- Iodine

The products tested within normal nutrient concentrations recommended in the Association of American Feed Control Officials (AAFCO) Dog and Cat Food Nutrient Profiles published in the AAFCO Official Publication (OP).

#### Nutritional Screening and Amino Acid Content

Because some products labelled "grain free" and containing legumes and/or potato products were potentially associated with DCM, Vet-LIRN collected case-related food samples and purchased store-bought products labelled "grain free". These products were tested, as well as grain-containing products not associated with development of DCM, to investigate any nutritional differences that could explain

the development of DCM. As of November 30, 2018, Vet-LIRN has tested grain-free products and grain-containing products for the following:

- protein, fat, moisture
- crude fiber, total dietary fiber, soluble fiber, insoluble fiber
- total starch, resistant starch
- cystine, methionine, and taurine

The average percent protein, fat, total taurine, total cystine, total methionine, total methionine-cystine, and resistant starch content on a dry matter basis were similar for both grain-free and grain-containing products (Table 1).

Table 1. Average values for grain-free and grain-containing products shown on a dry matter basis

Measurement	Average Grain-Containing	Average Grain-Free
Protein	28.8 %	29.6 %
Fat	15.2 %	16.6 %
Total Taurine	0.13 %	0.14 %
Total Cystine	0.3 %	0.29 %
Total Methionine	0.59 %	0.55 %
Total Methionine-Cystine	0.89 %	0.84 %
Total Dietary Fiber	8.6 %	12.1 %
Crude Fiber	2.5 %	4.6 %
Insoluble Fiber	7.2 %	11.7 %
Soluble Fiber	1.46	<1.41
Starch	37.4 %	26 %
Resistant Starch	<2.15 %	<2.15 %
Choline Chloride	3289 ppm	2731 ppm
Choline	2453 ppm	1979 ppm

All but one of the grain-free products had methionine-cystine values above the minimum nutrient concentration recommended in the AAFCO OP of 0.65% for adult maintenance foods for dogs. The grain-free foods had greater total dietary fiber, crude fiber, and insoluble fiber, and less starch and choline on average than the grain-containing products. One grain-free product contained choline levels below the minimum concentration recommended for adult maintenance food for dogs, as published in the AAFCO OP.

The FDA is still trying to better understand if (and how) taurine, cystine, and methionine metabolism (both absorption and excretion) may have a role in DCM in the context of the foods being fed.

## Case Information

Between January 1, 2014 and November 30, 2018, the FDA received reports of 325 dogs and 10 cats diagnosed with DCM. The FDA additionally received many reports of non-DCM cardiac disease in dogs and cats during this timeframe. In an effort to better understand the reported cardiac diseases, FDA investigated many of the DCM cases, as well as some of these non-DCM cardiac cases by reviewing medical records and performing dietary and environmental exposure interviews. Additionally, FDA is working to determine whether there is a disease continuum that includes cardiac changes that could indicate developing DCM or if there are other cardiac changes of importance.

FDA's review of medical records for reports is ongoing and the following data are a summary for only a subset of collected medical records for both DCM and non-DCM cardiac cases. Of 168 dogs and 6 cats whose medical records were reviewed, 104 dogs and 2 cats were DCM cases with heart changes characteristic of DCM on cardiac ultrasound – including decreased ventricular systolic function and dilation. Approximately 67% of dogs (n=71) of those with confirmed DCM had progressed to congestive heart failure. Of the pets with confirmed DCM, approximately 18% (n=19) also had evidence of degenerative valvular disease and 11% (n=12) had atrial fibrillation. Approximately 42% (n=45) of dogs with DCM had a history of allergies or sensitivities to an environmental allergen and/or food that was manifested as dermatitis, otitis, or gastrointestinal disease. Approximately 9% (n=9) and 8% (n=8) of dogs with DCM had a history of hypothyroidism and one or more tick-borne diseases (e.g. Lyme, Anaplasmosis), respectively.

According to the medical records reviewed for the non-DCM cardiac disease cases, other cardiac changes were present on echocardiogram, including degenerative valvular disease, tricuspid and mitral valve regurgitation, and borderline to decreased left ventricular systolic function. For animals without DCM, there may be a spectrum of cardiac changes visualized on echocardiogram (e.g. borderline decreased left systolic function in the absence of left ventricular dilation) if the animal is progressing toward or recovering from DCM. While not DCM, these cases are important to report to FDA, so we may better understand if they could be related to development of DCM or associated with certain diets.

### Taurine levels and cardiac disease status:

Eighty-three dogs and 2 cats (including both DCM and non-DCM cases) had both a taurine measurement and an echocardiogram (Table 2). A full summary of the taurine status and echocardiogram findings for the pets with a taurine measurement and echocardiogram is included in Table 2. Approximately 64% of dogs with DCM had a taurine measurement. Of the pets diagnosed with DCM, approximately 38% had at least one low blood taurine value (Table 4). Golden Retrievers represented approximately one third of all dogs with low taurine and DCM and approximately half of all dogs with low blood taurine regardless of type of cardiac findings. Table 3 shows the reported breed frequency for each category by breed of dog. Table 4 shows the taurine results for all dogs and cats with DCM.

Table 2. Number of pets with various taurine levels (either whole blood and/or plasma) and echocardiogram changes based on medical record review for dogs with a taurine test.

Status	Count
Low taurine with DCM	39 (37 dogs, 2 cats)

Normal taurine with DCM*	18 dogs
High taurine with DCM	11 dogs
Low taurine with non-DCM heart changes	10 dogs
Low taurine with normal heart	6 dogs
Normal taurine with non-DCM heart changes	1 dog
Normal taurine and normal heart	2 dogs

\*One dog with DCM had a low plasma taurine and normal whole blood. This dog was considered Normal Taurine with DCM.

Table 3. Pet breeds grouped by taurine (Tau) status and echocardiogram changes for dogs with a Tau test.

Breed	Low Tau DCM	Normal Tau DCM	High Tau DCM	Low Tau non-DCM	Normal Tau non-DCM	Low Tau Normal heart	Normal Tau Normal heart
Boxer Mix	1		1				
Doberman Pinscher		3					
German Shepherd		1	1				
Goldendoodle	1	1		1			
Golden Retriever	14	1	1	8	1	6	2
Great Dane	1	2	2				
Labrador Retriever	3	2	1				
Miniature Schnauzer		1	1				
Bluetick Coonhound	2						
Cat	2						
Cocker Spaniel	2						
Blueheeler Mix	1						
Doberman Mix	1						
French Bulldog	1						
Golden Retriever Mix	1						
Maltese	1						
Pitbull	1						
Pitbull Mix	1						
Samoyed	1						
Sheepadoodle	1						
Standard Poodle	1						
Viszla Mix	1						
White Shepherd	1						
Australian Shepherd Mix		1					
Boston Terrier		1					
Labrador Retriever Mix		1					
Shetland Sheepdog		1					

Shih Tzu		1					
Wheaten Terrier		1					
American Staffordshire Terrier			1				
Catahoula Leopard Dog			1				
Pug			1				
Yorkshire Terrier			1				
Flat Coated Retriever				1			
Sum	38	17	11	10	1	6	2

Table 4. Taurine results for dogs and cats with confirmed DCM.

Taurine Status* and Sample Type	Count
Low Taurine, Whole blood only	21 dogs
Low Taurine, Plasma only	10 dogs, 2 cats
Low Taurine, Whole blood and Plasma	5 dogs
Low Taurine, Plasma with Normal Whole blood	1 dog
Low Taurine, unknown sample type	1 dog
Normal, Whole blood only	12 dogs
Normal, Plasma only	2 dogs
Normal, Whole blood and Plasma	2 dogs
Normal, unknown sample type	1 dog
High Taurine, Whole blood only	8 dogs
High Taurine, Plasma only	1 dog
High Taurine, Whole blood and Plasma	1 dog
High Taurine, Whole blood with Normal Plasma	1 dog

\*The taurine status is based on reference ranges used by the laboratory that performed the test.

**Course of disease:**

According to recheck echocardiograms in the medical records, some pets with DCM improved after veterinary treatment, diet change, and taurine supplementation, while others improved with

appropriate veterinary care and diet change alone. Vet-LIRN has requested 30 additional repeat echocardiograms to better understand DCM heart changes over time. This repeat echocardiogram data are currently being collected and will be compared to the initial echocardiogram parameters to better understand the effects of diet change and/or taurine supplementation on the heart.

One example detailed in Table 4 describes a case in which a dog without taurine deficiency, according to the reference laboratory's reference range, improved with cardiac care and diet change alone. We provide the detailed echocardiogram data to show which parameters changed during recovery and at what rates.

The case involved a 3-year-old male, castrated, Beagle Mix, initially presented with a cough of six weeks duration that was treated with 30 days of doxycycline. The dog had been eating a limited ingredient grain-free diet containing a novel protein source and six legume-based ingredients. The whole blood and plasma taurine levels were above normal reference values. After DCM was diagnosed, the dog was diagnosed with a possible food allergy. This case shows the resolution of DCM at 2 years post presentation after treatment with cardiac prescriptions and diet change only. Taurine was not supplemented. A summary is below (Table 5).

Table 5. Echocardiogram changes in a 3-year-old Beagle mix over time and with a diet change

<b>Echocardiogram Parameter</b>	<b>Day 0 Original Diet</b>	<b>1 week Similar to original diet</b>	<b>Approx. 5 months Chicken &amp; Rice</b>	<b>Approx. 1 year Chicken &amp; Rice</b>	<b>Approx. 1.5 years Chicken &amp; Rice</b>	<b>Approx. 2 years Chicken &amp; Rice</b>
LA/Ao	1.28	1.81	1.24	1.31		1.17
IVSd (mm)	9.3	8.6	11.1	7.6	9.2	9.4
LVIDd (mm)	51.4	55.4	51.6	45.8	44.7	45
LVPWd (mm)	8.7	7.9	8.8	9.3	9.5	10.3
IVSs (mm)	10	10.3	14	11.3	12.2	14.6
LVIDs (mm)	41.6	44.6	39.1	33.3	27.9	27.9
LVPWs (mm)	9.3	7.9	11.8	12	11.7	13.8
FS %	18.99	19.4	24.31	27.25	37.48	37.88
EF (Teich) %	41.78	35.78	34.03	33.5	57.13	
Mitral Valve	Mild thickening, Mild mitral regurgitation	Unchanged	Unchanged	Mild thickening, Trace mitral regurgitation	Mild thickening	Normal
Tricuspid Valve	Trace to Mild	Unchanged	Unchanged	Normal	Normal	Normal

	tricuspid regurgitation					
Pulmonary hypertension	Mild	Mild	Mild	Normal	Normal	Normal
Right heart	Enlargement	Unchanged	Unchanged	Unchanged	Unchanged	Normal
AV Vmax (m/s)	1.56	1.49	1.85	1.78	2.14	2.24

MR: mitral regurgitation, TR: tricuspid regurgitation, Severity Index: +/- trace, +1 mild, +2 moderate, +3 marked, +4 severe

### **Necropsy**

As of November 30, 2018, Vet-LIRN has reviewed results of 15 gross necropsies from dogs with suspected heart disease, including 10 necropsies that Vet-LIRN coordinated from cases reported through the FDA Safety Reporting Portal. The dogs either died naturally or were euthanized and did not necessarily have a pre-mortem diagnosis of DCM. Of the 10 necropsies that Vet-LIRN coordinated, there have been 9 canine heart gross examinations, with one heart pending evaluation. During the gross evaluation, we measured dimensions including chamber lumen diameter, chamber wall thickness, and valve circumference. We collected other tissues for histopathology, including liver, kidney, gastrocnemius muscle, and spleen for 9 of the 10 requested necropsies. The histopathology results and data analysis are pending. The necropsy results will enable Vet-LIRN to evaluate the cases for any common histopathological lesions that could suggest a cause for illness and to confirm the antemortem diagnosis.

### **Prospective Diagnostic Sample Testing**

Vet-LIRN has been collaborating with Chesapeake Veterinary Cardiology Associates (CVCA) to collect medical records, an owner interview, and diagnostic samples from pets with DCM diagnosed by a board-certified veterinary cardiologist by echocardiogram. These cases are included in the overall number of DCM cases, but were selected for further study because their ongoing program of care with the practice will be comprehensively documented and provided in full to Vet-LIRN.

Upon confirmation of a DCM diagnosis, CVCA will collect blood (whole blood and plasma), urine, feces, DNA swabs, and food, if the pet is not receiving any supplements (e.g. taurine, cystine, or methionine) and is still eating a diet labeled "grain-free." Vet-LIRN will test the blood and urine for taurine, cystine, methionine, and other amino acids. Vet-LIRN is archiving feces and DNA from these cases for possible future testing.

CVCA will collect repeat urine, blood, and feces at 1 to 2 months and 6 months after the initial diagnosis and document any treatment or dietary changes, if any, that were recommended by the cardiologist. The repeat urine and blood samples will be tested for amino acid content and the feces archived. At the 6-month recheck, CVCA will also conduct a repeat echocardiogram to assess any changes to the heart. As of November 11, 2018, CVCA and Vet-LIRN have collected initial samples from 14 dogs. CVCA is currently collecting the 1 to 2-month samples. Two dogs have died and will not complete the sample collection. Vet-LIRN is currently evaluating the heart histopathology from those two dogs.

Vet-LIRN is also collecting food associated with each CVCA case and will test each diet for:

- protein, fat, moisture
- crude fiber, total dietary fiber, soluble fiber, insoluble fiber
- total starch, resistant starch
- free and total cystine, methionine, and taurine

Separate from the ongoing collaboration with CVCA, Vet-LIRN has contracted with a network lab to collect blood (whole blood and plasma), urine, feces, and DNA from healthy dogs without a known breed predisposition to DCM for comparison. The dog must also be consuming a grain-containing primary diet that meets the following criteria:

- not be labelled “grain-free”
- consuming the diet for at least 1 year before the samples are collected
- animal proteins are from either cattle, swine, poultry, and/or fish
- no more than 2 legume, pulse, or potato (including sweet potato) ingredients that must appear after the animal and grain ingredients
- the diet formulation was verified to be nutritionally adequate by animal feeding tests using AAFCO procedures

The blood and urine samples will be tested similarly to those collected in the cases from CVCA collaboration and compared to the values from the dogs diagnosed with DCM.

### **How You Can Help**

FDA encourages veterinary professionals to report well-documented cases of DCM in dogs whose illness is suspected of having a link to diet. You can submit information by using the electronic [Safety Reporting Portal](#) or calling your state’s [FDA Consumer Complaint Coordinators](#). The more information you are able to provide, particularly about feeding history, medical records, and diagnostic testing, the better. Detailed instructions can be found on [How to Report a Pet Food Complaint](#).

### **Additional Information**

- FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy
- FDA Provides Update on Investigation into Potential Connection Between Diet and Cases of Canine Heart Disease (February 2019)
- [FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease \(July 2018\)](#)
- Journal of American Veterinary Medical Association - [Diet-associated dilated cardiomyopathy in dogs: what do we know?](#) (December 2018)

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Document properties  
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Author: Norris, Anne  
Template: Normal.dotm  
Page count: 4  
Paragraph count: 371  
Line count: 720  
Word count: 2665  
Character count (spaces excluded): 14384  
Character count (spaces included): 16735

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Document Comments

Total Comments: 4  
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Author: Norris, Anne

Date: 2/1/2019 1:35:00 PM

Initial: NA

Range: Hyperlink to general web update

Scope: FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy

Author: Norris, Anne

Date: 2/1/2019 1:35:00 PM

Initial: NA

Range: Hyperlink to main investigation page

Scope: FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy

Author: Norris, Anne

Date: 2/1/2019 1:35:00 PM

Initial: NA

Range: Hyperlink to CVM Update for February update

Scope: FDA Provides Update on Investigation into Potential Connection Between Diet and Cases of Canine Heart Disease (February 2019)

Author: Norris, Anne

Date: 2/1/2019 1:35:00 PM

Initial: NA

Range: Are we allowed to link to this?

Scope: Journal of American Veterinary Medical Association - Diet-associated dilated cardiomyopathy in dogs: what do we know? (December 2018)

**All Medical Records**

Client: **B6**  
Address: **B6**

Patient: **B6**  
Breed: Labrador Retriever  
DOB: **B6**

Species: Canine  
Sex: Female  
(Spayed)

Home Phone: **B6**  
Work Phone: ( ) -  
Cell Phone: **B6**

**Referring Information**

**B6**

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

**Initial Complaint:**

Emergency

**SOAP Text** **B6** 1:23PM - **B6**

**B6** 12:13 PM NEW VISIT (ER)

Doctor: **B6** VMD

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: **B6**

**EXAM:**

**B6**

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

**B6**

**ASSESSMENT:**

A1: **B6**

**PLAN:**

- 1) **B6**
- 2)
- 3)
- 4)

Client communication: **B6**

**B6**

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

**B6** 1:25:46 PM

Prescribed **B6** - FHSA (5)

Instructions - Give 1/2 tablet orally every 12 hours. Give with food. - Expires **B6** No Refills

**Initial Complaint:**

Cardiology DCM study

SOAP Text **B6** 3:09PM - Rush, John

Subjective

Objective

Assessment

Plan

**Disposition/Recommendations**

Client:

**B6**

Patient:

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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:	<b>B6</b>
Species:	Canine
Breed:	Labrador Retriever
Sex:	Female (Spayed)
Age:	<b>B6</b> Years Old

### Lab Results Report

Accession ID:			
Test	Results	Reference Range	Units



4/7

**B6**

**B6**

Printed Sunday, February 24, 2019

### Vitals Results

<b>B6</b>	12:21:40 PM	Heart Rate (/min)	<b>B6</b>
	12:21:41 PM	Respiratory Rate	
	12:21:42 PM	Temperature (F)	
	12:21:43 PM	Weight (kg)	

### Patient History

<b>B6</b>	12:14 PM	UserForm	<b>B6</b>
	12:15 PM	UserForm	
	12:21 PM	Vitals	
	01:37 PM	Prescription	
	01:44 PM	UserForm	
	01:48 PM	Purchase	

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

**Patient History**

<b>B6</b>	02:06 AM	Vitals
	11:40 AM	Email
	01:27 PM	Appointment
	01:30 PM	UserForm
	02:03 PM	Treatment
	03:14 PM	UserForm

**B6**

**Best Available Copy**

**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, Labrador Retriever, Yellow

**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:** Putnam, Juli </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45A45E85E6E94413A4BD2C9FDBB3DE1B-JULIANN.PUT>  
**To:** Carey, Lauren; Hartogensis, Martine; Palmer, Lee Anne; DeLancey, Siobhan; Norris, Anne; Forfa, Tracey; Rotstein, David; Jones, Jennifer L  
**Sent:** 7/13/2018 1:45:16 PM  
**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thanks, I've incorporated Martine's portion below. Just to confirm,

**B5**

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

Proposed response:

**B5**

**From:** Carey, Lauren  
**Sent:** Friday, July 13, 2018 9:37 AM  
**To:** Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

I think Martine's example is good

**B5**

**B5**

**From:** Hartogensis, Martine  
**Sent:** Friday, July 13, 2018 9:33 AM  
**To:** Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi Juli,

You could also say something like:

**B5**

Looping in Jen as well...

Martine

**From:** Putnam, Juli  
**Sent:** Friday, July 13, 2018 9:29 AM  
**To:** Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Forfa, Tracey <[Tracey.Forfa@fda.hhs.gov](mailto:Tracey.Forfa@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>  
**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thank you, Lauren! How's this? I'm adding Dave to take a look as well.

**- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?**

**Proposed response:**

**B5**

**From:** Carey, Lauren  
**Sent:** Friday, July 13, 2018 9:18 AM  
**To:** Putnam, Juli <[JuliAnn.Putnam@fda.hhs.gov](mailto:JuliAnn.Putnam@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Forfa, Tracey <[Tracey.Forfa@fda.hhs.gov](mailto:Tracey.Forfa@fda.hhs.gov)>  
**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi,

**B5**

Thanks,  
Lauren

**From:** Putnam, Juli  
**Sent:** Friday, July 13, 2018 9:04 AM  
**To:** Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Forfa, Tracey <[Tracey.Forfa@fda.hhs.gov](mailto:Tracey.Forfa@fda.hhs.gov)>  
**Cc:** Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>  
**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thanks, everyone

B5

B5

see the draft proposed response below for your review.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

Proposed response:

B5

**From:** Hartogenesis, Martine

**Sent:** Thursday, July 12, 2018 6:21 PM

**To:** Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

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

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thanks Lee Anne!

B6

**From:** Palmer, Lee Anne

**Sent:** Thursday, July 12, 2018 6:20 PM

**To:** Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

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

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

B5

---

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

**Date:** July 12, 2018 at 6:16:01 PM EDT

**To:** Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

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

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi about

B5

to date . Can't see whole steam - will send them read all

---

**From:** Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

**Date:** July 12, 2018 at 5:28:58 PM EDT

**To:** DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>,  
Norris, Anne <Anne.Norris@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

**Cc:** Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Yes, me too.

As of right now, I believe we have about

**B5**

Lee Anne or Lauren, can you confirm?

---

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

**Date:** July 12, 2018 at 4:54:18 PM EDT

**To:** Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Hartogensis,  
Martine <Martine.Hartogensis@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

That works for me!

**Siobhan DeLancey, RVT, MPH**

O: 240-402-9973

M: **B6**

**From:** Putnam, Juli

**Sent:** Thursday, July 12, 2018 4:52 PM

**To:** DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>;  
Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

All good points. So can I consider this version CVM-cleared?

**B5**

**From:** DeLancey, Siobhan

**Sent:** Thursday, July 12, 2018 4:47 PM

**To:** Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis,  
Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

# B5

**Siobhan DeLancey, RVT, MPH**

O: 240-402-9973

M: **B6**

**From:** Putnam, Juli

**Sent:** Thursday, July 12, 2018 4:44 PM

**To:** Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

**Subject:** RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

**Importance:** High

Hi again - just following on this. Bloomberg is pinging me again. They want the list of brands/products. Can we

**B5**

# B5

**From:** Putnam, Juli

**Sent:** Thursday, July 12, 2018 3:49 PM

**To:** Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan (Siobhan.Delancey@fda.hhs.gov) <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

**Subject:** Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

**Importance:** High

Hi all - I know Dr. Solomon is out this week so including you all in the interest of time. Please let me know if you have edits to the responses and if we can answer the last one. Thanks!

Best,

Juli

**Reporter:** Aziza Kasumov

**Outlet:** Bloomberg

**Deadline:** asap

**Background:** I'm Aziza, a reporter for Bloomberg News working on a story about your statement from today about the potential link between certain dog foods and canine heart disease. I have a few more questions about the report, can you answer these for me? We're on tight deadline, so the sooner, the better.

**Questions and proposed responses:**

- Were the foods from several brands or from one brand of dog food? Can you name the companies that produced the foods linked to the reports, and which foods exactly the dogs ate? Was there one particular food brand that was heavily linked to the unusual reports?

**B5**

**B5**

**B5**

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?  
CVM, please advise.

**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** Hartogensis, Martine; Rotstein, David; Carey, Lauren; Norris, Anne; Palmer, Lee Anne  
**CC:** DeLancey, Siobhan; Burkholder, William  
**Sent:** 7/5/2018 11:01:43 AM  
**Subject:** RE: Redacted complaint file for the DCM webposting

**B5**

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



**From:** Hartogensis, Martine  
**Sent:** Tuesday, July 03, 2018 4:13 PM  
**To:** 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>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>  
**Cc:** DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>  
**Subject:** RE: Redacted complaint file for the DCM webposting

Hi Jen,

**B5**

**B5**

Thanks again for all the excellent work!

Martine

**From:** Jones, Jennifer L  
**Sent:** Tuesday, July 03, 2018 2:03 PM  
**To:** Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>  
**Cc:** DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>  
**Subject:** RE: Redacted complaint file for the DCM webposting

I updated the slide deck with a summary from some great articles. Bottom line

**B5**

**B5**

<https://academic.oup.com/in/article/131/2/276/4687012>

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



**From:** Rotstein, David  
**Sent:** Tuesday, July 03, 2018 8:26 AM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

Please check your calendar, if you don't see it, I'll resend the invite.

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**From:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Date:** July 3, 2018 at 8:19:29 AM EDT  
**To:** Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>, Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>, Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>, Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>, Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

**B5**

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



**From:** Carey, Lauren  
**Sent:** Monday, July 02, 2018 5:59 PM  
**To:** Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

Hi Martine,

**B5**

Thanks,

Lauren

**From:** Hartogensis, Martine  
**Sent:** Monday, July 02, 2018 5:28 PM  
**To:** Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.DeLancey@fda.hhs.gov](mailto:Siobhan.DeLancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

**B5**

Martine

**From:** Norris, Anne  
**Sent:** Monday, July 02, 2018 3:57 PM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.DeLancey@fda.hhs.gov](mailto:Siobhan.DeLancey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>  
**Subject:** FW: Redacted complaint file for the DCM webposting  
**Importance:** High

Hi Jen and Dave,

**B5**

Thanks,  
Anne

**From:** Palmer, Lee Anne  
**Sent:** Friday, June 15, 2018 8:51 AM  
**To:** Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.DeLancey@fda.hhs.gov](mailto:Siobhan.DeLancey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto: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**  
Tel: 240-402-5767  
[Leeanne.palmer@fda.hhs.gov](mailto:Leeanne.palmer@fda.hhs.gov)





**From:** Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>  
**To:** Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne; Palmer, Lee Anne  
**CC:** DeLancey, Siobhan; Burkholder, William  
**Sent:** 7/5/2018 1:59:37 PM  
**Subject:** RE: Redacted complaint file for the DCM webposting

Awesome! Thank you Jen!!

Martine

**From:** Jones, Jennifer L  
**Sent:** Thursday, July 05, 2018 7:02 AM  
**To:** Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>  
**Cc:** DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>  
**Subject:** RE: Redacted complaint file for the DCM webposting

**B5**

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



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**Sent:** Tuesday, July 03, 2018 4:13 PM  
**To:** 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>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>  
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**B5**

**B5**

**B5**

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**B5**

**B5**

<https://academic.oup.com/in/article/131/2/276/4687012>

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**Subject:** RE: Redacted complaint file for the DCM webposting

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**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>  
**Subject:** FW: Redacted complaint file for the DCM webposting  
**Importance:** High

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**B5**

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**Lee Anne M. Palmer, VMD, MPH**

*Team Leader HFV-242, Supervisory VMO*

**Center for Veterinary Medicine**

**OSC, Division of Veterinary Product Safety**

**U.S. Food and Drug Administration**

Tel: 240-402-5767

[Leeanne.palmer@fda.hhs.gov](mailto:Leeanne.palmer@fda.hhs.gov)



**From:** Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>  
**To:** Hartogensis, Martine; Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne  
**CC:** DeLancey, Siobhan; Burkholder, William  
**Sent:** 7/5/2018 5:49:46 PM  
**Subject:** RE: Redacted complaint file for the DCM webposting

Hello – back from Monday and Tuesday **B6** and working my way through emails. To answer these 2 questions:

**B5**

Martine

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help. In the attachment, there are

**B5**

Thanks,  
Anne

**B5**

Please ask me questions you have if I haven't made sense.

Thanks, Lee Anne

**From:** Hartogensis, Martine  
**Sent:** Thursday, July 5, 2018 10:00 AM  
**To:** 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>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>  
**Cc:** DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>  
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**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Burkholder, William <[William.Burkholder@fda.hhs.gov](mailto:William.Burkholder@fda.hhs.gov)>  
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**B5**

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



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**Sent:** Tuesday, July 03, 2018 4:13 PM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

Hi Jen,

This is excellent work!

**B5**

**B5**

Thanks again for all the excellent work!

Martine

**From:** Jones, Jennifer L  
**Sent:** Tuesday, July 03, 2018 2:03 PM  
**To:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
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I updated the slide deck with a summary from some great articles. Bottom line

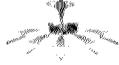
**B5**

**B5**

B5

<https://academic.oup.com/in/article/131/2/276/4687012>

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



**From:** Rotstein, David  
**Sent:** Tuesday, July 03, 2018 8:26 AM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

Please check your calendar, if you don't see it, I'll resend the invite.

---

**From:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Date:** July 3, 2018 at 8:19:29 AM EDT  
**To:** Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>, Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>, Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>, Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>, Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

B5

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



**From:** Carey, Lauren  
**Sent:** Monday, July 02, 2018 5:59 PM  
**To:** Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>  
**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** RE: Redacted complaint file for the DCM webposting

Hi Martine,

B5

Thanks,  
Lauren

**From:** Hartogensis, Martine

**Sent:** Monday, July 02, 2018 5:28 PM

**To:** Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>

**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>

**Subject:** RE: Redacted complaint file for the DCM webposting

**B5**

Martine

**From:** Norris, Anne

**Sent:** Monday, July 02, 2018 3:57 PM

**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Palmer, Lee Anne <[LeeAnne.Palmer@fda.hhs.gov](mailto:LeeAnne.Palmer@fda.hhs.gov)>; Carey, Lauren <[Lauren.Carey@fda.hhs.gov](mailto:Lauren.Carey@fda.hhs.gov)>

**Cc:** DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto:Martine.Hartogensis@fda.hhs.gov)>

**Subject:** FW: Redacted complaint file for the DCM webposting

**Importance:** High

Hi Jen and Dave,

**B5**

Thanks,  
Anne

**From:** Palmer, Lee Anne

**Sent:** Friday, June 15, 2018 8:51 AM

**To:** Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Hartogensis, Martine <[Martine.Hartogensis@fda.hhs.gov](mailto: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**

Tel: 240-402-5767

[Leeanne.palmer@fda.hhs.gov](mailto:Leeanne.palmer@fda.hhs.gov)





# Taurine deficiency in Newfoundlands fed commercially available complete and balanced diets

Robert C. Backus, DVM, PhD; Gabrielle Cohen, DVM; Paul D. Pion, DVM, DACVIM;  
Kathryn L. Good, DVM, DACVO; Quinton R. Rogers, PhD, DACVN;  
Andrea J. Fascetti, VMD, PhD, DACVN, DACVIM

**Objective**—To determine taurine status in a large group of Newfoundlands related by environment, diet, or breeding to a dog with dilated cardiomyopathy and taurine deficiency.

**Design**—Prospective study.

**Animals**—19 privately owned Newfoundlands between 5 months and 11.5 years old that had been fed commercial dry diets meeting established nutrient recommendations.

**Procedure**—Diet histories were obtained, and blood, plasma, and urine taurine concentrations and plasma methionine and cysteine concentrations were measured. In 8 dogs, taurine concentrations were measured before and after supplementation with methionine for 30 days. Ophthalmic examinations were performed in 16 dogs; echocardiography was performed in 6 dogs that were taurine deficient.

**Results**—Plasma taurine concentrations ranged from 3 to 228 nmol/mL. Twelve dogs had concentrations < 40 nmol/mL and were considered taurine deficient. For dogs with plasma concentrations < 40 nmol/mL, there was a significant linear correlation between plasma and blood taurine concentrations. For dogs with plasma concentrations > 40 nmol/mL, blood taurine concentrations did not vary substantially. Taurine-deficient dogs had been fed lamb meal and rice diets. Retinal degeneration, dilated cardiomyopathy, and cystinuria were not found in any dog examined for these conditions. The taurine deficiency was reversed by a change in diet or methionine supplementation.

**Conclusions and Clinical Relevance**—Results indicate a high prevalence of taurine deficiency among an environmentally and genetically related cohort of Newfoundlands fed apparently complete and balanced diets. Blood taurine concentrations indicative of taurine deficiency in Newfoundlands may be substantially less than concentrations indicative of a deficiency in cats. (*J Am Vet Med Assoc* 2003;223:1130–1136)

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**B4**

**B4**

## Letters to the Editor

### More feedback on taurine deficiencies in cats, dogs

I found the companion articles in the October 15, 2003, *JAVMA* (pp 1130–1141) issue regarding taurine deficiencies to be very educational and informative; however, I would like to question the last sentence of the second paragraph on page 1130 of the article that states, “In dogs, as in cats, bile acids are conjugated exclusively with taurine.” It is my understanding that dogs and cats conjugate primarily to taurine. However, dogs have the ability to convert to glycine conjugation, but cats undergo obligate conjugation with taurine.

Henry E. Childers, DVM  
Cranston, RI

### Dr. Backus responds:

Dr. Childers states, without a cited reference, that dogs have the ability to substitute glycine for taurine in the conjugation of bile acids. We know of no research that supports the suggestion that dogs will conjugate with glycine when taurine is low or absent in the liver. Glycine conjugates of bile acids are in the bile of many mammalian species,<sup>1</sup> including dogs and cats.<sup>2</sup> In normal healthy dogs, these conjugates reportedly are not in serum but are found in bile in a low concentration (< 2% of conjugates).<sup>3</sup> These glycine conjugates are probably not synthesized. Feeding glycine to taurine-depleted dogs with biliary fistulas does not induce detectable concentrations of glycine conjugates in secreted bile.<sup>4</sup> However, feeding preformed glycine conjugates will enrich bile with the conjugates. Hence, it is conceivable that glycine conjugates in dogs are ingested with food. In species in which glycine conjugates are found, the liver enzyme responsible for conjugation,

cholyl-CoA:N-acyltransferase, has specificity for both glycine and taurine. Such an overlap of specificity is not found in dogs; the conjugating enzyme of dogs is quite specific for taurine.<sup>5</sup>

The conjugation of bile acids with taurine was discussed in the context of postulated causes for taurine deficiency. Several lines of experimental evidence indicate that diet-induced taurine deficiencies of cats result from excessive gastrointestinal loss of bile acids conjugated with taurine.<sup>6</sup> During severe tissue depletion of taurine, cats continue to conjugate their bile acids with taurine rather than glycine. This specificity for taurine conjugation is so great that cats will secrete unconjugated bile acids over glycine conjugates. Because taurine conjugation of bile acids is as well defended in dogs as it is in cats, dietary factors that would accelerate bile loss in dogs would also increase the risk of taurine deficiency in dogs.

Robert C. Backus, PhD, DVM  
Quinton R. Rogers, PhD, DACVN  
Andrea J. Fascetti, VMD, PhD,  
DACVN, DACVIM  
Davis, Calif

1. Vessey DA. The biochemical basis for the conjugation of bile acids with either glycine or taurine. *Biochem J* 1978;174:621–626.

2. Washizu T, Hidenori I, Washizu M,

et al. Bile acid composition of dog and cat gall-bladder bile. *Jpn J Vet Sci* 1990;52:423–425.

3. Washizu T, Tomoda I, Kaneko JJ. Serum bile acid composition of the dog, cow, horse and human. *J Vet Med Sci* 1991;53:81–86.

4. O'Maille ER, Richards TG, Short AH. Acute taurine depletion and maximal rates of hepatic conjugation and secretion of cholic acid in the dog. *J Physiol* 1965;180:67–79.

5. Czuba B, Vessey DA. Identification of a unique mammalian species of cholyl-CoA:amino acid N-acyltransferase. *Biochim Biophys Acta* 1981;665:612–614.

6. Hickman MA, Morris JG, Rogers QR. Intestinal taurine and the enterohepatic circulation of taurocholic acid in the cat. In: Lombardini JR, Schaffer SW, Azuma J, eds. *Taurine: nutritional value and mechanisms of action*. New York: Plenum Press, 1992;45–54.

### Additional input on feral cat debate

I am writing in response to the ongoing debate about the control of feral cats. Feral domestic cats are an exotic invasive species that should be humanely removed from the environment like any other pest. The only reason that trap-neuter-return (TNR) programs exist for feral cats is because it is the same species as a commonly kept domestic pet, hence the intense emotional bond some people feel toward these animals. For example, I am unaware of any TNR programs for other exotic environmentally destructive species such as nutria (*Myocastor coypus*) or mongooses.

#### Instructions for Writing a Letter to the Editor

Readers are invited to submit letters to the editor. Letters may not exceed 500 words and 6 references. Not all letters are published; all letters accepted for publication are subject to editing. Those pertaining to anything published in the *JAVMA* should be received within one month of the date of publication. Submission via e-mail ([JournalLetters@avma.org](mailto:JournalLetters@avma.org)) or fax (847-925-9329) is encouraged; authors should give their full contact information including address, daytime telephone number, fax number, and e-mail address.

Letters containing defamatory, libelous, or malicious statements will not be published, nor will letters representing attacks on or attempts to demean veterinary societies, their committees or agencies. Viewpoints expressed in published letters are those of the letter writers and do not necessarily represent the opinions or policies of the AVMA.

As an animal welfare proponent, I believe that adoption and euthanasia are preferable and more humane options than returning these cats to a potentially hostile environment. I question Dr. Wulff (*JAVMA*, November 1, 2003, pp 1255–1256) when he claims that this issue is “about cats, wildlife, and doing our best to serve both honorably....” Whose interests do TNR programs really serve, human or feline? I propose that TNR programs are more about satisfying human emotional needs than about safeguarding the welfare of feral cats.

*Jonathan M. Sleeman, VetMB,  
DACZM  
Waynesboro, Va*

**Dr. Wulff responds:**

I salute Dr. Sleeman on his honesty in stating that euthanasia is a solution to address the problem of free-roaming cats. Because a large percentage of these cats are healthy yet unadoptable, and because there are better options available, I do not agree with him.

In addition, I do not understand how it can be said that euthanasia is a humane solution.

Although it can be done humanely, I don't see it as a humane act for a healthy cat. I wish Dr. Sleeman luck in selling that idea to the cat-feeding public. I can't believe they'll buy the idea that we're doing the cats a favor. I'm sure PETA, Alley Cat Allies, and the various humane societies will share their feelings on the subject.

I agree 100% that trap-neuter-return (TNR) programs serve human emotional needs. It's called the human-animal bond. People love cats and feel sorry for them, and they want to protect and feed them. These people are not criminals; they are kind, well-meaning people with good hearts. They may be wrong in some peoples' eyes, but if so, it's with honorable intent that there are a lot of people feeding cats.

Dr. Levy showed that 12% of families were feeding free-roaming cats (*JAVMA*, July 15, 2003, pp 202–205), which accounts for approximately 30% of the population studied. This isn't about whose needs are being served as much that it is about what the public spurred on by animal rights groups will feel about vet-

erinarians if we favor killing these cats as a blanket policy. Dr. Levy has also shown that a TNR program combined with adoption reduced cat colonies by 66% (*JAVMA*, January 1, 2003, pp 42–46). Could anyone who has unlimited funds with, personnel and cooperation from the colony keepers accomplish a cat-free park, let alone a county or state? Who knows? No one has tried and published their results in a peer-reviewed journal. What in the world would it cost? Who would pay for it?

This is too important an issue to be decided on by our biases. I cannot agree to a blanket policy of adoption or death. I work with these cats—they're not house-pet material. Still, people love them and will not sit quietly and watch them be destroyed. They will not look kindly on those who support the killing. We are veterinarians, and we are supposed to find solutions that help animals if we can. We need to work out something in the middle and realize that the public will rightly hold us accountable.

*Rick Wulff, DVM  
High Springs, Fla*



# Differences in Taurine Synthesis Rate among Dogs Relate to Differences in Their Maintenance Energy Requirement<sup>1-3</sup>

Kwang S. Ko,<sup>4</sup> Robert C. Backus,<sup>6\*</sup> John R. Berg,<sup>5</sup> Michael W. Lame,<sup>4</sup> and Quinton R. Rogers<sup>4</sup>

Department of <sup>4</sup>Molecular Biosciences and <sup>5</sup>Department of Chemistry, University of California, Davis, CA 95616 and <sup>6</sup>Department of Veterinary Medicine and Surgery, University of Missouri, Columbia, MO 65211

## Abstract

Diet-induced (taurine deficiency) dilated cardiomyopathy is reported more in large than small dogs possibly because taurine biosynthesis rate (TBR) is lower in large than small dogs. The TBR in 6 mongrels ( $37.9 \pm 2.1$  kg) and 6 beagles ( $12.8 \pm 0.4$  kg) was determined from the fractional dilution rate of urinary [ $1,2\text{-}^2\text{H}_2$ ]-taurine, (d4-tau). All dogs were given a 15.6% protein, 0.60% sulfur amino acid (SAA) diet in amounts to maintain an ideal body condition score. After 3 mo, 14.6 mg/kg body weight of d4-tau was given orally and TBR determined from d4-tau to taurine ratio in urine collected each d for 6 d. Enrichments of d4-tau were determined by GC-MS. Thereafter, mongrels and beagles were paired by ranking of SAA intake per metabolic body weight per  $\text{kg}^{0.75}$ . Each pair received the same amount of diet/ $\text{kg}^{0.75}$  for 2 wk, then TBR was again determined. Concentrations of taurine in plasma, blood, and urine and concentrations of plasma thiols were measured during each TBR determination. In Expt. 1, TBR and taurine concentrations in plasma and urine of mongrels were lower ( $P < 0.05$ ) than those of beagles. In Expt. 2, TBR and taurine concentrations in blood and plasma of mongrels were lower ( $P < 0.05$ ) than beagles. Together, the results support the hypothesis that large compared with small dogs have lower TBR when fed diets near-limiting in dietary SAA, but adequate to maintain ideal body condition. J. Nutr. 137: 1171–1175, 2007.

B4

B4

**B4**

**B4**

**B4**

**B4**

**B4**

# Effect of increasing taurine and methionine supplementation on urinary taurine excretion in a model insectivore, the giant anteater (*Myrmecophaga tridactyla*)

S. A. Nofs<sup>1</sup> | E. S. Dierenfeld<sup>2</sup>  | R. C. Backus<sup>3</sup> 

<sup>1</sup>Nashville Zoo at Grassmere, Nashville, TN, USA

<sup>2</sup>Ellen S. Dierenfeld, LLC, St. Louis, MO, USA

<sup>3</sup>Department of Veterinary Medicine and Surgery, University of Missouri, Columbia, MO, USA

## Correspondence

R. C. Backus, Department of Veterinary Medicine and Surgery, University of Missouri, Columbia, MO, USA.  
Email: backusr@missouri.edu

## Present address:

S. A. Nofs, Potter Park Zoo, 1301 S. Pennsylvania Ave., Lansing, MI 48912, USA

## Funding information

Morris Animal Foundation

## Summary

The giant anteater (*Myrmecophaga tridactyla*) is a highly specialized insectivore for which nutrient requirements are not clearly established, making diet formulation challenging for this species. Multiple clinical reports suggest anteaters have an obligate dietary taurine (TAU) requirement. Sulphur amino acid (SAA) metabolism in adult anteaters was evaluated using noninvasive methods to measure TAU synthesis potential from dietary methionine (MET) and a basal diet containing on a dry matter (DM) basis 1.7 mg TAU/kg DM and 6.9 g MET/kg DM. Urinary equilibrium times for TAU excretion were determined by feeding the basal diet with or without 1.5 g/kg DM supplemental TAU (crossover design;  $n = 4$ ). Effects of supplemental dietary TAU (1.7, 2.0, 2.4, 2.7, 3.0, 3.3 g/kg DM) or MET (6.9, 9.0, 11.2 g/kg DM) on urinary TAU were evaluated (randomized block trials;  $n = 5$  or 4 respectively). All urinary values (TAU, MET, unbound inorganic sulphate) were normalized to creatinine (CRT). Results indicate urinary TAU equilibrium in anteaters requires at least 2 weeks of feeding. Urinary ratio of TAU to CRT (TAU:CRT) increased as dietary TAU content increased from 1.7 to 3.0 g/kg DM, consistent with renal homeostatic modulation of TAU excretion. Our data indicate that TAU needs were met by TAU in the basal diet or by de novo synthesis. Supplemental MET resulted in ~five- to eightfold increases in urinary TAU:CRT excretion, further supporting existence of mechanisms for TAU synthesis from dietary SAA in anteaters. Adult anteaters appear able to synthesize TAU when diets contain adequate SAA, but dietary TAU may be critical if protein intakes are low or of poor quality. This study may provide guidance on choice of domestic canids vs. felids as suitable physiologic models for improved nutrition in giant anteaters, and also outlines a noninvasive method for assessing TAU status/metabolism that may be useful across species.

## KEYWORDS

amino acids, insectivory, nutrition, tamandua, taurine requirement, urine sulphate

# B4

**B4**

**B4**

**B4**

**B4**

**B4**

**B4**

**B4**

**B4**

**B4**

**From:** Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>  
**To:** Jones, Jennifer L; Queen, Jackie L  
**Sent:** 5/30/2018 11:20:22 AM  
**Subject:** FW: diet related DCM - a couple forms

Jen,

This is the second **B4** it used to made by **B4**. If we can get lot info, we can look into that.

**B4** manufactures a lot of product and does so according to each firm's specifications, but they do run a lot of different products (brands) on the same line .

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

**B6**



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**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]

**Sent:** Wednesday, May 30, 2018 6:09 AM

**To:** **B6**

**Cc:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; **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: diet related DCM - a couple forms

Hi all

We had another case yesterday on **B4, B5** I'll get that submitted to FDA today.

Happy to have you share the protocol and diet history. The protocol was designed for internal use so might be good to modify a few things:

**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](http://www.petfoodology.org)

**From:** [REDACTED] **B6**  
**Sent:** Tuesday, May 29, 2018 10:09 PM  
**To:** Freeman, Lisa <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)>  
**Cc:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>; Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>; Joshua A Stern <[jsstern@ucdavis.edu](mailto:jsstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; [REDACTED] **B6**; Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto:Olgica.Ceric@fda.hhs.gov)>  
**Subject:** Re: diet related DCM - a couple forms

Thank you so much for all your work Lisa! I just diagnosed a golden today with DCM that eats [REDACTED] **B4**, too. I am having the owners fill out the diet history form and will follow your protocol as above. [REDACTED] **B5**

[REDACTED] **B5**

Thanks,  
[REDACTED] **B6**

On Thu, May 24, 2018 at 3:21 PM, Freeman, Lisa <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)> wrote:  
Hi everyone

[REDACTED] **B5**

[REDACTED] **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](http://www.petfoodology.org)

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

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

**To:** Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>; Freeman, Lisa <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)>; Joshua A Stern <[istern@ucdavis.edu](mailto:istern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>

B6

B6

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto: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](mailto:dbadin@ncsu.edu)>; Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[istern@ucdavis.edu](mailto:istern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>

B6

B6

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto: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](mailto:dbadin@ncsu.edu)]

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

**To:** Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[istern@ucdavis.edu](mailto:istern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>

B6

Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto: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

**B6**

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L  
**Sent:** 5/30/2018 7:19:31 PM  
**Subject:** RE: reporting diet/DCM dogs

Hi Jennifer

Sorry to bug you but can you clarify what information you're looking for in these sections below (location of reportable food and location of the reportable food – contact information). This has confused me on my past submissions.

This is for another dog food being fed to a dog with DCM [B4]. The owner is holding the food so is this section supposed to be filled out with the owner's information? Or something else? The options for organization type make it look like this should be something else entered here.

Thanks  
Lisa

6-3323-2114-14291-141461134234

Safety Reporting Portal Safety Reporting Portal Safety Reporting Portal

Canada Academia Canada USA Vet Med Search Vitae Petfoodology USDA TUSK Library IT Web Request Form Tufts VMware Tufts VPN MeisterTask

**Other Phone**

**Fax**

**Location of the Reportable Food**

The Location of the Reportable Food is where the food is located within the responsible party's organization or company.

**\* Organization Name** [B6]

**\* Organization Type (select all that apply)**

**Official Establishment Inventory (OEI) Development and Maintenance Procedures**

- Acidified Food Processor
- Caterer/Catering Point
- Certified Shellfish Establishment
- Commissary
- Contract Sterilizer
- Grower
- Labeler/Relabeler
- Low Acid Canned Processor
- Manufacturer
- Own Label Distributor
- Repacker/Packer
- Salvage Operation
- Shipper
- Warehouse-Ambient Storage
- Warehouse-Frozen Storage
- Warehouse-Refrigerated Storage

**\* Country**

**\* Street Address Line 1**

**Street Address Line 2**

**\* City/Town**

**\* State**

**\* ZIP/Postal Code**

**Location of the Reportable Food - Contact Information**

**\* First Name**

**\* Last Name**

**\* Job Title**

**\* Email**

**\* Confirm Email**

**\* Primary Phone**

**Other Phone**

**Fax**

**\* Is this the food facility where the problem originated?** Please select

Organization Type (select all that apply) : \*Required

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](http://www.petfoodology.org)

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](http://www.petfoodology.org)

**From:** Freeman, Lisa  
**Sent:** Wednesday, May 30, 2018 6:01 AM  
**To:** Jennifer.Jones@fda.hhs.gov  
**Subject:** reporting diet/DCM dogs

Hi Jennifer

The dog eating [B4] that I reported last Friday died [B6] How should I report that? Owners are holding food for analysis. We have new one of [B4] that I'll submit today Also, did you have thoughts on [B5] Especially when it's a situation in which [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](http://www.petfoodology.org)

**Report Details - EON-303741**

<b>ICSR:</b>	1063738
<b>Type Of Submission:</b>	Initial
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2017-03-02 09:54:35 EST

<b>Reported Problem:</b>	<p><b>Problem Description:</b> A 3 year old spayed female whippet developed congestive heart failure in September 2015 and was treated with medications for congestive heart failure. She was evaluated by a veterinary cardiologist on 5/18/16 and findings consistent with dilated cardiomyopathy. Her housemate, a 4 year old castrated male whippet, developed congestive heart failure in April 2016 and was also evaluated on 5/18/16, and found to have dilated cardiomyopathy. Both dogs underwent blood testing for a heavy metal screen and were found to have increased total blood iron concentrations. Both dogs underwent MRI evaluation for heart and liver iron and were negative. The male dog died on [B6] and his heart was evaluated by a pathologist at the [B6] School of Veterinary Medicine. The findings were typical of idiopathic dilated cardiomyopathy, and results of special stains for iron were negative. Both dogs had been fed the same dry food (Earthborn Primitive Natural) as their only diet since January, 2015 (9 months prior to the female developing congestive heart failure and [B4] months prior to the male developing congestive heart failure. A sample of the food was submitted for analysis for iron content through a commercial laboratory [B4] [B4]. The sample, taken from a bag of food purchased at a pet food center in [B6] in April 2016, showed an iron content of [B6] mg/kg, which appears to be high, according to a veterinary nutritionist contacted.</p> <p><b>Date Problem Started:</b> 09/01/2015</p>
--------------------------	---

<b>Product Information:</b>	<p><b>Product Name:</b> Earthborn Holistic Primitive Natural</p> <p><b>Product Type:</b> Pet Food</p> <p><b>Lot Number:</b> <b>Lot Number:</b> M-2 L-1 B-11 N.W. 71452 Reg. No. II. PFO-0003 1830 <b>Expiration Date:</b> 08/18/2017</p> <p><b>UPC:</b> 3484671452</p> <p><b>Package Type:</b> BAG</p> <p><b>Package Size:</b> 12.7 kilogram</p> <p><b>Purchase Date:</b> 04/01/2016</p> <p><b>Number Purchased:</b> 1</p> <p><b>Possess Unopened Product:</b> No</p> <p><b>Possess Opened Product:</b> Yes</p> <p><b>Product Use Information:</b></p> <p><b>Manufacturer /Distributor Information:</b> <b>Name:</b> Midwestern Pet Foods, Inc. <b>Type(s):</b> Manufacturer <b>Address:</b> Evansville Indiana 47725 United States <b>Contact:</b> <b>Phone:</b> (800) 474-4163 <b>Web Address:</b> earthbornholisticpetfood.com</p> <p><b>Possess One or More Labels from This Product:</b> Yes</p> <p><b>Purchase Location Information:</b> <b>Name:</b> a "pet food center"</p>
-----------------------------	---

		<b>Address:</b> United States	
<b>Animal Information:</b>	<b>Name:</b>		
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes	
	<b>Contact:</b>	<b>Name:</b> B6	
		<b>Phone:</b> B6	
		<b>Email:</b> B6	
<b>Address:</b>	B6		
	<b>Healthcare Professional Information:</b>		
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6	
	<b>Contact:</b>	<b>Phone:</b>	B6
		<b>Email:</b>	B6
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
	<b>Reported to Other Parties:</b>	Other	
<b>Additional Documents:</b>	<b>Attachment:</b>	EarthbornPrimitive Analysis 2016.pdf	
	<b>Description:</b>	"as Fed" food analysis for iron	
	<b>Type:</b>	Analysis	

**Report Details - EON-303743**

<b>ICSR:</b>	1063739
<b>Type Of Submission:</b>	Followup
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2017-03-02 09:58:27 EST
<b>Initial Report Date:</b>	03/02/2017
<b>Parent ICSR:</b>	1063738
<b>Follow-up Report to FDA Request:</b>	Yes

<b>Reported Problem:</b>	<p><b>Problem Description:</b> A 3 year old spayed female whippet developed congestive heart failure in September 2015 and was treated with medications for congestive heart failure. She was evaluated by a veterinary cardiologist on 5/18/16 and findings consistent with dilated cardiomyopathy. Her housemate, a 4 year old castrated male whippet, developed congestive heart failure in April 2016 and was also evaluated on 5/18/16, and found to have dilated cardiomyopathy. Both dogs underwent blood testing for a heavy metal screen and were found to have increased total blood iron concentrations. Both dogs underwent MRI evaluation for heart and liver iron and were negative. The male dog died on B6 and his heart was evaluated by a pathologist at the B6 School of Veterinary Medicine. The findings were typical of idiopathic dilated cardiomyopathy, and results of special stains for iron were negative. Both dogs had been fed the same dry food (Earthborn Primitive Natural) as their only diet since January, 2015 (9 months prior to the female developing congestive heart failure and 15 months prior to the male developing congestive heart failure. A sample of the food was submitted for analysis for iron content through a commercial laboratory: B4 B4. The sample, taken from a bag of food purchased at a pet food center in B6 showed an iron content of B6 mg/kg, which appears to be high, according to a veterinary nutritionist contacted.</p> <p><b>Date Problem Started:</b> 09/01/2015</p>
--------------------------	---

<b>Product Information:</b>	<p><b>Product Name:</b> Earthborn Holistic Primitive Natural</p> <p><b>Product Type:</b> Pet Food</p> <p><b>Lot Number:</b> Lot Number: M-2 L-1 B-11 N.W. 71452 Reg. No. II. PFO-0003 1830 Expiration Date: 08/18/2017</p> <p><b>UPC:</b> 3484671452</p> <p><b>Package Type:</b> BAG</p> <p><b>Package Size:</b> 12.7 kilogram</p> <p><b>Purchase Date:</b> 04/01/2016</p> <p><b>Number Purchased:</b> 1</p> <p><b>Possess Unopened Product:</b> No</p> <p><b>Possess Opened Product:</b> Yes</p> <p><b>Product Use Information:</b></p> <p><b>Manufacturer /Distributor Information:</b> Name: Midwestern Pet Foods, Inc. Type(s): Manufacturer Address: Evansville Indiana 47725 United States Contact: Phone: (800) 474-4163 Web Address: earthbornholisticpetfood.com</p>
-----------------------------	---

		Possess One or More Labels from This Product:	Yes
	Purchase Location Information:	Name:	a "pet food center"
		Address:	United States
Animal Information:	Name:		
	Owner Information:	Owner Information provided:	Yes
		Contact: Name:	<b>B6</b>
		Phone:	
		Email:	
		Address:	<b>B6</b>
	Healthcare Professional Information:		
Sender Information:	Name:		
	Address:	<b>B6</b>	
	Contact: Phone:	<b>B6</b>	
	Email:		
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	
Additional Documents:			

---

**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Darcy Adin'  
**CC:** Rotstein, David; Norris, Anne; DeLancey, Siobhan  
**Sent:** 4/16/2018 1:48:17 PM  
**Subject:** RE: Call to discuss DCM cases

Yes, I can do 2 pm.

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



**From:** Darcy Adin [mailto:dbadin@ncsu.edu]  
**Sent:** Monday, April 16, 2018 9:43 AM  
**To:** 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:** Re: Call to discuss DCM cases

Thank you Jennifer. I will reach out to them to ask them to see if they are interested. Would it be possible to meet a bit earlier on thursday (say 2pm?)

Thanks!

Darcy

On Mon, Apr 16, 2018 at 8:20 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy.

Would you be available Thursday at 3pm eastern? If Dr. Freeman or any of the other cardiologists you mentioned below are interested, they can join the call as well.

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



**From:** Darcy Adin [mailto:dbadin@ncsu.edu]  
**Sent:** Friday, April 13, 2018 12:31 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** Re: Call to discuss DCM cases

Hi Jennifer,

Definitely! I'd love to chat more. I have not talked with Dr. Stern in a while but I can certainly reach out to him.

**B5, B6**

**B6**

Dr. Lisa Freeman (nutritionist at Tufts) and indirectly Dr. Ryan Fries at Illinois (he has

**B5**

I am free next week to chat wed-fri. Let me know how you would like to proceed - thank you!

Darcy

On Fri, Apr 13, 2018 at 9:05 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

Good morning Darcy,

I hope you're well. Are you able to chat more about the DCM cases from dogs eating grain free food that the cardiology community is seeing? I'd like to schedule a call with you and some of your colleagues who are also following the issue. I'd like to gather more information about the clinical findings and your ideas on what could be the cause. Do you have any contacts with Dr. Joshua Stern or other clinical research cardiologists that could provide additional information following this issue? I can include them on the call.

Thank you in advance for your time, and have a great weekend.

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](mailto:jennifer.jones@fda.hhs.gov)  
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



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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

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

---

**From:** Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>  
**To:** Jones, Jennifer L  
**Sent:** 4/18/2018 10:58:16 AM  
**Subject:** Re: hold-call with Dr. Adin re: DCM cases

Great! I will poll the group and got back to you

On Apr 18, 2018, at 6:46 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

Good morning Darcy,  
If Friday works best for the group, we can be available between 11 to 3pm eastern.  
Jen

Jennifer Jones, DVM  
Veterinary Medical Officer  
Tel: 240-402-5421  
<[image001.png](#)> <[image002.png](#)>

**From:** Darcy Adin [<mailto:dbadin@ncsu.edu>]  
**Sent:** Tuesday, April 17, 2018 5:18 PM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Subject:** Re: hold-call with Dr. Adin re: DCM cases

**B6** is free friday as well. If this works for you then I'll poll the others!

On Tue, Apr 17, 2018 at 5:16 PM, Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)> wrote:  
I will!

I haven't heard from her but Drs. Freeman and **B6** can't easily do thursday afternoon. I'm sure there is not going to be a time that is good for everyone but I would love for her to participate. She would be available earlier on thursday (before 11) but not sure if that will work for Dr. Stern on the west coast (I can ask if this is good for you) or friday except over lunch.

Would either of these options work for your team?  
Take care  
Darcy

On Tue, Apr 17, 2018 at 8:47 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:  
Thank you, Darcy.  
I hope **B6** can join. I haven't talked with her in many years. **B6**

Jennifer Jones, DVM  
Veterinary Medical Officer  
Tel: 240-402-5421  
<[image001.png](#)> <[image005.png](#)>

**From:** Darcy Adin [<mailto:dbadin@ncsu.edu>]  
**Sent:** Tuesday, April 17, 2018 8:38 AM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Subject:** Re: hold-call with Dr. Adin re: DCM cases

Thank you Jennifer. I will forward this on to Drs. Freeman (nutritionist at Tufts), Fries (cardiologist at Illinois) and [redacted] B5, B6 I am still waiting to hear back from [redacted] B5, B6 and [redacted] B5, B6  
Take care  
Darcy

On Apr 17, 2018, at 7:53 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

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Meeting number (access code) [redacted] B6  
Meeting password: [redacted] B6

### Join by phone

[redacted] B6 US Toll  
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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.

<mime-attachment.ics>

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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:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Darcy Adin'; 'Freeman, Lisa'; 'Joshua A Stern'; 'Fries, Ryan C'; [REDACTED] B6  
**CC:** Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica  
**Sent:** 4/20/2018 7:50:20 PM  
**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 you can just email me a spreadsheet with the data.

[REDACTED] B5

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

[REDACTED] B5

[REDACTED] B5

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>; [REDACTED] 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** Freema **B6** Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

**B6**

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

**B6**

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

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

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

Sincerely,  
Darcy Adin

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

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

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

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

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

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--

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

**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Freeman, Lisa'  
**Sent:** 4/23/2018 7:22:37 PM  
**Subject:** RE: hold-call with Dr. Adin re: DCM cases

Thank you, Lisa.

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



**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]  
**Sent:** Monday, April 23, 2018 8:37 AM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** RE: hold-call with Dr. Adin re: DCM cases

Dear Jennifer

**B5**

Please let me know if you need additional info  
Thanks for your work on this issue.  
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](http://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](mailto:dbadin@ncsu.edu)>; Freeman, Lisa <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; **B6**

**B6**

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto: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  
you can just email me a spreadsheet with the data.

**B5**

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](mailto:dbadin@ncsu.edu)>; Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; [REDACTED] **B6**

[REDACTED] **B6**

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto: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, [REDACTED] **B5**

**B5**

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](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; [REDACTED] **B6** [REDACTED] **B6**

Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto: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:

[REDACTED] **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](mailto: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](mailto:David.Rotstein@fda.hhs.gov)>, "Norris, Anne" <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>, "DeLancey, Siobhan" <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>, Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>

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--

Darcy B. Adin, DVM, DACVIM (Cardiology)  
Clinical Assistant Professor of Cardiology  
North Carolina State University

NC State Veterinary Hospital  
1060 William Moore Drive  
Raleigh, NC 27607  
919-513-6032

---

**From:** Darcy Adin <dbadin@ncsu.edu>  
**To:** Jones, Jennifer L  
**CC:** Freeman, Lisa; Joshua A Stern <[REDACTED] B6 [REDACTED]>; Rotstein, David  
**Sent:** 8/16/2018 12:49:22 PM  
**Subject:** Re: a few NCSU cases

Thanks Jennifer!

On Thu, Aug 16, 2018 at 8:13 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

Good morning everyone,

Here's our Vet-LIRN rapid necropsy document.

Take care,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



**From:** Jones, Jennifer L  
**Sent:** Wednesday, August 15, 2018 2:49 PM  
**To:** 'Freeman, Lisa' <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)>; Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>

**Cc:** Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)> <[REDACTED] B6 [REDACTED]>  
**Subject:** RE: a few NCSU cases

Thank you, Darcy! We'll be on the lookout for the cases.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]

**Sent:** Wednesday, August 15, 2018 8:50 AM

**To:** Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

**Cc:** Joshua A Stern <jstern@ucdavis.edu>

B6

**Subject:** RE: a few NCSU cases

That's really interesting, Darcy!

I wonder

B5

Thanks for sharing

Lisa

**From:** Darcy Adin <dbadin@ncsu.edu>

**Sent:** Tuesday, August 14, 2018 8:00 PM

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

**Cc:** Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>

B6

B6

**Subject:** a few NCSU cases

Hi Jennifer,

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

One of my residents saw a littermate pair of Dobermans back for their 3 month recheck after being diagnosed with DCM while eating Acana. Taurines were normal on these dogs back in April and I honestly didn't have a ton of hope for these dogs (B6) because they were dobermans and their genetic tests were abnormal (the female is homozygous positive for one mutation and negative for a 2nd, the male was heterozygous positive for one mutation and negative for a 2nd). But, 3 months after a diet change to Purina grain-based (and no taurine supplementation), they both have shown significant improvement (the less severely affected female has near normalized and the severely affected male (who was in heart failure) has also significantly improved.

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

Thank you!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

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Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

---

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L; Darcy Adin  
**CC:** Joshua A Stern; [REDACTED] Rotstein, David  
**Sent:** 8/16/2018 6:17:49 PM  
**Subject:** RE: a few NCSU cases

Hi Jen

[REDACTED] **B5**

Just want to be sure we get what you're

looking for.

We appreciate your putting this together. This will be helpful

Thanks

Lisa

**From:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Sent:** Thursday, August 16, 2018 8:13 AM  
**To:** Freeman, Lisa <lisa.freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>  
**Cc:** Joshua A Stern <jstern@ucdavis.edu>; [REDACTED] Rotstein, David  
<David.Rotstein@fda.hhs.gov>  
**Subject:** RE: a few NCSU cases

Good morning everyone,  
Here's our Vet-LIRN rapid necropsy document.  
Take care,  
Jen

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



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**Sent:** Wednesday, August 15, 2018 2:49 PM  
**To:** 'Freeman, Lisa' <Lisa.Freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>  
**Cc:** Joshua A Stern <jstern@ucdavis.edu>; [REDACTED]  
**Subject:** RE: a few NCSU cases

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



**From:** Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]  
**Sent:** Wednesday, August 15, 2018 8:50 AM  
**To:** Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Cc:** Joshua A Stern <jstern@ucdavis.edu>; [REDACTED]  
**Subject:** RE: a few NCSU cases

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**B5**

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Lisa

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**Sent:** Tuesday, August 14, 2018 8:00 PM

**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>

**Cc:** Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[istern@ucdavis.edu](mailto:istern@ucdavis.edu)>; [REDACTED] B6

[REDACTED] B6

**Subject:** a few NCSU cases

Hi Jennifer,

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

Thank you!  
Darcy

--

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

Owner: **B6**

Accession Number: **B6**

Reference Number:

Case Coordinator: **B6**

Received: **B6**

Finalized: **B6**

Sampled:

To: **B6**

Phone #: **B6**

Added Report

ANATOMIC PATHOLOGY RESULTS

SMALLANIMAL NECROPSY

ANIMAL ID **B6**

REF CASE NO 212267

SPECIES Canine

BREED Schnauzer

SEX Mc

AGE 3y

SPECIMEN DESC Body

GROSS An 8.2 kg, 2.5-year-old, castrated male miniature schnauzer dog is presented for postmortem examination. The animal was euthanized and the body is in fair postmortem condition with a euthanasia?to?necropsy interval of approximately 16 hours. **B6**

**B6**

**B6**

**B6** The heart is subjectively enlarged. **B6**

**B6**

Addended Report

Accession Number: **B6**

ANATOMIC PATHOLOGY RESULTS

**B6**

GROSS DIAGNOSIS

**B6**

2. Heart: mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation

**B6**

REPORT STATUS  
COMMENTS

PRELIMINARY REPORT-HISTOLOGY PENDING

Except for gross evidence of moderate to marked pulmonary edema and mild cardiac changes, gross examination is otherwise mostly unremarkable. The heart is mildly enlarged with mild mitral valve endocardiosis and associated mild left atrial dilation and left ventricular hypertrophy. This mild degree of cardiac changes does not fit well with the moderate to severe degree of pulmonary edema present. In addition to the mild structural changes, a functional cardiac abnormality may have been contributing to clinical disease in this patient. Samples of lung and heart were rushed and examined histologically. In addition to the pulmonary edema, there is also histologic evidence of diffuse, acute alveolar injury. These pulmonary changes can explain this patient's signs of respiratory distress. However, the heart is histologically unremarkable and the skeletal muscle was grossly unremarkable; as such, a cause for the markedly elevated CK is not yet identified. Histology of skeletal muscle is pending.

PATH RESIDENT  
SENIOR PATH  
DATE

**B6**

Final Necropsy Report  
MICROSCOPIC

**B6**

Addended Report

Accession Number: **B6**

ANATOMIC PATHOLOGY RESULTS

**B6**

Heart (slide 1), Skeletal muscle (slide 3), Kidneys (slide 3), Spleen (slide 3), Stomach (slide 4), Small intestine (slide 4), Colon (slide 4), Pancreas (slide 4), Adrenal gland (slide 4); **B6**

**B6**

FINAL DIAGNOSIS

**B6**

2. Heart: mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation

**B6**

COMMENTS

Histology reveals:

**B6**

**B6**

PATH RESIDENT  
SENIOR PATH  
FINALIZED DATE

**B6**

### NECROPSY REPORT FINAL REPORT

Animal ID: EON-361684  
 Accession Number: **B6**  
 Species: Canine  
 Date: (DON)  
 Sex, Age Class: UNK, Mature  
 Body Condition: Good  
 Condition at Investigation: Alive, Euthanized  
 Carcass Disposition/Post-Mortem Interval: ~5 minutes

#### ANCILLARY FINDINGS

Test	Test Sample	Result	Comment

#### TISSUES/SAMPLES RECEIVED

On 1 November 2018, cardiac measurements and sampling was conducted. Representative sections were placed in Cassettes #1-16. In addition, non-cardiac tissues were received, and representative sections were placed in Cassettes A-F. Received 7 February 2019 are 22 H&E slides. Letters or numbers in parentheses correspond to the slide number.

#### MICROSCOPIC DESCRIPTION

*Tissue Preservation:* Good

Respiratory System

**B6**

Hematolymphatic System

**B6**

Hepatobiliary System

**B6**

Integumentary System/Musculoskeletal System:

**B6**

Urogenital System:

**B6**

Digestive System:

**B6**

Cardiovascular System:

**B6**

B6

**B6**

Nervous System:

B6

Endocrine System:

B6

Sensory System:

**B6**

Body as a Whole:

Tissues with No Significant Histologic Findings:

B6

B6

**MORPHOLOGICAL DIAGNOSES**

Respiratory System

**B6**

Hematolymphatic System

**B6**

Hepatobiliary System

**B6**

Nervous System:

**B6**

Integumentary System/Musculoskeletal System:

**B6**

Urogenital System:

**B6**

Endocrine System:

**B6**

Digestive System:

**B6**

Cardiovascular System:

A. Heart:

- a. Atria and Ventricles: Cardiomyocyte attenuation (atrophy) and degeneration, diffuse, moderate with fatty infiltration, lymphocytic and histiocytic myocarditis, fibrosis (endocardial), wavy fibers, and edema.
- b. Left Atrioventricular Valve: Valvular endocardiosis, moderate.
- c. Arterial intimal cushions, multifocal, mild.

Sensory System:

**B6**

Body Cavity

**B6**

**FINAL DIAGNOSES/INTERPRETATIVE SUMMARY**

<b>Diagnosis</b>
Cardiomyopathy
Hepatic Chronic Passive Congestion
Interstitial Nephritis, MIId

Linked Cases: NA

Grossly, there was remarkable biventricular dilation and left atrial dilation. There was flattening of the ventricular endocardial surface as well as left atrioventricular valvular endocardiosis. Histopathologic finding were remarkable and including atrophy, degeneration, interstitial edema, inflammation, and fibrosis. These findings are consistent with a cardiomyopathy, specifically, a dilated cardiomyopathy. Though there was fatty infiltration in the right ventricle, the overall pattern of wavy fibers and degeneration are most aligned with an “attenuated wavy fiber” type of DCM.<sup>1</sup> Adin et al. (2019) proposed echocardiographic phenotypical differences based on diet type.<sup>2</sup> The role of taurine, diet, and breed are under continual and current investigation.

**RECOMMENDED TESTS**

TEST	PURPOSE	SITE	RESULT

DATE: 3/1/2019	REPORTING PATHOLOGIST: David S. Rotstein, DVM, MPVM, DACVP
-------------------	---

<sup>1</sup> Tidholm A and Jonsson L. 2005. Vet Pathol 42: 1-8.  
<sup>2</sup> Adin D et al. 2019. J Vet Cardiol Feb;21:1-9. doi: 10.1016/j.jvc.2018.11.002. Epub 2018 Dec 5.

**FIGURES**

No Figures

### NECROPSY REPORT FINAL REPORT

Animal ID: EON-362158  
 Accession Number: **B6**  
 Species: Canine  
 Date: **B6** (DON)  
 Sex, Age Class: M, Adult  
 Body Condition: Good  
 Condition at Investigation: Alive, Euthanized  
 Carcass Disposition/Post-Mortem Interval: ~5 minutes

#### GROSS FINDINGS/HISTORICAL FINDINGS

- DILATED CARDIOMYOPATHY (chronic congestive heart failure); heart 1.9% BW
- ABDOMINAL EFFUSION (MILD)
- GASTRITIS
- HEPATIC FIBRINOUS CAPSULITIS
- SPLENIC SIDEROCALCIFIC PLAQUES
- ABDOMINAL EFFUSION (~30.0 ML)
- UNDERWEIGHT (cachexia)

#### ANCILLARY FINDINGS

Test	Test Sample	Result	Comment

#### TISSUES/SAMPLES RECEIVED

On 30 November 2018, cardiac measurements and sampling was conducted. Representative sections were placed in Cassettes #1-17. In addition, non-cardiac tissues were received, and representative sections were placed in Cassettes A-F. Received 7 February 2019 are 23 H&E slides. Letters or numbers in parentheses correspond to the slide number.

#### MICROSCOPIC DESCRIPTION

*Tissue Preservation:* Good

Respiratory System

**B6**

**B6**

**B6**

Hematolymphatic System

**B6**

Hepatobiliary System

**B6**

Integumentary System/Musculoskeletal System:

**B6**

Urogenital System:

**B6**

Digestive System:

**B6**

Cardiovascular System:

**B6**

**B6**

Other:

**B6**

Nervous System:

**B6**

Endocrine System:

**B6**

Sensory System:

**B6**

Body as a Whole:

Tissues with No Significant Histologic Findings:

**B6**

**B6**

MORPHOLOGICAL DIAGNOSES

Respiratory System

B6

Hematolymphatic System

B6

Hepatobiliary System

B6

Nervous System:

B6

Integumentary System/Musculoskeletal System:

B6

Urogenital System:

B6

Endocrine System:

B6

Digestive System:

B6

Cardiovascular System:

A. Heart

- a. Cardiomyocyte attenuation (atrophy), multifocal, mild to moderate with Anitschkow cells, fibrosis, interstitial edema, cardiomyocyte degeneration, and perinuclear ceroid-lipofuscinosis ("wear and tear" pigment).
- b. Mitral, Tricuspid, and Pulmonic Valves: Endocardiosis, mild to moderate.

Sensory System:

B6

Body Cavity

FINAL DIAGNOSES/INTERPRETATIVE SUMMARY

Diagnosis
Cardiomyopathy

Pulmonary Edema
Chronic Passive Congestion

Linked Cases: NA

Grossly, there was dilation of the heart along with hepatic changes consistent with right sided heart failure. There was atrophy of myofibers in all heart sections. The left was more severely affected. These findings are consistent with a cardiomyopathy, specifically, a dilated cardiomyopathy. The presence of wavy fibers is most consistent with an “attenuated wavy fiber” type of DCM.<sup>1</sup> There was hepatic centrilobular hepatocellular atrophy and degeneration along with centrilobular venular fibrosis consistent with chronic passive congestion further supporting the cardiac disease. Similarly, there was pulmonary edema with heart failure cells (hemosiderin-laden macrophages). Adin et al. (2019) proposed echocardiographic phenotypical differences based on diet type.<sup>2</sup> The role of taurine, diet, and breed are under continual and current investigation.

The splenic siderocalcific plaque is an age-related incidental finding and indicates a site of capsular/subcapsular hemorrhage. In the stomach, gastric vessels were congested. There was no inflammation, helical bacteria, or mucosal changes that would support a gastritis.

<b>RECOMMENDED TESTS</b>
--------------------------

TEST	PURPOSE	SITE	RESULT

DATE: 3/15/2019	REPORTING PATHOLOGIST: David S. Rotstein, DVM, MPVM, DACVP
--------------------	---

<sup>1</sup> Tidholm A and Jonsson L. 2005. Vet Pathol 42: 1-8.

<sup>2</sup> Adin D et al. 2019. J Vet Cardiol Feb;21:1-9. doi: 10.1016/j.jvc.2018.11.002. Epub 2018 Dec 5.

**FIGURES**

See PowerPoint

**Report Details - EON-366756**

ICSR:	2055325
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:	2018-09-25 13:07:32 EDT
Reporter is the Animal Owner:	Yes

**Reported Problem:** **Problem Description:** B6 has been fed grain free dog food since 2013. I acquire B6 at 9 weeks of age from a reputable breeder. She was fed Purina ProPlan for Puppies from birth - early 2013. In early 2013 B6 was diagnosed with an impacted anal gland that ruptured and the vet recommended she be fed grain-free dog food. At that time, I began feeding Fromm's Beef Firtitta Grain Free. In late 2016 B6 began to experience steady diarrhea. After much vet intervention including a 2 night stay at vet hospital on IV, I changed B6 from Fromm's to a short transition time on ground beef w/rice and then to a fresh dog food, The Farmer's Dog Beef with Lentils. Her diarrhea completely cleared and she remained on The Farmer's Dog Beef with Lentils until I began reading about the issue with Low Taurine in Golden Retrievers. Based on UC Davis and Dr Stern studies, I obtained a blood sample for testing. UC Davis completed the test and her taurine level is low at B6 while the level for a Golden Retriever is B6. I had an echocardiogram done yesterday, Sept 24, 2018. The canine cardiologist evaluation is as follows: "Mild /early dilated cardiomyopathy-suspect taurine responsive. Trace mitral valve regurgitation. Normal left atrial dimensions. High normal left ventricular dimensions with moderately decreased heart muscle function. Normal right heart size. History of eating a grain-free diet. Low taurine." "No medications are indicated at this time. Begin Taurine 1000 mg twice daily. In two weeks, begin L-carnitine 1850 mg three times daily. In four weeks, begin fish oil supplements (omega-3 fatty acids) at approximately EPA 1500 mg and DHA 925 mg total per day. Change diet from grain free, legume foods. Cardiologist recommends follow up in 6 months.

<b>Date Problem Started:</b>	09/24/2018
<b>Concurrent Medical Problem:</b>	Yes
<b>Pre Existing Conditions:</b>	Occasional urinary tract infection due to small, hooded vulva.
<b>Outcome to Date:</b>	Stable

<b>Product Information:</b>	<b>Product Name:</b>	The Farmer's Dog Beef Recipe	
	<b>Product Type:</b>	Pet Food	
	<b>Lot Number:</b>		
	<b>Package Type:</b>	PACKET	
	<b>Package Size:</b>	24 Ounce	
	<b>Purchase Date:</b>	09/13/2018	
	<b>Possess Unopened Product:</b>	Yes	
	<b>Possess Opened Product:</b>	Yes	
	<b>Storage Conditions:</b>	Frozen and refrigerate	
	<b>Product Use Information:</b>	<b>Description:</b>	Fed twice a day adding green beans
	<b>First Exposure Date:</b>	09/13/2018	
	<b>Last Exposure Date:</b>	09/25/2018	
	<b>Time Interval between Product Use and Adverse Event:</b>	18 Months	
	<b>Product Use</b>	Yes	

	<b>Stopped After the Onset of the Adverse Event:</b>	
	<b>Perceived Relatedness to Adverse Event:</b>	Probably related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>	<b>Name:</b>	On line purchase with manufacturer
	<b>Address:</b>	United States
<b>Product Name:</b>	Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food	
<b>Product Type:</b>	Pet Food	
<b>Lot Number:</b>		
<b>Package Type:</b>	BAG	
<b>Package Size:</b>	26 Pound	
<b>Purchase Date:</b>	01/20/2013	
<b>Number Purchased:</b>	1	
<b>Possess Unopened Product:</b>	No	
<b>Possess Opened Product:</b>	No	
<b>Storage Conditions:</b>	Store in original bag inside of a sealed plastic pet food storage container from The Container Store	
<b>Product Use Information:</b>	<b>Description:</b>	Fed twice daily morning / night
	<b>First Exposure Date:</b>	01/20/2013
	<b>Time Interval between Product Use and Adverse Event:</b>	4 Years
	<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
	<b>Adverse Event Abate After Product Stop:</b>	Unknown
	<b>Product Use Started Again:</b>	No
	<b>Perceived Relatedness to Adverse Event:</b>	Probably related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b>	Yes
	<b>Manufacturer /Distributor Information:</b>	
<b>Purchase Location Information:</b>	<b>Name:</b>	Various speciality pet food store
	<b>Address:</b>	United States
<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b>

	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> Retriever - Golden
	<b>Gender:</b> Female
	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 79 Pound
	<b>Age:</b> B6 Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 1
	<b>Number of Animals Reacted:</b> 1
	<b>Owner Information:</b>
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> CVCA Cardiac Care for Pets
	<b>Contact:</b> Name: B6
	Phone: [Redacted]
	Email: [Redacted]
	<b>Address:</b> B6
	United States
	<b>Type of Veterinarian:</b> Referred veterinarian
	<b>Date First Seen:</b> 09/24/2018
<b>Permission to Release Records to FDA:</b> Yes	
<b>Sender Information:</b>	<b>Name:</b> B6
	<b>Address:</b> United States
	<b>Contact:</b> Phone: [Redacted]
	Email: B6
	<b>Reporter Wants to Remain Anonymous:</b> No
	<b>Permission To Contact Sender:</b> Yes
	<b>Preferred Method Of Contact:</b> Email
	<b>Reported to Other Parties:</b> Other Store/Place of Purchase
<b>Additional Documents:</b>	

**B6**

Our Services include **B6**

- Blood Bank
- Cardiology
- Critical Care
- Diagnostic Imaging
- Emergency Medicine
- Hemodialysis
- Internal Medicine
- Oncology
- Surgery

### Cardiology Report

**Client Information:**

**B6**

**Patient Information:**

**B6**  
**B6** - Neutered Male - Canine  
Pomeranian  
2.12 kilograms

**Primary Veterinarian:**

**B6**

**Other Partner Veterinarians:**

**Exam Date:** Tuesday, January 9, 2018

**Services provided at the** **B6** **hospital.**

**Diagnosis:** Dilated Cardiomyopathy (suspect taurine deficient cardiomyopathy), Congestive Heart Failure, Alopecia X

**History (from ER):**

**B6** presents for further care of possible congestive heart failure. He was noted to have an acute onset of wheezing, coughing and increased respiratory rate. He was taken to his PDVM who performed radiographs which revealed a very enlarged heart with evidence of early pulmonary infiltrates. He has no history of a heart murmur or of any cardiac disease. He did have an episode six months ago of sneezing and some coughing that responded to antibiotics, but otherwise he has been healthy, except that he has Alopecia X. Not currently taking anything other than regular flea medication. Supplements include melatonin, lignan, probiotics, and fish oils. Diet is Zignature kangaroo.

**Cardiovascular Examination (1/10/18):**

**B6**

**Diagnostics:**

**B6**

**Assessment:**

**B6** has been diagnosed with dilated cardiomyopathy (DCM), which is a primary problem with the squeezing function of the heart, leading to secondary heart enlargement. **B6** heart disease is advanced at this time, and it has caused high pressure within the left side of the heart. This high pressure has backed up into the blood vessels of the lungs, and has caused the fluid component of blood to leak out into the lung tissue (called pulmonary edema), leading to the clinical signs that you have seen at home, such as coughing/wheezing and difficulty breathing.

DCM is most commonly seen in large and giant breed dogs and would be very unexpected in a Pomeranian. Another cause that can mimic DCM includes a deficiency in taurine, a protein found in meats. Interestingly, there have been other cases of taurine deficient DCM reported in dogs eating the same diet as **B6**. For this reason, this is my top

CS Patient ID: **B6** Patient: **B6** Client: **B6**

suspicion. Taurine deficiency is reversible with supplementation and many dogs can make a full recovery and come off heart medications.

If **B6** heart disease is not due to taurine deficiency, then it will continue to progress and he will require life-long medications. In this case, his prognosis is more guarded and he may only be manageable for a period of 6-12 months.

**B6**

**Medications:**

**B6**

**Monitoring:**

- Please watch **B6** for signs of recurrent congestive heart failure such as increase in respiratory rate or effort, coughing, decreased appetite, and lethargy. Please monitor **B6** respiratory rate and keep a daily record. When asleep or resting very quietly **B6** respiratory rate should be 20-30 breaths/min or less. If you notice a respiratory rate that is trending upward or persistently elevated above 35-40 breaths/min (for 2-3 days), please call the **B6** Cardiology service or your primary care veterinarian.

**Follow-Up:**

- A recheck cardiology examination, chemistry profile, and chest x-rays are recommended in 1-2 weeks.  
- Long-term, recheck chemistry profiles are recommended every 3 months. These blood tests can be performed with your primary care veterinarian.  
- A recheck echocardiogram is recommended in 6 months to determine if **B6** heart disease has reversed and if medications may be able to be stopped.

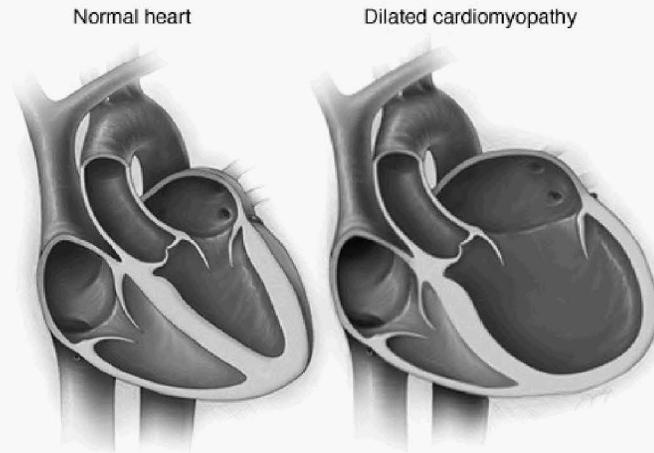
Thank you for referring **B6** to the Cardiology Service at **B6** **B6**. We appreciate the opportunity to participate in the care of your patients and thank you for entrusting our hospital with your clients and their pets; your continued confidence is greatly appreciated. Please call or email us if you have any questions or concerns.

Sincerely,

**B6**

\*\*\*For prescription refills, please call **B6** and ask for the Cardiology Prescription Refill Line. Please be aware that it can take up to 72 hours to get prescriptions refilled. This line, along with our email, will be monitored Tuesday – Friday, 8:00 am to 6:00 pm. **If you have an emergency please call the front desk immediately at **B6**** as it may take us up to 72 hours to answer emails.\*\*\*

# Dilated Cardiomyopathy (DCM)



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Dilated cardiomyopathy, or DCM, is a heart condition characterized by a decreased pumping ability of the heart. This leads to volume retention within the heart and dilation of the heart chambers. In some dogs, this may only occur on the left side, while others have all chambers affected. This predisposes to the development of congestive heart failure and arrhythmias, which can cause sudden death in affected dogs.

This condition is most common in large to giant breeds, including Doberman pinschers, Irish wolfhounds, Great Danes, and Boxers. In these breeds, it is suspected of having a genetic basis as numerous abnormalities have been described in people with this condition. In veterinary medicine, we are aware of certain genetic defects that cause DCM including PDK4 & DCM2 in Dobermans and RBM20 in standard schnauzers, among others. Not all affected dogs will have one of these mutations however, and in these dogs, the disease is typically idiopathic meaning that no definitive cause can be identified.

There are also other conditions that can mimic DCM such as chronic doxorubicin toxicity (a chemotherapy agent), chronic myocarditis (i.e., inflammation of the heart muscle), or a nutritional deficiency in taurine. Taurine is a part of proteins that are found in meat products. Animals that are fed vegetarian diets that are not supplemented with taurine, and occasionally, dogs that are fed diets where this nutrient is just unavailable for absorption, are at risk for manifesting this disease. Importantly, this form of the disease may be reversible if supplementation is initiated and some dogs are able to be weaned completely from cardiac medications.

Treatment of this disease revolves around management of the complications (heart failure, arrhythmias) as well as taurine supplementation if there is concern for a dietary cause. There are currently no surgeries that have been shown to improve the prognosis in these dogs.

Prognosis for this disease is variable depending upon the underlying cause. Dobermans with the genetic or idiopathic form of the disease are known to be at a high risk for sudden death and heart failure may only be manageable for 3-6 months. In other breeds with the idiopathic form of this disease, the prognosis is better with survivals averaging 6-12 months and, in general, lower risks for sudden death. As stated above, taurine deficiency is potentially reversible to the point that medications may be discontinued; however, resolution generally takes at least 4 months to become evident on an echocardiogram.

## Congestive heart failure (CHF)

CHF is a result of very severe heart disease. When there is severe heart disease, the normal function of the heart (left-sided, right-sided, or both) is so impaired that it cannot handle the normal flow of blood/fluid in the body and therefore, the fluid backs up. Congestion refers to this backup of fluid either into the lungs (left-sided heart failure) or body (right-sided heart failure). The most common causes of CHF include a stiff heart that does not stretch and fill appropriately, impaired heart valves that leak, or disease resulting in a poor pumping function of the heart. Complete diagnostic evaluations, including echocardiograms, allow the management of the heart disease to be tailored to the individual patient. The goal of treatment of CHF in animals is to remove the fluid and allow the patient to be able to breathe comfortably and live a good quality of life. Because severe disease will always progress, it is important to monitor for signs of worsening disease, that is, return of congestion so that treatment can be modified appropriately.

### *Monitoring left sided congestive heart failure (CHF): pulmonary edema*

Pulmonary edema is the back up of fluid into the lungs. When animals have evidence of pulmonary edema, they will have an increased rate and sometimes effort of breathing, coughing, and exercise intolerance.

**At home monitoring:**

The most sensitive means of monitoring for pulmonary edema is counting the sleeping respiratory rate at home. Keeping a log of how fast your pet is breathing during deep sleep can be helpful in determining if fluid is starting to build up in the lungs. A normal dog or cat should have a sleeping respiratory rate of 20-30 breaths per minute (bpm) or less. One breath is one excursion of the chest up and down. Panting is not excessive breathing. Panting can indicate many things and therefore, cannot be used as a determination of breathing rate. An awake animal who is managed for CHF will probably have a respiratory rate over 30 breaths/min, therefore it is important to consider the rate only while sleeping. Some animals also have underlying lung disease that might increase the breathing rate, therefore, this may need to be taken into consideration. It is most important to get a baseline when it is believed that there is no evidence of congestion (as assessed by yourself and your veterinarian). If you notice a consistent increased rate over a few days, then you should call your veterinarian as they will be able to determine if your pet is showing signs of congestion and determine the best course of action. As a general guideline, a rate between 30-45 breaths/min may indicate a small amount of fluid or could possibly be normal for a patient who has consistently had this higher breathing rate. If your pet's respiratory rate jumps up above 40-44 breaths/min when it has been consistently under 30 breaths/min, then it is likely that there is fluid in the lungs. You should call your veterinarian or consider taking your pet into the veterinarian soon.

Chest x-rays are needed to document congestive heart failure. However, if there is only a small amount of fluid, the x-rays may not always give a clear answer. Many times, the diagnosis of congestion is based on your observations at home (particularly respiratory rate), physical examination findings, as well as the x-ray results. If after x-rays and a review of your observations at home it is still difficult to determine if there is truly congestion, a trial with an increased dose of lasix can be tried. If you can determine by monitoring the breathing rate or resolution of the clinical signs that the lasix helps significantly, then congestion can be confidently identified.

**Medications**

**B6**

**B6**

CS Patient ID: **B6** Patient: **B6** Patient: **B6**

**Report Details - EON-362878**

ICSR: 2053969  
 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: 2018-08-20 16:33:06 EDT

**Reported Problem:**  
**Problem Description:** Taken to RDVM for lameness. Dilated cardiomyopathy and CHF diagnosed 8/6 /18. Started on meds [B6] We saw at Tufts 8/16 /18. Clinically improved but still has significant DCM and CHF plus arrhythmia. We added [B6] WB taurine pending. Another dog in household (also a Doberman) was eating the same food but was echoed today and has no signs of DCM.  
**Date Problem Started:** 08/06/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Hypothyroid, obesity, osteoarthritis, behavioral issues  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana Free Run Poultry dry  
**Product Type:** Pet Food  
**Lot Number:**  
**UPC:** 6499250125  
**Package Type:** BAG  
**Package Size:** 25 Pound  
**Possess Unopened Product:** No  
**Possess Opened Product:** Yes  
**Product Use Information:**  
**Description:** Fed to 2 Dobermans in household.  
**First Exposure Date:** 09/01/2016  
**Last Exposure Date:** 08/16/2018  
**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:** Probably related  
**Other Foods or Products Given to the Animal During This Time Period:** Yes  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** [B6]

	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> Doberman Pinscher
	<b>Gender:</b> Male
	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 45 Kilogram
	<b>Age:</b> B6 years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 2
	<b>Number of Animals Reacted:</b> 1
	<b>Owner Information:</b>
	<b>Owner Information provided:</b> Yes
	<b>Contact:</b>
	<b>Name:</b> B6
	<b>Phone:</b>
	<b>Email:</b>
	<b>Address:</b> B6 United States
	<b>Healthcare Professional Information:</b>
	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine
	<b>Contact:</b>
	<b>Name:</b> Lisa Freeman
	<b>Phone:</b> (508) 887-4523
	<b>Email:</b> lisa.freeman@tufts.edu
	<b>Address:</b> 200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b> Lisa Freeman
	<b>Address:</b> 200 Westboro Rd North Grafton Massachusetts 01536 United States
	<b>Contact:</b>
	<b>Phone:</b> 5088874523
	<b>Email:</b> lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b> Yes
	<b>Preferred Method Of Contact:</b> Email
	<b>Reported to Other Parties:</b> None
<b>Additional Documents:</b>	<b>Attachment:</b> B6 cardio report 8-16-18.pmx.pdf
	<b>Description:</b> Cardio report
	<b>Type:</b> Sonogram
	<b>Attachment:</b> B6 discharge 8-16-18.pdf
	<b>Description:</b> Discharge report
	<b>Type:</b> Other

<b>Attachment:</b>	<b>B6</b>	prnx.pdf
<b>Description:</b>	Chest rads from rdvm	
<b>Type:</b>	Radiographs	
<b>Attachment:</b>	<b>B6</b>	profile 8-16-18.prx.pdf
<b>Description:</b>	Chemistry profile	
<b>Type:</b>	Laboratory Report	

**Report Details - EON-374786**

ICSR: 2060599  
 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: 2018-12-27 10:09:22 EST

**Reported Problem:**  
**Problem 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.  
**Date Problem Started:** 08/20/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** B6  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana Free Run Poultry dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018  
**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:** 38.1 Kilogram  
**Age:** 10 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 2  
**Number of Animals Reacted:** 2  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** B6  
**Phone:** B6  
**Email:**  
**Address:** B6  
 United States  
**Healthcare Professional Information:** **Practice Name:** Tufts Cummings School of Veterinary Medicine  
**Contact:** **Name:** Lisa Freeman

			<b>Phone:</b> (508) 887-4523
			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b>	medical records.pdf
	<b>Description:</b>	Medical records	
	<b>Type:</b>	Medical Records	

**Report Details - EON-383005**

ICSR:	2064397
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:	2019-03-21 17:33:50 EDT
Initial Report Date:	12/27/2018
Parent ICSR:	2060599
Follow-up Report to FDA Request:	Yes

Reported Problem:	<b>Problem Description:</b>	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]
	<b>Date Problem Started:</b>	08/20/2018
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	[B6]
	<b>Outcome to Date:</b>	Better/Improved/Recovering

Product Information:	<b>Product Name:</b>	Acana Free Run Poultry dry
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Product Use Information:</b>	<b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

Animal Information:	<b>Name:</b>	[B6]
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Doberman Pinscher
	<b>Gender:</b>	Female
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	38.1 Kilogram
	<b>Age:</b>	10 Years
	<b>Assessment of Prior Health:</b>	Excellent
	<b>Number of Animals Given the Product:</b>	2
	<b>Number of Animals Reacted:</b>	2
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
	<b>Contact:</b> <b>Name:</b> [B6]	
	<b>Phone:</b> [B6]	
	<b>Email:</b> [B6]	
	<b>Address:</b> [B6]	

			<b>B6</b> United States	
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine		
	<b>Contact:</b>	<b>Name:</b>	Lisa Freeman	
		<b>Phone:</b>	(508) 887-4523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States			
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
	<b>Reported to Other Parties:</b>	None		
<b>Additional Documents:</b>	<b>Attachment:</b>	Medical Record.pdf		
	<b>Description:</b>	Updated diet history, echo, ECG and Holter monitor		
	<b>Type:</b>	Medical Records		

**Report Details - EON-390790**

ICSR:	2069328
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:	2019-06-18 12:50:49 EDT
Initial Report Date:	12/27/2018
Parent ICSR:	2060599
Follow-up Report to FDA Request:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	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]
	<b>Date Problem Started:</b>	08/20/2018
	<b>Date of Recovery:</b>	06/11/2019
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	[B6]
	<b>Outcome to Date:</b>	Recovered Completely

<b>Product Information:</b>	<b>Product Name:</b>	Acana Free Run Poultry dry
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Product Use Information:</b>	<b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

<b>Animal Information:</b>	<b>Name:</b>	[B6]
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Doberman Pinscher
	<b>Gender:</b>	Female
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	38.1 Kilogram
	<b>Age:</b>	10 Years
	<b>Assessment of Prior Health:</b>	Excellent
	<b>Number of Animals Given the Product:</b>	2
	<b>Number of Animals Reacted:</b>	2
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b> <b>Name:</b> [B6]
		<b>Phone:</b> [B6]
	<b>Email:</b> [B6]	
	<b>Address:</b> [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

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Massachusetts  
01536  
United States

**Sender Information:**

**Name:**

Lisa Freeman

**Address:**

200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States

**Contact:**

**Phone:** 5088874523

**Email:** lisa.freeman@tufts.edu

**Permission To Contact Sender:**

Yes

**Preferred Method Of Contact:**

Email

**Reported to Other Parties:**

None

**Additional Documents:**

**Attachment:**

**B6**

-2019-06-12-1033.pdf

**Description:**

Idexx NT pro-BNP

**Type:**

Laboratory Report

**Attachment:**

Diet hx 6-11-2019.pdf

**Description:**

med records

**Type:**

Medical Records

**Attachment:**

Echo report V9.pdf

**Description:**

Echo report

**Type:**

Echocardiogram

**Report Details - EON-383005**

ICSR:	2064397
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:	2019-03-21 17:33:50 EDT
Initial Report Date:	12/27/2018
Parent ICSR:	2060599
Follow-up Report to FDA Request:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Housemate was diagnosed with DCM [B6] - previously reported. [B6] was asymptomatic but eating same diet (Acana) so was screened [B6] - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on [B6] echo. Will recheck in 3 months WB taurine: [B6]
	<b>Date Problem Started:</b>	08/20/2018
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	[B6]
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	Acana Free Run Poultry dry
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Product Use Information:</b>	<b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

<b>Animal Information:</b>	<b>Name:</b>	[B6]
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Doberman Pinscher
	<b>Gender:</b>	Female
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	38.1 Kilogram
	<b>Age:</b>	10 Years
	<b>Assessment of Prior Health:</b>	Excellent
	<b>Number of Animals Given the Product:</b>	2
	<b>Number of Animals Reacted:</b>	2
<b>Owner Information:</b>	<b>Owner Information provided:</b>	Yes
	<b>Contact:</b>	<b>Name:</b> [B6]
		<b>Phone:</b> [B6]
		<b>Email:</b> [B6]
	<b>Address:</b>	[B6]

			<b>B6</b> United States	
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine		
	<b>Contact:</b>	<b>Name:</b>	Lisa Freeman	
		<b>Phone:</b>	(508) 887-4523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States			
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
	<b>Reported to Other Parties:</b>	None		
<b>Additional Documents:</b>	<b>Attachment:</b>	Medical Record.pdf		
	<b>Description:</b>	Updated diet history, echo, ECG and Holter monitor		
	<b>Type:</b>	Medical Records		

**Report Details - EON-380708**

ICSR: 2063115  
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 17:00:13 EST

Reported Problem: **Problem Description:** DCM and CHF diagnosed 2/16/19. 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.  
**Date Problem Started:** 02/16/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana, Natural Balance, Pctcurcan (see diet history for additional details)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Description:** Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance")  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Terrier - Bull - American Pit  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 18 Kilogram  
**Age:** B6 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1  
**Owner Information:** Owner Yes

**Information provided:**  
**Contact:** Name: B6  
Phone: B6  
Email: B6  
**Address:** B6  
United States

**Healthcare Professional Information:** **Practice Name:** Tufts Cummings School of Veterinary Medicine

		<b>Contact:</b>	<b>Name:</b> Lisa Freeman
			<b>Phone:</b> (508) 887-4523
			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States

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	<b>Contact:</b>	<b>Phone:</b> 5088874523
		<b>Email:</b> lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes
<b>Preferred Method Of Contact:</b>	Email	

<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview.pdf
	<b>Description:</b>	Medical records
	<b>Type:</b>	Medical Records

**Report Details - EON-390104**

ICSR: 2068046  
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 17:24:05 EDT  
Initial Report Date: 02/24/2019  
Parent ICSR: 2063115  
Follow-up Report to FDA Request: Yes

Reported Problem: **Problem Description:** DCM and CHF diagnosed 2/16/19. 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.  
**Date Problem Started:** 02/16/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.  
**Outcome to Date:** Better/Improved/Recovering

Product Information: **Product Name:** Acana, Natural Balance, Petcurean (see diet history for additional details)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Description:** Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance")  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

Animal Information: **Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Terrier - Bull - American Pit  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 18 Kilogram  
**Age:** B6 years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1  
**Owner Information:** Owner Yes

**Information provided:**  
**Contact: Name:** B6  
**Phone:**  
**Email:**  
**Address:** B6

**B6**

United States

<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine	
	<b>Contact:</b>	<b>Name:</b>	Lisa Freeman
		<b>Phone:</b>	(508) 887-4523
		<b>Email:</b>	lisa.freeman@tufts.edu
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		

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		<b>Contact:</b>	<b>Phone:</b>	5088874523
			<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			

<b>Additional Documents:</b>	<b>Attachment:</b>	Diet hx 5-13-2019.pdf	
	<b>Description:</b>	Diet History form	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	Troponin 3-6-2019.pdf	
	<b>Description:</b>	Lab work	
	<b>Type:</b>	Laboratory Report	
	<b>Attachment:</b>	Follow-up records pt 2.pdf	
	<b>Description:</b>	Medical Records	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	Follow-up records pt 1.pdf	
	<b>Description:</b>	Medical Records	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	Recheck chem 21 5-13-2019.pdf	
	<b>Description:</b>	Lab work	
	<b>Type:</b>	Laboratory Report	



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: Cardiovet@tufts.edu OR clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

Dr. <b>B6</b>	Phone:	508 887 4669
Tufts University-Clinical Pathology Lab	Fax:	9 508 839 7936
Attn: <b>B6</b>	Animal Name:	<b>B6</b>
200 Westboro Road	Owner Name:	
North Grafton, MA 01536	Species:	Canine
USA	Date Received:	Mar 06, 2019

GI Lab Accession: **B6**

<u>Test</u>	<u>Result</u>	<u>Control Range</u>	<u>Assay Date</u>
Ultra-Sensitive Troponin I Fasting	<b>B6</b>	≤0.06	03/06/19

**B6**

Comments:

**Important  
Notices:**

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---

**GI Lab Contact Information**

Phone: (979) 862-2861

Fax: (979) 862-2864

Email: [gilab@cvm.tamu.edu](mailto:gilab@cvm.tamu.edu)

[vetmed.tamu.edu/gilab](http://vetmed.tamu.edu/gilab)

**Report Details - EON-380708**

ICSR: 2063115  
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 17:00:13 EST

Reported Problem: **Problem Description:** DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and tauronin pending Dog changed to Purina HA vegetar an 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.  
**Date Problem Started:** 02/16/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana, Natural Balance, Petcurran (see diet history for additional details)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Description:** Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance")  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Terrier - Bull - American Pit  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 18 Kilogram  
**Age:** B6 years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1  
**Owner Information:** Owner Yes

**Information provided:**  
**Contact Name:** B6  
**Phone:**  
**Email:**  
**Address:** B6  
United States

**Healthcare Professional Practice Name:** Tufts Cummings School of Veterinary Medicine

		<b>Contact:</b>	<b>Name:</b> Lisa Freeman
			<b>Phone:</b> (508) 887-4523
			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview.pdf	
	<b>Description:</b>	Medical records	
	<b>Type:</b>	Medical Records	

**Report Details - EON-390104**

ICSR: 2068046  
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 17:24:05 EDT  
Initial Report Date: 02/24/2019  
Parent ICSR: 2063115  
Follow-up Report to FDA Request: Yes

Reported Problem: **Problem Description:** DCM and CHF diagnosed 2/16/19. 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.  
**Date Problem Started:** 02/16/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.  
**Outcome to Date:** Better/Improved/Recovering

**Product Information:**  
**Product Name:** Acana, Natural Balance, Petcurean (see diet history for additional details)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Description:** Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance")  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Terrier - Bull - American Pit  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 18 Kilogram  
**Age:** B6 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1  
**Owner Information:** Owner Yes

**Information provided:**  
**Contact: Name:** B6  
**Phone:**  
**Email:**  
**Address:** B6

**B6**

United States

<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine	
	<b>Contact:</b>	<b>Name:</b>	Lisa Freeman
		<b>Phone:</b>	(508) 887-4523
		<b>Email:</b>	lisa.freeman@tufts.edu
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		

<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
		<b>Contact:</b>	<b>Phone:</b>	5088874523
			<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			

<b>Additional Documents:</b>	<b>Attachment:</b>	Diet hx 5-13-2019.pdf	
	<b>Description:</b>	Diet History form	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	Troponin 3-6-2019.pdf	
	<b>Description:</b>	Lab work	
	<b>Type:</b>	Laboratory Report	
	<b>Attachment:</b>	Follow-up records pt 2.pdf	
	<b>Description:</b>	Medical Records	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	Follow-up records pt 1.pdf	
	<b>Description:</b>	Medical Records	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	Recheck chem 21 5-13-2019.pdf	
	<b>Description:</b>	Lab work	
	<b>Type:</b>	Laboratory Report	



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: Cardiovet@tufts.edu OR clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

<b>B6</b>	<b>Phone:</b>	508 887 4669
Tufts University-Clinical Pathology Lab	<b>Fax:</b>	9 508 839 7936
Attn: <b>B6</b>	Animal Name:	<b>B6</b>
200 Westboro Road	Owner Name:	
North Grafton, MA 01536	Species:	Canine
USA	Date Received:	Mar 06, 2019

GI Lab Accession **B6**

<u>Test</u>	<u>Result</u>	<u>Control Range</u>	<u>Assay Date</u>
Ultra-Sensitive Troponin I Fasting	<b>B6</b>	≤0.06	03/06/19

**B6**

Comments:

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Notices:**

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**Feline Chronic Pancreatitis-** Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at [pyamkate@cvm.tamu.edu](mailto:pyamkate@cvm.tamu.edu).

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Fax: (979) 862-2864

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[vetmed.tamu.edu/gilab](http://vetmed.tamu.edu/gilab)



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: [Cardiovet@tufts.edu](mailto:Cardiovet@tufts.edu) OR [clinpath@tufts.edu](mailto:clinpath@tufts.edu)

GI Lab Assigned Clinic ID: 11405

Dr:	<b>B6</b>	Phone:	508 887 4669
Tufts University-Clinical Pathology Lab		Fax:	9 508 839 7936
Attn:	<b>B6</b>	Animal Name:	<b>B6</b>
200 Westboro Road		Owner Name:	
North Grafton, MA 01536		Species:	Canine
USA		Date Received:	Mar 06, 2019

GI Lab Accession **B6**

<u>Test</u>	<u>Result</u>	<u>Control Range</u>	<u>Assay Date</u>
Ultra-Sensitive Troponin I Fasting	<b>B6</b>	≤0.06	03/06/19

**B6**

Comments:

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---

**GI Lab Contact Information**

Phone: (979) 862-2861

Fax: (979) 862-2864

Email: [gilab@cvm.tamu.edu](mailto:gilab@cvm.tamu.edu)

[vetmed.tamu.edu/gilab](mailto:vetmed.tamu.edu/gilab)

**Report Details - EON-370755**

ICSR: 2058695  
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 13:35:47 EST  
Reporter is the Animal Owner: Yes

**Reported Problem:**  
**Problem Description:** Low taurine level, eating Wellness Simple grain free for 3 months prior to testing and Wellness Core Low fat Grain Free food for 3 years before that. Taurine level was **B6** Echo showed NO DCM  
**Date Problem Started:** 08/06/2018  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Unknown

**Product Information:**  
**Product Name:** Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food  
**Product Type:** Pet Food  
**Lot Number:**  
**UPC:** 7634489329  
**Package Type:** BAG  
**Package Size:** 24 Pound  
**Purchase Date:** 05/21/2018  
**Possess Unopened Product:** No  
**Possess Opened Product:** No  
**Storage Conditions:** In original bag in covered container in garage

**Product Use Description:** 4 cups a day  
**Product Use Information:**  
**First Exposure Date:** 05/21/2018  
**Last Exposure Date:** 08/31/2018  
**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:** Definitely related  
**Other Foods or Products Given to the Animal During This Time Period:** No

**Manufacturer Name:** Wellpet LLC

	<b>/Distributor Information:</b>		<b>Type(s):</b> Distributor
			<b>Address:</b> Massachusetts 01876-1274 United States
			<b>Contact:</b>
			<b>Possess One or More Labels from This Product:</b> Yes
	<b>Purchase Location Information:</b>		<b>Name:</b> Chewy.com
			<b>Address:</b> United States
<b>Animal Information:</b>	<b>Name:</b>		<b>B6</b>
	<b>Type Of Species:</b>		Dog
	<b>Type Of Breed:</b>		Retriever - Golden
	<b>Gender:</b>		Male
	<b>Reproductive Status:</b>		Neutered
	<b>Weight:</b>		71 Pound
	<b>Age:</b>		<b>B6</b> Years
	<b>Assessment of Prior Health:</b>		Excellent
	<b>Number of Animals Given the Product:</b>		1
	<b>Number of Animals Reacted:</b>		1
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>		<b>Practice Name:</b> UC Davis
			<b>Contact: Name:</b> Joshua Stern <b>Phone:</b> (530) 752-2475
			<b>Address:</b> Davis California United States
		<b>Type of Veterinarian:</b> Referred veterinarian	
		<b>Date First Seen:</b> 08/14/2018	
		<b>Permission to Release Records to FDA:</b> No	
<b>Sender Information:</b>	<b>Name:</b>		<b>B6</b>
	<b>Address:</b>		<b>B6</b> United States
	<b>Contact:</b>		<b>Email:</b> <b>B6</b>
	<b>Reporter Wants to Remain Anonymous:</b>		No
	<b>Permission To Contact Sender:</b>		Yes
	<b>Preferred Method Of Contact:</b>		Email
	<b>Reported to Other Parties:</b>		None
<b>Additional Documents:</b>	<b>Attachment:</b>		<b>B6</b> aurine level.pdf
	<b>Description:</b>		Taurine results from UC Davis
	<b>Type:</b>		Laboratory Report

<b>Attachment:</b>	<b>B6</b>	echo.pdf
<b>Description:</b>	Echocardiogram report	
<b>Type:</b>	Echocardiogram	

**Report Details - EON-380743**

ICSR: 2063134  
 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: 2019-02-25 07:58:43 EST

**Reported Problem:**  
**Problem Description:** Housemate (half sister; [B6]) - (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated)  
**Date Problem Started:** 02/01/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** [B6] puppy  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Product Use Information:** **Description:** Please see diet history for more info (and refer to [B6] diet history for more complete info - all dogs eat same diets)  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** [B6]  
**Type Of Species:** Dog  
**Type Of Breed:** Bulldog  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Weight:** 22.1 Kilogram  
**Age:** 8 Years  
**Assessment of Prior Health:** Good  
**Number of Animals Given the Product:** 6  
**Number of Animals Reacted:** 3  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** [B6]  
**Phone:** [B6]  
**Email:** [B6]  
**Address:** [B6]  
 United States  
**Healthcare Professional Practice Name:** Tufts Cummings School of Veterinary Medicine

	<b>Information:</b>	<b>Contact:</b>	<b>Name:</b> Lisa Freeman
			<b>Phone:</b> (508) 887-4523
			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States

<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			

<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview.pdf	
	<b>Description:</b>	Medical record	
	<b>Type:</b>	Medical Records	

**Report Details - EON-380742**

ICSR: 2063133  
 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: 2019-02-25 07:43:42 EST

**Reported Problem:**

**Problem Description:** DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food

**Date Problem Started:** 01/15/2019

**Concurrent Medical Problem:** Yes

**Pre Existing Conditions:** Anxiety - takes fluoxetine

**Outcome to Date:** Stable

**Product Information:**

**Product Name:** Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe

**Product Type:** Pet Food

**Lot Number:**

**Product Use Information:** **Description:** Please see diet history

**Manufacturer /Distributor Information:**

**Purchase Location Information:**

**Animal Information:**

**Name:** B6

**Type Of Species:** Dog

**Type Of Breed:** Bulldog

**Gender:** Female

**Reproductive Status:** Neutered

**Weight:** 19.8 Kilogram

**Age:** B6 Years

**Number of Animals Given the Product:** 6

**Number of Animals Reacted:** 3

**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

		<b>Address:</b> 200 Westboro Rd North Grafton Massachusetts 01536 United States
--	--	---

<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			

<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview.pdf	
	<b>Description:</b>	Med records	
	<b>Type:</b>	Medical Records	

**Report Details - EON-380745**

ICSR: 2063135  
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: 2019-02-25 08:12:41 EST

**Reported Problem:**  
**Problem Description:** Eating BEG diet - 2 other dogs in household diagnosed with DCM ( **B6** **B6** - already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts 2/20/19 Probable **B5** /diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Taurine and troponin pending  
**Date Problem Started:** 02/20/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** **B6**  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Product Use Description:** Please see diet history for more info (and also see **B6** diet history for exact diets)  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** **B6**  
**Type Of Species:** Dog  
**Type Of Breed:** Bulldog  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 24.2 Kilogram  
**Age:** **B6** Years  
**Assessment of Prior Health:** Good  
**Number of Animals Given the Product:** 6  
**Number of Animals Reacted:** 3  
**Owner Information:** Owner Yes  
**Contact:** Name: **B6**  
Phone: **B6**  
Email: **B6**  
**Address:** **B6**

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

**Report Details - EON-390207**

ICSR:	2068098
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:	2019-06-11 15:06:46 EDT
Initial Report Date:	11/09/2018
Parent ICSR:	2058678
Follow-up Report to FDA Request:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Diagnosed with DCM, CHF, and atrial fibrillation 11/5/18. 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. Genetic testing - negative for DCM1 & DCM2 Normal taurine levels - plasma B6 whole blood B6 Patient was humanely euthanized B6 due to worsening CHF. Specimens were not collected for evaluation per owner.
	<b>Date Problem Started:</b>	11/05/2018
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Died Euthanized
	<b>Date of Death:</b>	B6

<b>Product Information:</b>	<b>Product Name:</b>	Earthborn grain free weight management dry
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

<b>Animal Information:</b>	<b>Name:</b>	B6
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Doberman Pinscher
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	45.2 Kilogram
	<b>Age:</b>	B6 Years
	<b>Assessment of Prior Health:</b>	Excellent
	<b>Number of Animals Given the Product:</b>	1
	<b>Number of Animals Reacted:</b>	1
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b>
		<b>Name:</b> B6
	<b>Phone:</b> B6	
	<b>Email:</b> B6	
	<b>Address:</b> 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:**

Follow-up med records pt 4.pdf

**Description:**

Med records

**Type:**

Medical Records

**Attachment:**

Follow-up med records pt 2.pdf

**Description:**

Med records

**Type:**

Medical Records

**Attachment:**

Follow-up med records pt 3.pdf

**Description:**

Med records

**Type:**

Medical Records

**Attachment:**

Follow-up med records pt 1.pdf

**Description:**

Med records

**Type:**

Medical Records

**Report Details - EON-390031**

<b>ICSR:</b>	2067992
<b>Type Of Submission:</b>	Followup
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-06-10 10:48:40 EDT
<b>Initial Report Date:</b>	04/29/2019
<b>Parent ICSR:</b>	2066404
<b>Follow-up Report to FDA Request:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on <b>B6</b> and taurine. Taurine levels prior to supplementation was WNL.
	<b>Date Problem Started:</b>	03/01/2019
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	NutriSource Adult Chicken and Rice formula
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>UPC:</b>	9B15P 18581
	<b>Package Type:</b>	BAG
	<b>Package Size:</b>	30 Pound
	<b>Possess Opened Product:</b>	Yes
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
	<b>Product Name:</b>	PureVita Venison & Red Lentils Grain-Free Dry Dog Food
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG

<b>Animal Information:</b>	<b>Name:</b>	<b>B6</b>
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	American Pit Bull Terrier
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	32 Kilogram
	<b>Age:</b>	<b>B6</b> years
<b>Assessment of Prior Health:</b>	Excellent	

	<b>Number of Animals Given the Product:</b>	1																										
	<b>Number of Animals Reacted:</b>	1																										
	<b>Owner Information:</b>	<table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>Owner Information provided:</b>	Yes	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6	<b>Address:</b>	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States												
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<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine																											
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<b>Type of Veterinarian:</b>	Referred veterinarian																											
<b>Permission to Release Records to FDA:</b>	Yes																											
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	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States																										
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<b>Phone:</b>	B6																											
<b>Email:</b>	B6																											
	<b>Permission To Contact Sender:</b>	Yes																										
	<b>Preferred Method Of Contact:</b>	Email																										
	<b>Reported to Other Parties:</b>	None																										
<b>Additional Documents:</b>	<b>Attachment:</b>	Diet Hx 5-3-2019.pdf																										
	<b>Description:</b>	Med records																										
	<b>Type:</b>	Medical Records																										
	<b>Attachment:</b>	Recheck chem 21 5-3-2019.pdf																										
	<b>Description:</b>	Lab work																										
	<b>Type:</b>	Laboratory Report																										

<b>Attachment:</b>	<b>B6</b>	troponin 5-30-2019.pdf
<b>Description:</b>	Lab work	
<b>Type:</b>	Laboratory Report	



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 **B6**@tufts.edu

GI Lab Assigned Clinic ID: 23523

<b>B6</b> Tufts Cummings School of Vet Med - Cardiology/Nutrition 200 Westboro Road North Grafton, MA 01536 USA	Phone: 508 887 4696 Fax: Animal Name: Owner Name: Species: Canine Date Received: May 30, 2019	<b>B6</b>
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Tufts Cummings School of Vet Med - Cardiology/Nutrition Tracking Number: 444116  
 GI Lab Accession: **B6**

<u>Test</u>	<u>Result</u>	<u>Reference Interval</u>	<u>Assay Date</u>
Ultra-Sensitive Troponin I Fasting	<b>B6</b> ng/mL	≤0.06	05/31/19

**B6**

Comments:

**GI Lab Contact Information**

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

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

**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:**

<b>Problem Description:</b>	Older housemate diagnosed with DCM and CHF. Screening <b>B6</b> 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
<b>Date Problem Started:</b>	11/07/2018
<b>Concurrent Medical Problem:</b>	No
<b>Outcome to Date:</b>	Stable

**Product Information:**

<b>Product Name:</b>	Zignature trout & salmon dry
<b>Product Type:</b>	Pet Food
<b>Lot Number:</b>	
<b>Package Type:</b>	BAG
<b>Product Use Information:</b>	<b>Description:</b> <b>B6</b> is four and was born on <b>B6</b> . 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.
<b>Manufacturer /Distributor Information:</b>	
<b>Purchase Location Information:</b>	

**Animal Information:**

<b>Name:</b>	<b>B6</b>												
<b>Type Of Species:</b>	Dog												
<b>Type Of Breed:</b>	Retriever - Labrador												
<b>Gender:</b>	Male												
<b>Reproductive Status:</b>	Neutered												
<b>Weight:</b>	25.9 Kilogram												
<b>Age:</b>	3 Years												
<b>Assessment of Prior Health:</b>	Excellent												
<b>Number of Animals Given the Product:</b>	3												
<b>Number of Animals Reacted:</b>	2												
<b>Owner Information:</b>	<table border="1"><tr><td><b>Owner Information provided:</b></td><td>Yes</td></tr><tr><td><b>Contact:</b></td><td><table border="1"><tr><td><b>Name:</b></td><td><b>B6</b></td></tr><tr><td><b>Phone:</b></td><td><b>B6</b></td></tr><tr><td><b>Email:</b></td><td><b>B6</b></td></tr></table></td></tr><tr><td><b>Address:</b></td><td><b>B6</b></td></tr></table>	<b>Owner Information provided:</b>	Yes	<b>Contact:</b>	<table border="1"><tr><td><b>Name:</b></td><td><b>B6</b></td></tr><tr><td><b>Phone:</b></td><td><b>B6</b></td></tr><tr><td><b>Email:</b></td><td><b>B6</b></td></tr></table>	<b>Name:</b>	<b>B6</b>	<b>Phone:</b>	<b>B6</b>	<b>Email:</b>	<b>B6</b>	<b>Address:</b>	<b>B6</b>
<b>Owner Information provided:</b>	Yes												
<b>Contact:</b>	<table border="1"><tr><td><b>Name:</b></td><td><b>B6</b></td></tr><tr><td><b>Phone:</b></td><td><b>B6</b></td></tr><tr><td><b>Email:</b></td><td><b>B6</b></td></tr></table>	<b>Name:</b>	<b>B6</b>	<b>Phone:</b>	<b>B6</b>	<b>Email:</b>	<b>B6</b>						
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<b>Email:</b>	<b>B6</b>												
<b>Address:</b>	<b>B6</b>												

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

**Report Details - EON-383627**

ICSR:	2064872
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:	2019-03-28 16:47:21 EDT
Initial Report Date:	11/09/2018
Parent ICSR:	2058685
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	DCM and arrhythmias diagnosed at time of <b>B6</b> 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:	<b>B6</b>
	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:	<b>B6</b>
	Type Of Species:	Dog
	Type Of Breed:	Boxer (German Boxer)
	Gender:	Male
	Reproductive Status:	Intact
	Weight:	34.8 Kilogram
	Age:	<b>B6</b> Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
Owner Information:	Owner Information	Yes

	<table border="1"> <tr> <td><b>provided:</b></td> <td></td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>provided:</b>		<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6	<b>Address:</b>	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States																
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<b>Type:</b>	Medical Records																														

IDEXX VetConnect 1-888-433-9987

Client: **B6**  
Patient: **B6**  
Species: CANINE  
Breed:  
Gender: MALE  
Age: 8Y

Date: 03/27/2019  
Requisition #: 1A  
Accession #: **B6**  
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	<b>B6</b>	0 - 900 pmol/L			<b>B6</b>

**Comments:**

1  
**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.

**Report Details - EON-380742**

ICSR: 2063133  
 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: 2019-02-25 07:43:42 EST

**Reported Problem:**  
**Problem Description:** DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far. 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food  
**Date Problem Started:** 01/15/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** B6  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Product Use Information:** Description: Please see diet history  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Bulldog  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 19.8 Kilogram  
**Age:** B6 Years  
**Number of Animals Given the Product:** 6  
**Number of Animals Reacted:** 3  
**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

		<b>Address:</b> 200 Westboro Rd North Grafton Massachusetts 01536 United States
--	--	---

<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			

<b>Additional Documents:</b>	<b>Attachment:</b>	rpt_medical_record_preview.pdf	
	<b>Description:</b>	Med records	
	<b>Type:</b>	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:** B6  
**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:** B6 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 2  
**Number of Animals Reacted:** 1  
**Owner Information:** Owner Information provided: Yes  
**Contact:** Name: B6  
 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

			<b>Email:</b> lisa.freeman@tufts.edu	
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
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	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			
<b>Additional Documents:</b>	<b>Attachment:</b>	B6 compiled records smaller.pdf		
	<b>Description:</b>	B6 compiled records		
	<b>Type:</b>	Medical Records		

**Report Details - EON-345833**

ICSR: 2040529  
 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: 2018-01-22 18:21:03 EST

**Reported Problem:**  
**Problem Description:** B6 had been diagnosed with a new heart murmur a couple of months earlier, then developed difficulty breathing and cough and was diagnosed with congestive heart failure. Echocardiogram showed evidence of dilated cardiomyopathy and chronic degenerative valve disease. B6 is the biologic niece of B6. FDA ICSR ID 2040528  
**Date Problem Started:** 08/18/2017  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** B6  
**Outcome to Date:** Died Euthanized  
**Date of Death:** B6

**Product Information:**  
**Product Name:** California Natural Grain-Free Kangaroo and Red Lentils Recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Possess Unopened Product:** No  
**Possess Opened Product:** No  
**Product Use Information:**  
**Description:** B6 had been fed this product for years for management of food allergy.  
**Last Exposure Date:** 08/24/2017  
**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:** Probably related  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Retriever - Labrador  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 25.6 Kilogram  
**Age:** 5 Years

	<b>Assessment of Prior Health:</b>	Excellent																
	<b>Number of Animals Given the Product:</b>	4																
	<b>Number of Animals Reacted:</b>	4																
	<b>Owner Information:</b>	<table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Other Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td></td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>Owner Information provided:</b>	Yes	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Other Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td></td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>		<b>Other Phone:</b>		<b>Email:</b>		<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States
	<b>Owner Information provided:</b>	Yes																
<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Other Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td></td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>		<b>Other Phone:</b>		<b>Email:</b>										
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<b>Healthcare Professional Information:</b>	<table border="1"> <tr> <td><b>Practice Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Other Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td></td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>Practice Name:</b>	B6	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Other Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td></td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>		<b>Other Phone:</b>		<b>Email:</b>		<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States	
<b>Practice Name:</b>	B6																	
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<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States															
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United States																		

<b>Sender Information:</b>	<b>Name:</b>	B6						
	<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States				
	B6							
	United States							
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Other Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td></td> </tr> </table>	<b>Phone:</b>	B6	<b>Other Phone:</b>		<b>Email:</b>	
	<b>Phone:</b>	B6						
<b>Other Phone:</b>								
<b>Email:</b>								
<b>Permission To Contact Sender:</b>	Yes							
<b>Preferred Method Of Contact:</b>	Phone							
<b>Reported to Other Parties:</b>	Other							

<b>Additional Documents:</b>	<b>Attachment:</b>	cardio0010.pdf
	<b>Description:</b>	Initial echo report and emergency visit report at which time euthanasia was elected
	<b>Type:</b>	Medical Records

Report Details - EON-365610	
ICSR:	2054966
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:	2018-09-16 11:38:42 EDT
Reported Problem:	<b>Problem Description:</b> DCM and CHF - had been having respiratory signs for ~1 month prior to diagnosis at Tufts Littermate is <b>B6</b> (already reported by owner after being diagnosed with DCM and CHF in July 2018) Owner has another Great Dane at home (~1 year of age) eating the same diet that will be screened soon Owner approved submission of this report and talking to FDA Will send rest of medical records by email (sorry - too many to upload)
	<b>Date Problem Started:</b> 09/12/2018
	<b>Concurrent Medical Problem:</b> Yes
	<b>Pre Existing Conditions:</b> Dermatitis
	<b>Outcome to Date:</b> Stable
Product Information:	<b>Product Name:</b> 4Health beef stew canned
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Package Type:</b> CAN
	<b>Product Use Information:</b> <b>Description:</b> 2 tablespoons 3x/day since Jan, 2017
	<b>Manufacturer /Distributor Information:</b>
	<b>Purchase Location Information:</b>
	<b>Product Name:</b> Taste of the Wild Prey Beef dry (will provide full diet history)
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Package Type:</b> BAG
	<b>Product Use Information:</b> <b>Description:</b> 9 cups/day
	<b>First Exposure Date:</b> 06/01/2018
	<b>Manufacturer /Distributor Information:</b>
<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> <b>B6</b>
	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> Great Dane
	<b>Gender:</b> Male
	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 69.5 Kilogram
	<b>Age:</b> <b>B6</b> Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 2
	<b>Number of Animals Reacted:</b> 1
<b>Owner Information:</b> <b>Owner</b> Yes	

		<b>Information provided:</b>							
		<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td rowspan="3" style="text-align: center; vertical-align: middle;"><b>B6</b></td> </tr> <tr> <td><b>Phone:</b></td> </tr> <tr> <td><b>Email:</b></td> </tr> </table>	<b>Name:</b>	<b>B6</b>	<b>Phone:</b>	<b>Email:</b>		
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<b>Phone:</b>									
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		<b>Address:</b>	<table border="1"> <tr> <td style="text-align: center; vertical-align: middle;"><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States				
<b>B6</b>									
United States									
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine						
		<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>Lisa Freeman</td> </tr> <tr> <td><b>Phone:</b></td> <td>(508) 887-4523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	<b>Name:</b>	Lisa Freeman	<b>Phone:</b>	(508) 887-4523	<b>Email:</b>	lisa.freeman@tufts.edu
		<b>Name:</b>	Lisa Freeman						
<b>Phone:</b>	(508) 887-4523								
<b>Email:</b>	lisa.freeman@tufts.edu								
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States								
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman							
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States							
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Phone:</b></td> <td>5088874523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	<b>Phone:</b>	5088874523	<b>Email:</b>	lisa.freeman@tufts.edu			
	<b>Phone:</b>	5088874523							
	<b>Email:</b>	lisa.freeman@tufts.edu							
<b>Permission To Contact Sender:</b>	Yes								
<b>Preferred Method Of Contact:</b>	Email								
<b>Additional Documents:</b>	<b>Attachment:</b>	taurine.pdf							
	<b>Description:</b>	Taurine results							
	<b>Type:</b>	Laboratory Report							

**B6**

Acc: **B6**

**B6**

Tx's checked by \_\_\_\_\_  
IVF Rate checked by \_\_\_\_\_

TREATMENT SHEET

Patient: **B6**  
Species: Canine  
Breed: Great Dane  
Color: Black  
Rabies Due:

Sex: MN  
DoB: **B6**

IVF: Type \_\_\_\_\_ Rate \_\_\_\_\_  
(Maintenance Rate = \_\_\_\_\_ ml/hr)

Dr: **B6** Date: **B6**

*2 leashes & collar on cage*

Alerts: dog Aggressive per O

Tech: **B6** Ward: Sr 1

Problem/DDx: CHF, Arrhythmia

Admit Date: **B6**

**IVC**  
**IV CATHETER**

Weight: 166.5 lbs

Diet: bland

Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_

Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_

Treatment	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
	A	A	A	A	A	A	A	A	A	A	A	P	P	P	P	P	P	P	P	P	P	P	P	P

**B6**

NURSING NOTES ON OTHER SIDE OF TREATMENT SHEET

CHANGES FOR FOLLOWING DAY

\_\_\_\_\_

Oxygen Time

Date IN \_\_\_\_\_ Time IN \_\_\_\_\_

Date Out \_\_\_\_\_ Time Out \_\_\_\_\_

Room Air (20.5% - 22.5%)

Date IN \_\_\_\_\_ Time Out \_\_\_\_\_

Oxygen Settings  
HI \_\_\_\_\_ Low \_\_\_\_\_  
Air temp \_\_\_\_\_ Floor heat: ON / OFF

Written By: \_\_\_\_\_

**B6**

Acc: **B6**

**B6**

TREATMENT SHEET

Tx's checked by \_\_\_\_\_

IVF Rate checked by \_\_\_\_\_

Patient: **B6**  
 Species: Canine  
 Breed: Great Dane  
 Color: Black  
 Rabies Due:

Sex: MN  
 DoB: **B6**

IVF: Type \_\_\_\_\_ Rate \_\_\_\_\_  
 (Maintenance Rate = \_\_\_\_\_ mL/hr)

Dr: **B6** Date: **B6**

Alerts: Dog Aggressive

Tech: \_\_\_\_\_ Ward: \_\_\_\_\_

Problem/DDx: CHF, Arrhythmia

Admit Date \_\_\_\_\_

Weight: 166.5 lbs \_\_\_\_\_ kg

Diet: \_\_\_\_\_

IV CATHETER  
 Date: **B6** Gage: 8 Site: cep Set by: **B6**  
 Date: \_\_\_\_\_ Gage: \_\_\_\_\_ Site: \_\_\_\_\_ Set by: \_\_\_\_\_

Treatment	1	2	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
	A	A	A	A	A	A	A	A	A	A	A	A	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Food																										
Water																										
Stool																										
Urine																										

**B6**

NURSING NOTES ON OTHER SIDE OF TREATMENT SHEET!

CHANGES FOR FOLLOWING DAY

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Oxygen Time

Date IN \_\_\_\_\_ Time IN \_\_\_\_\_

Date Out \_\_\_\_\_ Time Out \_\_\_\_\_

Room Air (20.5% - 22.5%)

Date IN \_\_\_\_\_ Time Out \_\_\_\_\_

Oxygen Settings

Hi \_\_\_\_\_ Low \_\_\_\_\_  
 Air temp \_\_\_\_\_ Floor heat: ON / OFF

Written by: \_\_\_\_\_

**B6**

**B6**

**B6**

**B6**

**B6**

Acc: **B6**

**B6**

Tx's checked by \_\_\_\_\_  
IVF Rate checked by \_\_\_\_\_

TREATMENT SHEET

Patient: **B6**  
Species: Canine  
Breed: Great Dane  
Color: Black  
Rabies Due:

Sex: MN  
DoB: **B6**

*2 leashes & collar on cage*

IVF: Type \_\_\_\_\_ Rate \_\_\_\_\_  
(Maintenance Rate = \_\_\_\_\_ mL/hr)

Dr: **B6** Date: **B6**

Alerts: *Dog Aggressive per O*

Tech: **B6** Ward: *SOR 1*

Problem/DDx: *CHF, Arrhythmia*

Admit Date: **B6**

**IV CATHETER**

Weight: *166.5* lbs \_\_\_\_\_ kg

Diet: *bland*

Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_  
Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_

Treatment	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
	A	A	A	A	A	A	A	A	A	A	A	P	P	P	P	P	P	P	P	P	P	P	P	P

**B6**

NURSING NOTES ON OTHER SIDE OF TREATMENT SHEET!

CHANGES FOR FOLLOWING DAY

Oxygen Time  
Date IN \_\_\_\_\_ Time IN \_\_\_\_\_  
Date Out \_\_\_\_\_ Time Out \_\_\_\_\_  
**Room Air (20.5% - 22.5%)**  
Date IN \_\_\_\_\_ Time Out \_\_\_\_\_  
**Oxygen Settings**  
Hi \_\_\_\_\_ Low \_\_\_\_\_  
Air temp \_\_\_\_\_ Floor heat: ON / OFF  
*Written By:* \_\_\_\_\_

**B6**

Acc: **B6**

**B6**

TREATMENT SHEET

Tx's checked by \_\_\_\_\_  
IVF Rate checked by \_\_\_\_\_

Patient: **B6**  
Species: Canine  
Breed: Great Dane  
Color: Black  
Rabies Due:

Sex: MN  
DoB: **B6**

IVF: Type \_\_\_\_\_ Rate \_\_\_\_\_  
(Maintenance Rate = \_\_\_\_\_ mL/hr)

Dr: **B6** Date: **B6**

Alerts: Dog Aggressive  
Problem/DDx: CHF, Arrhythmia

Tech: \_\_\_\_\_ Ward: \_\_\_\_\_  
Admit Date \_\_\_\_\_

Weight: 166.5 lbs \_\_\_\_\_ kg

Diet: \_\_\_\_\_

IV CATHETER  
Date: **B6** Gage: 18 Site: cep Set by: **B6**  
Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_

Treatment	1	2	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
	A	A	A	A	A	A	A	A	A	A	A	A	A	P	P	P	P	P	P	P	P	P	P	P	P	P
Food																										
Water																										
Stool																										
Urine																										

B6

NURSING NOTES ON OTHER SIDE OF TREATMENT SHEET!

CHANGES FOR FOLLOWING DAY

**Oxygen Time**  
Date IN \_\_\_\_\_ Time IN \_\_\_\_\_  
Date Out \_\_\_\_\_ Time Out \_\_\_\_\_  
**Room Air (20.5% - 22.5%)**  
Date IN \_\_\_\_\_ Time Out \_\_\_\_\_  
**Oxygen Settings**  
HI \_\_\_\_\_ Low \_\_\_\_\_  
Air temp \_\_\_\_\_ Floor heat: ON / OFF  
Written By: \_\_\_\_\_

**B6**

**B6**

**B6**

**B6**

**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:** 9/7/2018 8:54:26 PM  
**Subject:** Another Tufts! FW: Zignature Kangaroo limited ingredient grain free dry: Lisa Freeman - EON-364572  
**Attachments:** 2054747-report.pdf; 2054747-attachments.zip

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 <pfreventcreation@fda.hhs.gov>  
**Sent:** Friday, September 07, 2018 4:44 PM  
**To:** Cleary, Michael \* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6  
**Subject:** Zignature Kangaroo limited ingredient grain free dry: Lisa Freeman - EON-364572

A PFR Report has been received and PFR Event [EON-364572] has been created in the EON System.

A "PDF" report by name "2054747-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 "2054747-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-364572  
**ICSR #:** 2054747  
**EON Title:** PFR Event created for Zignature Kangaroo limited ingredient grain free dry; 2054747

<b>AE Date</b>	07/23/2016	<b>Number Fed/Exposed</b>	
<b>Best By Date</b>		<b>Number Reacted</b>	1
<b>Animal Species</b>	Dog	<b>Outcome to Date</b>	Recovered Completely

<b>Breed</b>	Mixed (Dog)		
<b>Age</b>	5 Years		
<b>District Involved</b>	PFR-New England DO		

**Product information**

**Individual Case Safety Report Number:** 2054747

**Product Group:** Pet Food

**Product Name:** Zignature Kangaroo limited ingredient grain free dry

**Description:** Developed DCM and CHF on Zignature Kangaroo limited ingredient grain free dry. Changed to Hill's ideal balance chicken and rice dry at time of diagnosis and has improved significantly on last echo (6/13/18) - fractional shortening and heart size now normal and starting to wean off meds

**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:** Recovered Completely

**Number of Animals Reacted With Product:** 1

Product Name	Lot Number or ID	Best By Date
Zignature Kangaroo limited ingredient 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**

=====  
 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-364572**

ICSR: 2054747  
 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: 2018-09-07 16:41:17 EDT

**Reported Problem:**  
**Problem Description:** Developed DCM and CHF on Zignature Kangaroo limited ingredient grain free dry. Changed to Hill's ideal balance chicken and rice dry at time of diagnosis and has improved significantly on last echo (6/13/18) - fractional shortening and heart size now normal and starting to wean off meds  
**Date Problem Started:** 07/23/2016  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Recovered Completely

**Product Information:**  
**Product Name:** Zignature Kangaroo limited ingredient grain free dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Storage Conditions:** Owner may be able to figure out exact date of starting Zignature based on online purchases  
**Product Use Information:**  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Mixed (Dog)  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Weight:** 26.2 Kilogram  
**Age:** 5 Years  
**Assessment of Prior Health:** Excellent  
**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

		<b>Address:</b> 200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
	<b>Contact:</b>	<b>Phone:</b> 5088874523
		<b>Email:</b> lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes
<b>Preferred Method Of Contact:</b>	Email	
<b>Additional Documents:</b>	<b>Attachment:</b>	cardio consult 7-23-16.pdf
	<b>Description:</b>	Will send the rest by email - too many files to upload individually
	<b>Type:</b>	Medical Records



# 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.



# Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

## Network Procedures for Owners

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

The following items are explained below:

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

### 1. General Introduction:

#### 1.1. What is the goal of the case investigation?

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

#### 1.2. What is the focus of a case investigation?

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

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

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

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

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



## Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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

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

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

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

## 2. Billing:

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

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

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

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

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

No, we cannot pay for treatment or cremation.



## **Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations**

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

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

### **3. Step by Step Process:**

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

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

#### **Vet-LIRN requests that:**

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

### **4. Types of Services and Tests:**

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

A veterinary examination may include:

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

#### **4.2. Will your animal be tested more than once?**



## **Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations**

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

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

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

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

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

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

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

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

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

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

---

**From:** Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>  
**To:** Rotstein, David; Jones, Jennifer L  
**Sent:** 4/30/2018 8:15:16 PM  
**Subject:** RE: DCM cases - proposed diet history

Thanks – on my list for tomorrow morning to have a read – the day has flown by. The good news – they reinstalled SAS and JMP today, so baby steps...

**From:** Rotstein, David  
**Sent:** Friday, April 27, 2018 9:00 PM  
**To:** Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** Fwd: DCM cases - proposed diet history

Lee Anne,

Thought you would be interested and could provide any comments/suggestions

---

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**Date:** April 27, 2018 at 7:27:27 PM EDT  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>, Joshua A Stern <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:** DCM cases - proposed diet history

Hi everyone

I'm attaching a proposed diet history form. I met with our cardiology group yesterday [REDACTED] B5

[REDACTED] B5

[REDACTED] B5

Please let me know if you have any comments – [REDACTED] B5

[REDACTED] B5

[REDACTED] B5

Our group also discussed a [REDACTED] B5

[REDACTED] B5

[REDACTED] B5

Thanks  
Lisa

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

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

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

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

**B6**

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto: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](mailto:dbadin@ncsu.edu)>; Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; [REDACTED] **B6**

**B6**

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto: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](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto: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



# Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

## Network Procedures for Owners

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

The following items are explained below:

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

### 1. General Introduction:

#### 1.1. What is the goal of the case investigation?

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

#### 1.2. What is the focus of a case investigation?

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

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

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

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

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



## Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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

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

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

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

## 2. Billing:

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

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

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

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

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

No, we cannot pay for treatment or cremation.



## **Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations**

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

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

### **3. Step by Step Process:**

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

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

#### **Vet-LIRN requests that:**

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

### **4. Types of Services and Tests:**

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

A veterinary examination may include:

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

#### **4.2. Will your animal be tested more than once?**



## **Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations**

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

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

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

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

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

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

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

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

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

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

**Report Details - EON-367899**

ICSR: 2055822  
 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: 2018-10-09 09:33:20 EDT

**Reported Problem:**  
**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:** Stable

**Product 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:**  
**Name:** [B6]  
**Type Of Species:** Dog  
**Type Of Breed:** Doberman Pinscher  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 33.4 Kilogram  
**Age:** [B6] Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 2  
**Number of Animals Reacted:** 2  
**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

			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b>	medical records combined.pdf
	<b>Description:</b>	medical records	
	<b>Type:</b>	Medical Records	

Report Details - EON-366516		
ICSR:	2055229	
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:	2018-09-22 18:33:37 EDT	
Reported Problem:	<b>Problem Description:</b> DCM and CHF Probably primary DCM in predisposed breed but given diet history, some possibility of diet-associated DCM Taurine WNL	
	<b>Date Problem Started:</b> 09/08/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b> <b>Description:</b> Owner has given consent to have FDA contact her for any additional questions	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> B6	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Doberman Pinscher	
	<b>Gender:</b> Male	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 34.2 Kilogram	
	<b>Age:</b> B6 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 2	
	<b>Number of Animals Reacted:</b> 1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b> <b>Name:</b> B6 <b>Phone:</b> <b>Email:</b>
		<b>Address:</b> B6 United States
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine
<b>Contact:</b> <b>Name:</b> Lisa Freeman <b>Phone:</b> (508) 887-4523		

			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
<b>Additional Documents:</b>	<b>Attachment:</b>	discharge 9-20-18.pdf	
	<b>Description:</b>	Discharge 9-20-18	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	bnp.pdf	
	<b>Description:</b>	BNP	
	<b>Type:</b>	Laboratory Report	
	<b>Attachment:</b>	cardio appointment 9-20-18.pdf	
	<b>Description:</b>	Cardio appt 9-20-18	
	<b>Type:</b>	Echocardiogram	
	<b>Attachment:</b>	cardio consult 9-8-18.pdf	
	<b>Description:</b>	cardio consult 9-8-18	
	<b>Type:</b>	Echocardiogram	
	<b>Attachment:</b>	discharge 9-9-18.pdf	
	<b>Description:</b>	Discharge 9-9-18	
	<b>Type:</b>	Medical Records	

Client: **B6**  
Patient: **B6**  
Species: CANINE  
Breed: DOBERMAN\_PINSCH  
Gender: MALE NEUTERED  
Age: 8Y

Date: 09/10/2018  
Requisition #: 426657  
Accession #: **B6**  
Ordered by: **B6**

IDEXX VetConnect 1-888-433-9967  
TUFTS UNIVERSITY  
200 WESTBORO RD  
NORTH GRAFTON, Massachusetts 01536-1828  
508-839-5395  
Account #80735

CARDIOPET proBNP - CANINE

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

Comments:

1

# B6

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

**Report Details - EON-390200**

ICSR:	2068093
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:	2019-06-11 14:25:21 EDT
Initial Report Date:	11/10/2018
Parent ICSR:	2058697
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	DCM and CHF diagnosed 10/31/18. On BEG diet. Normal taurine levels
	Date Problem Started:	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 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
Owner Information:	Owner	Yes	

	<b>Information provided:</b>							
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6
<b>Name:</b>	B6							
<b>Phone:</b>	B6							
<b>Email:</b>	B6							
	<b>Address:</b>	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States				
<b>B6</b>								
United States								
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine						
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>Lisa Freeman</td> </tr> <tr> <td><b>Phone:</b></td> <td>(508) 887-4523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	<b>Name:</b>	Lisa Freeman	<b>Phone:</b>	(508) 887-4523	<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Name:</b>	Lisa Freeman						
	<b>Phone:</b>	(508) 887-4523						
<b>Email:</b>	lisa.freeman@tufts.edu							
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States							
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman						
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States						
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Phone:</b></td> <td>5088874523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	<b>Phone:</b>	5088874523	<b>Email:</b>	lisa.freeman@tufts.edu		
	<b>Phone:</b>	5088874523						
	<b>Email:</b>	lisa.freeman@tufts.edu						
<b>Permission To Contact Sender:</b>	Yes							
<b>Preferred Method Of Contact:</b>	Email							
<b>Additional Documents:</b>	<b>Attachment:</b>	Follow-up med records pt 1.pdf						
	<b>Description:</b>	Med records						
	<b>Type:</b>	Medical Records						
	<b>Attachment:</b>	Follow-up med records pt 3.pdf						
	<b>Description:</b>	Med records						
	<b>Type:</b>	Medical Records						
	<b>Attachment:</b>	Follow-up med records pt 2.pdf						
	<b>Description:</b>	Med records						
	<b>Type:</b>	Medical Records						

**Report Details - EON-383914**

ICSR: 2065085  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2019-04-01 17:42:39 EDT

**Reported Problem:**  
**Problem Description:** 3/15/2019 - Acute onset of difficulty breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF  
**Date Problem Started:** 03/15/2019  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** ACANA - Heritage Red Meat Formula Dog Food (Grain-free)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:**  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:**  
**Type Of Species:** Dog  
**Type Of Breed:** Shepherd Dog - German  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 25.9 Kilogram  
**Age:** B6 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 2  
**Number of Animals Reacted:** 1  
**Owner Information:**  
**Owner Information provided:** Yes  
**Contact:** Name: B6  
 Phone: 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 Road  
 North Grafton

		Massachusetts 01536 United States
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Permission to Release Records to FDA:</b>	Yes

<b>Sender Information:</b>	<b>Name:</b>	
	<b>Address:</b>	<b>B6</b> United States
	<b>Contact:</b>	<b>Phone:</b>
		<b>Email:</b>
		<b>B6</b>
	<b>Permission To Contact Sender:</b>	Yes
	<b>Preferred Method Of Contact:</b>	Email
<b>Reported to Other Parties:</b>	None	

<b>Additional Documents:</b>	<b>Attachment:</b>	Medical record 4-1-2019.pdf
	<b>Description:</b>	Medical records
	<b>Type:</b>	Medical Records

**Report Details - EON-384833**

ICSR:	2065712
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-04-11 16:39:13 EDT
Initial Report Date:	04/01/2019
Parent ICSR:	2065085
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	3/15/2019 - Acute onset of difficulty breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF. Patient suddenly collapsed, within seconds of collapse patient died. <b>B6</b>
	Date Problem Started:	03/15/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Other
	Date of Death:	<b>B6</b>

Product Information:	Product Name:	ACANA - Heritage Red Meat Formula Dog Food (Grain-free)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	
	Type Of Species:	Dog
	Type Of Breed:	Shepherd Dog - German
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	25.9 Kilogram
	Age:	<b>B6</b> 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: <b>B6</b>	
	Phone: <b>B6</b>	
Address:	<b>B6</b> United States	

<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine	
	<b>Contact:</b>	<b>Name:</b>	Lisa Freeman
		<b>Phone:</b>	(508) 887-4523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States	
<b>Type of Veterinarian:</b>	Referred veterinarian		
<b>Permission to Release Records to FDA:</b>	Yes		

<b>Sender Information:</b>	<b>Name:</b>			
	<b>Address:</b>	<b>B6</b>		
		United States		
	<b>Contact:</b>	<b>Phone:</b>		
		<b>Email:</b>	<b>B6</b>	
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
<b>Reported to Other Parties:</b>	None			

<b>Additional Documents:</b>	<b>Attachment:</b>	Troponin 4-4-19.pdf	
	<b>Description:</b>	Lab results	
	<b>Type:</b>	Laboratory Report	
	<b>Attachment:</b>	Diet hx 4-4-19 and owners patient log.pdf	
	<b>Description:</b>	Patient notes	
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	Chem 4-4-19.pdf	
	<b>Description:</b>	Lab results	
	<b>Type:</b>	Laboratory Report	



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

Dr. Freeman  
 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:  
 Owner Name: **B6**  
 Species: Canine  
 Date Received: Apr 04, 2019

Clinical Pathology Tracking Number: 441842

GI Lab Accession: **B6**

Test	Result	Control Range	Assay Date
Ultra-Sensitive Troponin I Fasting	<b>B6</b> ng/mL	≤0.06	04/05/19

**B6**

Comments:

**Important  
Notices:**

**Internal Medicine Conference**

**Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see <http://texasimconference.tamu.edu>**

**Ongoing studies**

**Cobalamin Supplementation Study-** Dogs and cats with cobalamin deficiency with normal PLI, and either normal or low (consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at [chchang@cvm.tamu.edu](mailto:chchang@cvm.tamu.edu) for further information.

**Chronic Pancreatitis with Uncontrolled Diabetes Mellitus-** Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial (medication provided at no cost). Contact Dr. Sue Yee Lim at [slim@cvm.tamu.edu](mailto:slim@cvm.tamu.edu) or Dr. Sina Marsilio at [smarsilio@cvm.tamu.edu](mailto:smarsilio@cvm.tamu.edu)

**Dogs with Primary Hyperlipidemia-** Prescription diet naïve dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu) for more information.

**Dogs with Chronic Pancreatitis-** Dogs with chronic pancreatitis (cPLi >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu)

**Chronic enteropathies in dogs-** Please fill out this brief form <http://tinyurl.com/ibd-enroll> to see if your patient qualifies.

**Feline Chronic Pancreatitis-** Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at [pyamkate@cvm.tamu.edu](mailto:pyamkate@cvm.tamu.edu).

**We can not accept packages that are marked "Bill Receiver"**

**Use our preprinted shipping labels to save on shipping. Call 979-862-2861 for assistance. The GI Lab is not here to accept packages on the weekend. Samples may be compromised if you ship for arrival on Saturday or Sunday or if shipped via US Mail.**

---

**GI Lab Contact Information**

Phone: (979) 862-2861

Fax: (979) 862-2864

Email: [gilab@cvm.tamu.edu](mailto:gilab@cvm.tamu.edu)

[vetmed.tamu.edu/gilab](mailto:vetmed.tamu.edu/gilab)

Report Details - EON-385697		
ICSR:	2066104	
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:	2019-04-22 13:04:20 EDT	
Reported Problem:	<b>Problem Description:</b> Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd: <u>Be</u> and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF	
	<b>Date Problem Started:</b> 03/17/2019	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
	<b>Product Name:</b> Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b>	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Retriever - Golden	
	<b>Gender:</b> Male	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 38 Kilogram	
	<b>Age:</b> 12 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 1	
	<b>Number of Animals Reacted:</b> 1	
	<b>Owner Information:</b> <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center;"><b>Owner</b></td> <td>Yes</td> </tr> </table>	<b>Owner</b>
<b>Owner</b>	Yes	

	<b>Information provided:</b>							
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>		<b>Email:</b>	B6
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B6								
United States								
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	<b>Phone:</b>	B6						
	<b>Email:</b>	B6						
	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States						
<b>Practice Name:</b>	Tufts University							
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<b>Email:</b>	lisa.freeman@tufts.edu							
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States							
	<b>Permission to Release Records to FDA:</b>	Yes						
<b>Sender Information:</b>	<b>Name:</b>	B6						
	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States						
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Phone:</b>	B6	<b>Email:</b>	B6		
	<b>Phone:</b>	B6						
	<b>Email:</b>	B6						
	<b>Permission To Contact Sender:</b>	Yes						
<b>Preferred Method Of Contact:</b>	Email							
<b>Reported to Other Parties:</b>	None							
<b>Additional Documents:</b>	<b>Attachment:</b>	Tufts Medical record.pdf						
	<b>Description:</b>	Medical records						
	<b>Type:</b>	Medical Records						

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**From:** Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  
**To:** Rotstein, David; Cleary, Michael \*; HQ Pet Food Report Notification; [B6]  
**Sent:** 6/11/2019 6:20:55 PM  
**Subject:** Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food; [B6] - EON-390198  
**Attachments:** 2068091-report.pdf; 2068091-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390198] has been created in the EON System.

A "PDF" report by name "2068091-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068091-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390198

**ICSR #:** 2068091

**EON Title:** Related PFR Event created for Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food Natural Chicken & Brown Rice; 2068091

<b>AE Date</b>	03/17/2019	<b>Number Fed/Exposed</b>	1
<b>Best By Date</b>		<b>Number Reacted</b>	1
<b>Animal Species</b>	Dog	<b>Outcome to Date</b>	Better/Improved/Recovering
<b>Breed</b>	Retriever - Golden		
<b>Age</b>	12 Years		
<b>District Involved</b>	PFR-New England DO		

**Product information**

**Individual Case Safety Report Number:** 2068091

**Product Group:** Pet Food

**Product Name:** Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice

**Description:** Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O

suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd [B6] and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF Normal plasma and whole blood taurine levels

**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
Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice		
Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food		

This report is linked to:

**Initial EON Event Key:** EON-385697

**Initial ICSR:** 2066104

**Sender information**

[B6]

USA

**Owner information**

[B6]

USA

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

[B6]

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

[B6]

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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](mailto:FDAREportableFoods@fda.hhs.gov) immediately.

**Report Details - EON-390198**

<b>ICSR:</b>	2068091
<b>Type Of Submission:</b>	Followup
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-06-11 14:13:53 EDT
<b>Initial Report Date:</b>	04/22/2019
<b>Parent ICSR:</b>	2066104
<b>Follow-up Report to FDA Request:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd [B6] and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF Normal plasma and whole blood taurine levels
	<b>Date Problem Started:</b>	03/17/2019
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
	<b>Product Name:</b>	Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

<b>Animal Information:</b>	<b>Name:</b>	
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Retriever - Golden
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	38 Kilogram
	<b>Age:</b>	12 Years
	<b>Assessment of Prior Health:</b>	Excellent

	<b>Number of Animals Given the Product:</b>	1																										
	<b>Number of Animals Reacted:</b>	1																										
	<b>Owner Information:</b>	<table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>Owner Information provided:</b>	Yes	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>		<b>Email:</b>	B6	<b>Address:</b>	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States												
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	<b>Healthcare Professional Information:</b>	<table border="1"> <tr> <td><b>Practice Name:</b></td> <td>Tufts Cummings School of Veterinary Medicine</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td>200 Westboro Road North Grafton Massachusetts 01536 United States</td> </tr> <tr> <td><b>Practice Name:</b></td> <td>Tufts University</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>Lisa Freeman</td> </tr> <tr> <td><b>Phone:</b></td> <td>508-887-4523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td>200 Westboro Rd North Grafton Massachusetts 01536 United States</td> </tr> <tr> <td><b>Permission to Release Records to FDA:</b></td> <td>Yes</td> </tr> </table>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States	<b>Practice Name:</b>	Tufts University	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>Lisa Freeman</td> </tr> <tr> <td><b>Phone:</b></td> <td>508-887-4523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	<b>Name:</b>	Lisa Freeman	<b>Phone:</b>	508-887-4523	<b>Email:</b>	lisa.freeman@tufts.edu	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	<b>Permission to Release Records to FDA:</b>	Yes
<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine																											
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<b>Permission to Release Records to FDA:</b>	Yes																											
<b>Sender Information:</b>	<b>Name:</b>	B6																										
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<b>Email:</b>	B6																											
	<b>Permission To Contact Sender:</b>	Yes																										
	<b>Preferred Method Of Contact:</b>	Email																										
	<b>Reported to Other Parties:</b>	None																										
<b>Additional Documents:</b>	<b>Attachment:</b>	At home ECG readings.pdf																										
	<b>Description:</b>	ECGs																										
	<b>Type:</b>	Medical Records																										

<b>Attachment:</b>	Recheck ECG 4-30-2019.pdf
<b>Description:</b>	Hospital ECG
<b>Type:</b>	Medical Records
<b>Attachment:</b>	Follow-up med records pt 1.pdf
<b>Description:</b>	Med records
<b>Type:</b>	Medical Records
<b>Attachment:</b>	Follow-up med records pt 2.pdf
<b>Description:</b>	Med records
<b>Type:</b>	Medical Records

Report Details - EON-386301	
ICSR:	2066404
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-04-29 16:02:28 EDT
Reported Problem:	<b>Problem Description:</b> Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on <b>B6</b> <b>B6</b> Taurine levels prior to supplementation was WNL.
	<b>Date Problem Started:</b> 03/01/2019
	<b>Concurrent Medical Problem:</b> No
	<b>Outcome to Date:</b> Stable
Product Information:	<b>Product Name:</b> NutriSource Adult Chicken and Rice formula
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>UPC:</b> 9B15P 18581
	<b>Package Type:</b> BAG
	<b>Package Size:</b> 30 Pound
	<b>Possess Opened Product:</b> Yes
	<b>Product Use Information:</b>
	<b>Manufacturer /Distributor Information:</b>
	<b>Purchase Location Information:</b>
	<b>Product Name:</b> PureVita Venison & Red Lentils Grain-Free Dry Dog Food
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Package Type:</b> BAG
	<b>Product Use Information:</b>
	<b>Manufacturer /Distributor Information:</b>
<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> <b>B6</b>
	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> American Pit Bull Terrier
	<b>Gender:</b> Male
	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 32 Kilogram
	<b>Age:</b> <b>B6</b> Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 1
	<b>Number of Animals Reacted:</b> 1
<b>Owner Information:</b> <b>Owner</b> Yes	

	<b>Information provided:</b>							
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td></td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>		<b>Email:</b>	B6
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<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine						
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	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States						
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<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>Lisa Freeman</td> </tr> <tr> <td><b>Phone:</b></td> <td>(508) 887-4523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	<b>Name:</b>	Lisa Freeman	<b>Phone:</b>	(508) 887-4523	<b>Email:</b>	lisa.freeman@tufts.edu	
<b>Name:</b>	Lisa Freeman							
<b>Phone:</b>	(508) 887-4523							
<b>Email:</b>	lisa.freeman@tufts.edu							
<b>Type of Veterinarian:</b>	Referred veterinarian							
<b>Permission to Release Records to FDA:</b>	Yes							
<b>Sender Information:</b>	<b>Name:</b>	B6						
	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States						
	<b>Contact:</b>	<table border="1"> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Phone:</b>	B6	<b>Email:</b>	B6		
<b>Phone:</b>	B6							
<b>Email:</b>	B6							
	<b>Permission To Contact Sender:</b>	Yes						
	<b>Preferred Method Of Contact:</b>	Email						
	<b>Reported to Other Parties:</b>	None						
<b>Additional Documents:</b>	<b>Attachment:</b>	Med records pt 2.pdf						
	<b>Description:</b>	Medical Records						
	<b>Type:</b>	Medical Records						
	<b>Attachment:</b>	Med records pt 1 4-29-2019.pdf						
	<b>Description:</b>	Medical Records						
	<b>Type:</b>	Medical Records						

**Report Details - EON-390031**

<b>ICSR:</b>	2067992
<b>Type Of Submission:</b>	Followup
<b>Report Version:</b>	FPSR.FDA.PETF.V.V1
<b>Type Of Report:</b>	Adverse Event (a symptom, reaction or disease associated with the product)
<b>Reporting Type:</b>	Voluntary
<b>Report Submission Date:</b>	2019-06-10 10:48:40 EDT
<b>Initial Report Date:</b>	04/29/2019
<b>Parent ICSR:</b>	2066404
<b>Follow-up Report to FDA Request:</b>	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on [B6] Taurine levels prior to supplementation was WNL.
	<b>Date Problem Started:</b>	03/01/2019
	<b>Concurrent Medical Problem:</b>	No
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	NutriSource Adult Chicken and Rice formula
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>UPC:</b>	9B15P 18581
	<b>Package Type:</b>	BAG
	<b>Package Size:</b>	30 Pound
	<b>Possess Opened Product:</b>	Yes
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
	<b>Product Name:</b>	PureVita Venison & Red Lentils Grain-Free Dry Dog Food
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG

<b>Animal Information:</b>	<b>Name:</b>	[B6]
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	American Pit Bull Terrier
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	32 Kilogram
	<b>Age:</b>	[B6] Years
<b>Assessment of Prior Health:</b>	Excellent	

	<b>Number of Animals Given the Product:</b>	1																										
	<b>Number of Animals Reacted:</b>	1																										
	<b>Owner Information:</b>	<table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	<b>Owner Information provided:</b>	Yes	<b>Contact:</b>	<table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>	<b>Name:</b>	B6	<b>Phone:</b>	B6	<b>Email:</b>	B6	<b>Address:</b>	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States												
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	<b>Preferred Method Of Contact:</b>	Email																										
	<b>Reported to Other Parties:</b>	None																										
<b>Additional Documents:</b>	<b>Attachment:</b>	Diet Hx 5-3-2019.pdf																										
	<b>Description:</b>	Med records																										
	<b>Type:</b>	Medical Records																										
	<b>Attachment:</b>	Recheck chem 21 5-3-2019.pdf																										
	<b>Description:</b>	Lab work																										
	<b>Type:</b>	Laboratory Report																										

<b>Attachment:</b>	<b>B6</b>	roponin 5-30-2019.pdf
<b>Description:</b>	Lab work	
<b>Type:</b>	Laboratory Report	



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: **B6**

GI Lab Assigned Clinic ID: 23523

**B6**

Tufts Cummings School of Vet Med - Cardiology/Nutrition  
 200 Westboro Road  
 North Grafton, MA 01536  
 USA

Phone: 508 887 4696

Fax:

Animal Name:

**B6**

Owner Name:

Species:

Canine

Date Received:

May 30, 2019

Tufts Cummings School of Vet Med -  
 Cardiology/Nutrition Tracking Number:  
 444116

GI Lab Accession: **B6**

<u>Test</u>	<u>Result</u>	<u>Reference Interval</u>	<u>Assay Date</u>
Ultra-Sensitive Troponin I Fasting	<b>B6</b> ng/mL	≤0.06	05/31/19

**B6**

Comments:

**GI Lab Contact Information**

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

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

Report Details - EON-388960		
ICSR:	2067506	
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:	2019-05-28 15:31:05 EDT	
Reported Problem:	<b>Problem Description:</b> Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermittent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.	
	<b>Date Problem Started:</b> 05/17/2019	
	<b>Concurrent Medical Problem:</b> Yes	
	<b>Pre Existing Conditions:</b> Previously diagnosed (Jan 2019) with with a 1-2/6 heart murmur - asymptomatic, rDVM rec rechecking in 1 year.	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b>	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Spaniel - Cocker American	
	<b>Gender:</b> Female	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 14 Kilogram	
	<b>Age:</b> B6 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 1	
	<b>Number of Animals Reacted:</b> 1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b> Name: B6 Phone: B6
		<b>Address:</b> B6 United States
	<b>Healthcare Professional</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine

	<b>Information:</b>	<b>Contact:</b>	<b>Name:</b>	B6	
			<b>Phone:</b>		
			<b>Email:</b>	B6	
		<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States		
		<b>Practice Name:</b>	Tufts University Cummings School of Veterinary Medicine		
		<b>Contact:</b>	<b>Name:</b>	Lisa Freeman	
			<b>Phone:</b>	508 887 4696	
	<b>Type of Veterinarian:</b>	Referred veterinarian			
	<b>Permission to Release Records to FDA:</b>	Yes			
<b>Sender Information:</b>	<b>Name:</b>	B6			
	<b>Address:</b>	200 Westboro Road North Grafton Massachusetts 01536 United States			
	<b>Contact:</b>	<b>Phone:</b>	B6		
		<b>Email:</b>	B6		
	<b>Permission To Contact Sender:</b>	Yes			
	<b>Preferred Method Of Contact:</b>	Email			
<b>Reported to Other Parties:</b>	None				
<b>Additional Documents:</b>	<b>Attachment:</b>	Med Rec pt 1.pdf			
	<b>Description:</b>	Medical Records			
	<b>Type:</b>	Medical Records			
	<b>Attachment:</b>	Med Rec pt 2.pdf			
	<b>Description:</b>	Medical Records			
	<b>Type:</b>	Medical Records			

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**From:** Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  
**To:** Rotstein, David; Cleary, Michael \*; HQ Pet Food Report Notification;  
B6  
**Sent:** 6/10/2019 8:20:57 PM  
**Subject:** Fromm Game Bird Recipe Dog - Four-Star - Dry -Grain-Free formula B6  
B6 EON-390092  
**Attachments:** 2068038-report.pdf; 2068038-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390092] has been created in the EON System.

A "PDF" report by name "2068038-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068038-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390092

**ICSR #:** 2068038

**EON Title:** Related PFR Event created for Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula; 2068038

<b>AE Date</b>	04/16/2019	<b>Number Fed/Exposed</b>	1
<b>Best By Date</b>		<b>Number Reacted</b>	1
<b>Animal Species</b>	Dog	<b>Outcome to Date</b>	Better/Improved/Recovering
<b>Breed</b>	Hound (unspecified)		
<b>Age</b>	B6 Years		
<b>District Involved</b>	PFR-New England DO		

**Product information**

**Individual Case Safety Report Number:** 2068038

**Product Group:** Pet Food

**Product Name:** Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula

**Description:** Patient presented to rDVM for evaluation of abdominal distension x 5 weeks and increase in respiratory rate and effort. FAST scan revealed moderate ascites. Patient was referred to Tufts for further evaluation. Findings consistent with advanced DMVD with suspect L-CHF and poor contractile function.

Considering LA enlargement and severity of MR and AI, we would expect a better systolic function.

**B6**

10mg BID is recommended. Mild respiratory effort and occasional b-lines vote in favor to L-CHF.

There is enough cardiac changes to justify L and R CHF. Since patient is on a BEG diet, it is unclear whether diet is playing a role on decreased contractile function. Recommend transition to a grain-based, low sodium diet and consider Taurine supplementation. Abdominocentesis was performed (5 liters of serous sanguineous fluid) and analysis is recommended. Recommend hospitalization, patient on telemetry monitoring and respiratory watch. Fluid check in the morning and kidney values daily while in the hospital. Since patient is on a BEG diet, recommend transition to a grain-based, low sodium diet.

**Submission Type:** Followup

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

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

**Number of Animals Treated With Product:** 1

**Number of Animals Reacted With Product:** 1

Product Name	Lot Number or ID	Best By Date
Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula		

This report is linked to:

**Initial EON Event Key:** EON-388971

**Initial ICSR:** 2067510

**Sender information**

**B6**

**Owner information**

**B6**

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

<https://eon.fda.gov/eon/browse/EON-390092>

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

<https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issuelid=407364&parentIssueTypeId=12>

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**Report Details - EON-390092**

ICSR:	2068038
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 16:15:32 EDT
Initial Report Date:	05/28/2019
Parent ICSR:	2067510
Follow-up Report to FDA Request:	Yes

Reported Problem:	<b>Problem Description:</b>	Patient presented to rDVM for evaluation of abdominal distension x 5 weeks and increase in respiratory rate and effort. FAST scan revealed moderate ascites. Patient was referred to Tufts for further evaluation. Findings consistent with advanced DMVD with suspect L-CHF and poor contractile function. Considering LA enlargement and severity of MR and AI, we would expect a better systolic function. <b>B6</b> is recommended. Mild respiratory effort and occasional b-lines were in favor of L-CHF. There is enough cardiac changes to justify L and R CHF. Since patient is on a BEG diet, it is unclear whether diet is playing a role on decreased contractile function. Recommend transition to a grain-based, low sodium diet and consider Taurine supplementation. Abdominocentesis was performed (5 liters of serous sanguineous fluid) and analysis is recommended. Recommend hospitalization, patient on telemetry monitoring and respiratory watch. Fluid check in the morning and kidney values daily while in the hospital. Since patient is on a BEG diet, recommend transition to a grain-based, low sodium diet.
	<b>Date Problem Started:</b>	04/16/2019
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	<b>B6</b>
	<b>Outcome to Date:</b>	Better/Improved/Recovering

Product Information:	<b>Product Name:</b>	Fromm Game Bird Recipe Dog Four-Star Dry Grain-Free formula
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Product Use Information:</b>	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

Animal Information:	<b>Name:</b>	
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Hound (unspecified)
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	38.9 Kilogram
	<b>Age:</b>	<b>B6</b> Years
	<b>Assessment of Prior Health:</b>	Good
	<b>Number of Animals</b>	1

	<b>Given the Product:</b>																								
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<b>Attachment:</b>	Follow-up medical records.pdf
<b>Description:</b>	Medical Records
<b>Type:</b>	Medical Records



Gastrointestinal Laboratory  
 Dr. J.M. Steiner  
 Department of Small Animal Clinical Sciences  
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 4474 TAMU  
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Website User ID: lisa.freeman@tufts.edu OR **B6**

GI Lab Assigned Clinic ID: 23523

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 Tufts Cummings School of Vet Med - Cardiology/Nutrition  
 200 Westboro Road  
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 USA

Phone: 508 887 4696  
 Fax:  
 Animal Name: **B6**  
 Owner Name:  
 Species: Canine  
 Date Received: May 30, 2019

Tufts Cummings School of Vet Med -  
 Cardiology/Nutrition Tracking Number:  
 309861

GI Lab Accession: **B6**

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	<b>B6</b>	≤0.06	05/31/19

**B6**

Comments:

GI Lab Contact Information

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

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

**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** Palmer, Lee Anne; Rotstein, David; Palmer, Lee Anne; Queen, Jackie L  
**CC:** Ceric, Olgica; Nemser, Sarah; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'  
**Sent:** 5/9/2018 10:53:13 AM  
**Subject:** RE: Zignature Kangaroo Formula: 800.261- EON-351031- [B6] vet  
**Attachments:** EON-351031- [B6] MRx.pdf

This was the product with low Taurine we recently tested (per feline AAFCO minimum Tau).

Golden Retriever with low blood taurine and a persistent history of arytenoid dysfunction, possible [B6] responsive infectious [B6] Since 9 months old

MRx summary:

**Presenting complaint 2/23/2018:** CHF possible, consult; tachycardia, last 3 days dyspneic, no cough, poor appetite for 2 days, usually ravenous, decreased energy level, on [B6] over a year, tried [B6] but discontinued because it wasn't helping; long history of a panting and swallowing disorder à diagnosed w/ DCM & L-CHF, tentative pulmonary edema à start [B6] à 2/27 breathing better, eating ok, increased [B6] for gagging à 3/1 Tau low, dog still on Zignature Kangaroo diet à vet said legumes in the diet likely prevent Met & Cys absorption à switched to Royal Canin Kangaroo & Oat; the dog was on Zignature Kangaroo last 2-3 years, eats milkbones and baked dog treats from a bakery; before the Zignature, he ate Acana Ranch Lamb, Natural Balance Bison & SP, Natural Balance Fish & SP, Zignature Trout & Salmon à no supplements were taken before the DCM diagnosis à by 3/13 dog was eating Royal Canin Kangaroo à 3/22 restless at night but [B6] try [B6]

**PE 2/23:** [B6] gallop, panting; at rest/lying down still tachypneic

**Labs:** 2/23 **Whole Blood Tau:** [B6]

**2/23 Echocardiogram:** dilated LV w/ poor systolic function, LA enlarged, mod MR & TR, dec aortic and pulmonic flow

**Prior MHx:** [B6]

**B6**

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



**From:** Jones, Jennifer L  
**Sent:** Friday, April 13, 2018 6:39 AM  
**To:** Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>  
**Cc:** Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>  
**Subject:** RE: Zignature Kangaroo Formula: [B6] - EON-351031

Thanks, Lee Anne. No, I wasn't expecting it, but I can start with MRx!

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



**From:** Palmer, Lee Anne  
**Sent:** Thursday, April 12, 2018 1:39 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Cc:** Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>  
**Subject:** FW: Zignature Kangaroo Formula: [REDACTED] - EON-351031

Hi Jen – were you expecting this one? Thx - LA

**From:** PFR Event [mailto:pfpreventcreation@fda.hhs.gov]  
**Sent:** Thursday, April 12, 2018 1:36 PM  
**To:** Cleary, Michael \* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [REDACTED]  
**Subject:** Zignature Kangaroo Formula: [REDACTED] - EON-351031

A PFR Report has been received and PFR Event [EON-351031] has been created in the EON System.

A "PDF" report by name "2045676-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-351031

**ICSR #:** 2045676

**EON Title:** PFR Event created for Zignature Kangaroo Formula; 2045676

<b>AE Date</b>	02/22/2018	<b>Number Fed/Exposed</b>	1
<b>Best By Date</b>		<b>Number Reacted</b>	1
<b>Animal Species</b>	Dog	<b>Outcome to Date</b>	Stable
<b>Breed</b>	Retriever - Golden		
<b>Age</b>	6 Years		
<b>District Involved</b>	PFR [REDACTED] DO		

**Product information**

**Individual Case Safety Report Number:** 2045676

**Product Group:** Pet Food

**Product Name:** Zignature Kangaroo Formula

**Description:** Feb 23, 2018 Patient presented to the cardiology service at [REDACTED]

Falls for tachypnea. He was diagnosed with dilated cardiomyopathy and left side congestive heart failure. Whole blood taurine level was [REDACTED] At the time, patient consuming Zignature Kangaroo Formula and was advised to change.

**Submission Type:** Initial

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

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

**Number of Animals Treated With Product: 1**

**Number of Animals Reacted With Product: 1**

<b>Product Name</b>	<b>Lot Number or ID</b>	<b>Best By Date</b>
Zignature Kangaroo Formula		

**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**

**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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## Patient History Report

<b>Client:</b> <b>Phone:</b> <b>Address:</b>	B6	<b>Patient:</b> B6 <b>Species:</b> Canine <b>Age:</b> B6 <b>Color:</b> Blonde	<b>Breed:</b> Retriever, Golden <b>Sex:</b> Neutered Male
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Date	Type	Staff	History
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4/12/2018	C	B6	MEDICAL COMMENTS ***ADDENDUM 4/20/2018 4/12/2018 13:26 FDA Safety Reporting Portal - Individual Case Safety Report Number (ICSR) 2045676 ADDENDUM on 4/20/2018 at 08:34:23 from B6 B6 permission signed and returned to CS
3/24/2018	P		<div style="border: 1px dashed black; padding: 10px; font-size: 2em; font-weight: bold; margin: 0 auto;">B6</div> <div style="border: 1px dashed black; padding: 2px 5px; font-size: 0.8em; font-weight: bold; margin: 5px auto;">B6</div>
3/24/2018	C		PHARMACY NOTE TTO. Meds have been refilled
3/24/2018	P		<div style="border: 1px dashed black; padding: 10px; font-size: 2em; font-weight: bold; margin: 0 auto;">B6</div>
3/22/2018	C		COMMUNICATIONS WITH CLIENT 3/22/2018 13:03 dog is restless at night, making breathing sound, but sRR is consistently at 22 brpm, so i do not think do has pulmonary edema, will try B6 recheck in end of april  <div style="border: 1px dashed black; padding: 20px; font-size: 4em; font-weight: bold; text-align: center; margin: 10px auto;">B6</div>

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6

## Patient History Report

Client:  
Phone:  
Address:

B6

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
3/13/2018	C	B6	<p>COMMUNICATIONS WITH CLIENT</p> <p>3/13/2018 10:36</p> <p>SWO - Owner consented to reporting <b>B6</b> case to the FDA. He has been on the Zignature Kangaroo for the past 2-3 years. Treats include Milkbones and baked dog treats from pet bakery. Prior to the Zignature Kangaroo, he consumed the Acana Ranch Lamb, Natural Balance Sweet Potato and Bison, Natural Balance Sweet Potato and Fish, Zignature Trout &amp; Salmon. He was receiving no supplements prior to his DCM diagnosis. Owner will forward me a copy of her most recent Chewy.com receipt for the Zignature. She does not have the bag anymore. I will email her for additional information. She is now feeding the Royal Canin Kangaroo and Oats.</p>
3/1/2018	D		Taurine Deficiency Final
3/1/2018	C		<p>COMMUNICATIONS WITH DOCTOR</p> <p>3/1/2018 13:22</p> <p>i called vet, to let them know taurine is low, she is still on kangaroo diet from Zignature, rec to change diet. The legumes in diet are most likely preventing methionine and cystine absorption, should switch to Royal Canin kangaroo and oats, i originally lm and he called back. he said he would call owner</p>
3/1/2018	C		<p>COMMUNICATIONS WITH CLIENT</p> <p>3/1/2018 13:20</p> <p>i called client to let her know taurine is low, she is still on kangaroo diet from Zignature, rec she talk to her vet at last appt, and she did to day at a recheck, and told her to wait. The legumes in diet are most likely preventing methionine and cystine absorption, should switch to Royal Canin kangaroo and oats, I will call her vet.</p>
2/27/2018	C		<p>COMMUNICATIONS WITH CLIENT</p> <p>2/27/2018 11:03</p> <p>i called owner, dog is breathing better, eating fine, getting sRR 18-26, did have throat issues, does gagging, pred helped, increased pred again, continue as planned, waiting on taurine level. if normla will start <b>B6</b></p>
2/24/2018	L		Miscellaneous results from <b>B4, B6</b>

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

B6

## Patient History Report

Client: Phone: Address:	B6	Patient: B6 Species: Canine Age: B6 Color: Blonde	Breed: Retriever, Golden Sex: Neutered Male
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Date	Type	Staff	History
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(East) Requisition ID: B6      Posted      Final  
 Asc: B6      Profile: Taurine RE: 16759 Taurine B6  
 Normal Values (nmols/ml)

Level	Normal Range	Critical
Cat Plasma	60-120	Less than
40		
Whole Blood	300-600	Less than
200		
Dog Plasma	60-120	Less than
40		
Whole Blood	200-350	Less than
150		

TEST PERFORMED AT: B4, B6      LABORATORY

2/23/2018	C		PHARMACY NOTE <div style="border: 1px dashed black; padding: 5px; text-align: center; font-size: 1.5em; font-weight: bold;">                     B6                 </div>
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2/23/2018 D 2/23/2018 D 2/23/2018 D 2/23/2018 I	B6	Pulmonary Edema Tentative Taurine Deficiency Tentative Date Diagnosis made final: 03/01/18 Dilated Cardiomyopathy Tentative Cardiology Discharge Instructions B6 2/23/2018  A cardiologist has evaluated B6 and has diagnosed her with Dilated Cardiomyopathy (DCM). DCM means your pet has poor muscle contraction of the heart. This means the heart muscle does not pump as well as a normal dog. The heart has enlarged due to the poor muscle contraction. The change in the heart has caused fluid to form in the lungs, causing increased respiratory rate.  Please take a sleeping respiratory rate (sRR) at home. WHILE YOUR PET IS SLEEPING, count the number of times they breathe in over 15 seconds. Your pet should have 8 breathes or less over 15 seconds while sleeping. Do this once a day over the next 3 days, then 2 times a week thereafter. The free app software for iPhone and Google Play that can help with this is Cardalis
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B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

I have submitted blood for a taurine level. The result may not return for 2 weeks. In the mean time, please start Taurine at home, 2 gram two times a day with food. This can be purchased at any health food store. I will call in about 2 weeks with a taurine level.

### MEDICATIONS:

**B6**

Watch for the following clinical signs and call a veterinarian if you see any of these:  
Excessive panting or wheezing  
Restlessness, unable to get comfortable  
Decreased appetite  
Lethargy/weakness, less interactive or hiding  
Collapse or fainting  
Sudden rear leg or front leg lameness  
Open-mouth breathing

It has been a pleasure meeting you and caring for your **B6**. Thank you for entrusting us with her care. If you have any further questions or problems, don't hesitate to call.

2/23/2018 P

**B6**

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative med note, V: Vital signs

**B6**

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

2/23/2018 P

**B6**

**B6**

2/23/2018 C

CARDIAC EVALUTION - CLOSED 02/24/2018 - Cardiac Evaluation

Date of evaluation: Friday, February 23, 2018

CHIEF COMPLAINT: tachypnea

HISTORY: last 3 days has been working hard to breath. No coughing. Appetite has been poor last 2 days, usually ravenous. Energy level seems down. No cardiac medications **B6** for over year, Tried thyroid medication but stopped it, did not help. Has long history of panting and swallowing disorder.

PHYSICAL EXAM:

**B6**

**B6**

ECHOCARDIOGRAM 2/23/18:

**B6**

**B6**

COMMENTS: dilated LV with poor systolic function. Left atrial enlargement. Large EPSS. Moderate MR and TR. Reduce aortic and pulmonic flows. no pleural or pericardial effusion

DIAGNOSIS/PROBLEM LIST: dilated cardiomyopathy (DCM), left side congestive heart failure (LCHF)

SUMMARY: The dilated cardiomyopathy may be related to diet and taurine deficiency. There have been personal communications amongst cardiologist of a rash of cases of Golden Retrievers on grain free and/or kangaroo diets that have taurine deficiency cardiomyopathy. We pulled a whole blood level taurine today and started **B6** I also started **B6** as below. If taurine deficiency

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

**B6**

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Date: 4/20/2018 5:17 PM

## Patient History Report

<b>Client:</b>	<b>B6</b>	<b>Patient:</b>	B6	<b>Breed:</b>	Retriever, Golden
<b>Phone:</b>		<b>Species:</b>	Canine	<b>Sex:</b>	Neutered Male
<b>Address:</b>		<b>Age:</b>	B6	<b>Color:</b>	Blonde

Date	Type	Staff	History
------	------	-------	---------

cardiomyopathy, this could be reversible. It could take 2 months to see echo changes, but dog may feel better within a month. Recheck echocardiogram in 2 months. We should recheck a taurine level in 2 weeks. They will most likely do that with B6

**MEDICATIONS:**

B6

2/23/2018 V	B6	Feb 23, 2018 01:06 PM Staff: <span style="border: 1px solid black; padding: 2px;">B6</span>	Weight : 40.00 kilograms room 14
2/23/2018 CK		CHF poss, setup by rdvm Reason for Visit: Consult Date Patient Checked Out: 02/23/18 Practice TF	
2/23/2018 CB		Callback - Call Client Back (CB) --- Note from <span style="border: 1px solid black; padding: 2px;">B6</span> on 2/23/2018 at 15:51:32 --- Called Wedgewood Pharmacy, spoke to <span style="border: 1px solid black; padding: 2px;">B6</span> --- Note from <span style="border: 1px solid black; padding: 2px;">B6</span> on 2/23/2018 at 15:06:34	
		B6	
2/22/2018 TC		RECORDS FROM <span style="border: 1px solid black; padding: 2px;">B6</span> (see attachment) - TENTATIVE 2/22/2018 14:47 rDVM records attached. - Attachment(s)	
3/10/2017 C		COMMUNICATIONS WITH CLIENT 3/10/2017 10:26 <div style="border: 1px dashed black; padding: 10px; text-align: center; font-size: 2em; font-weight: bold; margin-top: 5px;">B6</div>	

3/8/2017 L		Endocrinology results from <span style="border: 1px solid black; padding: 2px;">B4, B6</span> (East) Requisition ID: 315958	Posted	Final
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B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date Type Staff History

Test	Result	Reference Range
TSH	<b>B6</b>	0 - 0.60
Ascn: <b>B6</b>	Profile: TSH	

3/7/2017 C **B6** RADIOLOGY REVIEW - CLOSED 03/08/2017

**B6**

This review was written by: **B6**

3/7/2017 V

Mar 7, 2017 04:21 PM Staff **B6**

Weight : 41.40 kilograms

3/7/2017 CK

**B6**

recheck for ESO  
Reason for Visit: Recheck  
Date Patient Checked Out: 03/07/17 Practice TF

3/7/2017 C

**B6**

IM PHYSICAL EXAM NEW  
3/7/2017 10:10

Chief Complaint: reevaluation of hard swallowing; upper airway noise

History: **B6** was originally evaluated in 2015 for hard swallowing, gagging. A laryngeal exam at that time revealed a nodule on the larynx which was biopsied as granulomatous. He has been on low dose prednisone since. Owner still notices hard swallowing and sometimes regurgitation. He also has upper airway noise when sleeping- breathes through nose and no nasal discharge. Occasional hoarse bark. No diarrhea, no pu/pd. He has gained weight. In 2015 a myasthenia titer was negative. Diet includes zignature kangaroo. unsure of current dose of pred 1 tab in morning and sometimes 1/2 tab at night unsure what strength

Previous Medical Problems:

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

**B6**

Page 7 of 30

Date: 4/20/2018 5:17 PM

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

Medications/Supplements:

Current Diet:

**B6**

Diagnostics:

Lab Work: see below

**B6**

Problems/Differential Diagnoses/Assessment:

**B6**

Treatment:

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

# Patient History Report

Client:  
Phone:  
Address:

B6

Patient: B6  
 Species: Canine  
 Age: B6  
 Color: Blonde

Breed: Retriever, Golden  
 Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

Plan/Recommendations:

3/7/2017 L

Hematology results from				Requisition
ID: 315958	Posted	Final		
Test	Result		Reference Range	
HCT	B6		36 - 60	
HGB			12.1 - 20.3	
MCHC			30 - 38	
WBC			4.0 - 15.5	
Bands			0 - 3	
RBC			4.8 - 9.3	
MCV			58 - 79	
MCH			19 - 28	
ABS BASO			0 - 150	
Platelet C			170 - 400	
Platelet E				
Neutrophil			60 - 77	
Lymphocyte			12 - 30	
Monocytes			3 - 10	
Eosinophil			2 - 10	
Basophils			0 - 1	
Absolute N			2060 - 10600	
Absolute L			690 - 4500	
Absolute M			0 - 840	
Absolute E			0 - 1200	

Ascn: B6 Profile: Complete Blood Count

Platelet count reflects the minimum number due to platelet clumping.

3/7/2017 L

Chemistry results from				Requisition
ID: 315958	Posted	Final		
Test	Result		Reference Range	
ALB	B6		2.7 - 4.4	
ALKP			5 - 131	
ALT			12 - 118	
AMYL			290 - 1125	
AST			15 - 66	
BUN/UREA			6 - 31	
Ca			8.9 - 11.4	
Chloride			102 - 120	
CHOL			92 - 324	
CK			59 - 895	
CREA			0.5 - 1.6	
GGT			1 - 12	

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B6

# Patient History Report

Client:  
Phone:  
Address:

B6

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

GLU	B6	70 - 138
Mg		1.5 - 2.5
PHOS		2.5 - 6.0
Potassium		3.6 - 5.5
Sodium		139 - 154
TBIL		0.1 - 0.3
TP		5.0 - 7.4
TRIG		29 - 291
GLOB		1.6 - 3.6
A/G Ratio		0.8 - 2.0
B/C Ratio		4 - 27
Na/K Ratio		27 - 38

3/7/2017 L

Endocrinology results from **B4, B6**  
**B4, B6** Requisition ID: 315958      Posted      Final  
 Test      Result      Reference Range  
 T4      **B6** µg/dL L      0.8 - 3.5  
 Asc: **B6**      Profile: Total T4

The Total T4 result is less than 1.0 mcg/dl. A Free-T4 by equilibrium dialysis may be helpful in supporting the diagnosis of hypothyroidism in patients demonstrating clinical signs compatible with hypothyroidism. Please contact Customer Service for this additional testing.

3/7/2017 L

Miscellaneous results from **B4, B6**  
**B4, B6** Requisition ID: 315958      Posted      Final  
 Asc: **B6**      Profile: Superchem

B6

3/6/2017 C

B6

COMMUNICATIONS WITH CLIENT  
 3/6/2017 12:55  
 sto confirmed appt w/ **B6** @ 330 on 3/7

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

## Patient History Report

Client: Phone: Address:	B6	Patient: <span style="border: 1px dashed black; padding: 2px;">B6</span> Species: Canine Age: <span style="border: 1px dashed black; padding: 2px;">B6</span> Color: Blonde	Breed: Retriever, Golden Sex: Neutered Male
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Date	Type	Staff	History
------	------	-------	---------

2/26/2017	C	B6	COMMUNICATIONS WITH CLIENT 2/26/2017 10:15 LMOM to confirm 3:30 pm ESO appt tomorrow
2/23/2017	TC		RECORDS FROM RDVM/LDVM (see attachment) - TENTATIVE 2/23/2017 20:36 Records from <span style="border: 1px dashed black; padding: 2px;">B6</span> Attachment(s)
2/23/2017	C		COMMUNICATIONS WITH DOCTOR 2/23/2017 17:18 <span style="border: 1px dashed black; padding: 2px;">B6</span> to request updated records from 5/3/15 forward be faxed
2/20/2016	C		RECEPTION ACTIONS NOTE faxed ref letters and labs to <span style="border: 1px dashed black; padding: 2px;">B6</span> per o's req
9/28/2015	C		OUTSIDE PHARMACY RX ***ADDENDUM 10/2/2015 - Closed Sep 30/2015  <div style="text-align: center; font-size: 4em; font-weight: bold; margin: 20px 0;">                         B6                     </div>

Is this medication a controlled substance?

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

B6

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

Additional Comments: faxed  
ADDENDUM on 10/1/2015 at 21:11:18 from **B6**

**B6**

9/28/2015 C

COMMUNICATIONS WITH CLIENT

9/28/2015 13:29

**B6** was good for 2 months, then small flair up, then went away again for a few months. last time, we discussed repeat abx treat may not be helpful. discussed that we can repeat abx treatment as it worked for such a long period of time. discussed dual treatment for **B6**

**B6**

**B6**

6/1/2015 C

**B6**

OUTSIDE PHARMACY RX - Closed Jun 04/2015

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

Page 12 of 30

Date: 4/20/2018 5:17 PM

## Patient History Report

<b>Client:</b> <b>Phone:</b> <b>Address:</b>	<div style="font-size: 2em; font-weight: bold;">B6</div>	<b>Patient:</b> <span style="border: 1px dashed black; padding: 2px;">B6</span> <b>Species:</b> Canine <b>Age:</b> <span style="border: 1px dashed black; padding: 2px;">B6</span> <b>Color:</b> Blonde	<b>Breed:</b> Retriever, Golden <b>Sex:</b> Neutered Male
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Date	Type	Staff	History
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6/1/2015	C		COMMUNICATIONS WITH CLIENT 6/1/2015 16:05 within the last 3 days stopped doing the neck movement/episodes that he was having. still sounds congested. when he barks there sounds like there is something in there. would continue <span style="border: 1px dashed black; padding: 2px;">B6</span> unless we are planning to rescope him. owner needs refill of <span style="border: 1px dashed black; padding: 2px;">B6</span> will touch base in 1-2 wks.
----------	---	--	--

5/17/2015	C	<div style="font-size: 1.5em; font-weight: bold;">B6</div>	COMMUNICATIONS WITH CLIENT 5/17/2015 10:26 swo and asked how <span style="border: 1px dashed black; padding: 2px;">B6</span> is doing, owner said she started ab's yesterday and so far he is doing well, owner will recheck in one week
-----------	---	--	--

5/15/2015	C		OUTSIDE PHARMACY RX - Closed May 17/2015 <div style="border: 1px dashed black; padding: 50px; text-align: center; font-size: 4em; font-weight: bold; margin-top: 20px;">B6</div>
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5/15/2015	C	<div style="font-size: 1.5em; font-weight: bold;">B6</div>	OUTSIDE PHARMACY RX <div style="border: 1px dashed black; padding: 2px; display: inline-block;">B6</div>
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# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

Prescribing doctor: **B6**

**B6**

5/15/2015 C

**B6**

COMMUNICATIONS WITH CLIENT \*\*\*ADDENDUM 5/15/2015  
5/15/2015 16:27

**B6**

5/12/2015 C

**B6**

COMMUNICATIONS WITH CLIENT  
5/12/2015 14:50

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date Type Staff History

**B6**

5/12/2015 C

**B6**

IM TREATMENT NEW  
5/12/2015

Internal Medicine Assessment: **B6**

**B6**

5/8/2015 L

Miscellaneous results from **B4, B6**  
**B4, B6** Requisition ID: 315958 Posted Final  
Ascn: **B6** Profile: Histopathology, Full Written  
Report  
RE: 7801 History:

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date Type Staff History

**B6**

Received: Multiple fragments - all processed.

RE: 601 Biopsy

DESCRIPTION/MICROSCOPIC FINDINGS/COMMENTS:

**B6**

MICROSCOPIC FINDINGS: **B6**

**B6**

PROGNOSIS: Good

COMMENT: **B6**

**B6**

PATHOLOGIST:

PATHOLOGIST: **B6**

email: **B6**

5/7/2015 I

**B6**

For your pet's safety, he/she was intubated for the anesthetic. You may notice

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

# Patient History Report

<b>Client:</b> <b>Phone:</b> <b>Address:</b>	<div style="border: 1px dashed black; padding: 10px; font-size: 2em; font-weight: bold;">B6</div>	<b>Patient:</b> <span style="border: 1px dashed black; padding: 2px;">B6</span> <b>Species:</b> Canine <b>Age:</b> <span style="border: 1px dashed black; padding: 2px;">B6</span> <b>Color:</b> Blonde	<b>Breed:</b> Retriever, Golden <b>Sex:</b> Neutered Male
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Date	Type	Staff	History
------	------	-------	---------

5/7/2015	I	<div style="border: 1px dashed black; padding: 5px; text-align: center; font-weight: bold;">B6</div>	<div style="border: 1px dashed black; padding: 50px; font-size: 4em; font-weight: bold;">B6</div>
5/7/2015	I		

5/7/2015	C		<p>COMMUNICATIONS WITH CLIENT                      5/7/2015 14:10                      called owner post procedure. discussed scope findings. and discussed possible causes for findings. no treatment recommended until results available. okay to d/c at 5 pm.</p>
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5/7/2015	C	<div style="border: 1px dashed black; padding: 5px; text-align: center; font-weight: bold;">B6</div>	<p>ENDOSCOPIC EVALUATION</p> <div style="border: 1px dashed black; padding: 50px; text-align: center; font-size: 4em; font-weight: bold;">B6</div>
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Lower Gastrointestinal:

Bronchoscopy:

Rhinocopy:

Cystoscopy:

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

Other:

Biopsies: **B6**

Culture/Sensitivity:

Visual Inspection: **B6**

Initial Recommendations: **B6**

5/7/2015 C

**B6**

IM TREATMENT NEW  
5/7/2015

Internal Medicine Assessment: **B6**

**B6**

Treatment: no treatment today

Recommended Follow-up Care: **B6**

5/7/2015 C

**B6**

IM PHYSICAL EXAM  
Chief Complaint:

History: **B6**

**B6**

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**B6**

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

**B6**

Significant Physical Exam Findings: Mentation: BAR

**B6**

Radiographic Findings: CHIEF COMPLAINT/HISTORY: 5/3/2015. Internal  
Medicine Assessment:

**B6**

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

## Patient History Report

Client:  
Phone:  
Address:

B6

Patient: B6  
 Species: Canine  
 Age: B6  
 Color: Blonde

Breed: Retriever, Golden  
 Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

B6

5/7/2015 L

Test	Result	Reference Range	Posted	Final
ALB =	B6	2.3 - 4.0		
ALKP =		23 - 212		
ALT =		10 - 125		
AMYL =		500 - 1500		
BUN/UREA =		7 - 27		
Ca =		7.9 - 12.0		
Chloride =		109 - 122		
CHOL =		110 - 320		
CREA =		0.5 - 1.8		
GGT <		0 - 11		
GLU =		74 - 143		
LIPA =		200 - 1800		
PHOS =		2.5 - 6.8		
Potassium =		3.5 - 5.8		
Sodium =		144 - 160		
TBIL =		0.0 - 0.9		
TP =		5.2 - 8.2		
GLOB =		2.5 - 4.5		
ALB/GLOB =				
BUN/CREA =				
Na/K =				
OSM calc =				

PCV=49% TS= 6.8g/dl (serum norm)

5/7/2015 V

B6

May 7, 2015 10:20 AM Staff: B6  
 Weight : 36.60 kilograms

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

B6

## Patient History Report

Client:  
Phone:  
Address:

B6

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

B6

5/7/2015 L

Hematology results from IDEXX VetLab In-clinic		
Laboratory Requisition ID: 197	Posted	Final
Test	Result	Reference Range
HCT =	B6	37.3 - 61.7
HGB =		13.1 - 20.5
MCHC =		32.0 - 37.9
WBC =		5.05 - 16.76
NEUT =		2.95 - 11.64
%NEUT =		
EOS =		0.06 - 1.23
%EOS =		
PLT *		148 - 484
Retics =		10.0 - 110.0
%Retics =		
RBC =		5.65 - 8.87
MCV =		61.6 - 73.5
MCH =		21.2 - 25.9
RDW =		13.6 - 21.7
MPV -		8.7 - 13.2
PDW -		9.1 - 19.4
PCT -		0.14 - 0.46
LYMPHS =		1.05 - 5.10
%LYMPHS =		
MONOS =	0.16 - 1.12	
%MONOS =		
BASO =	0.00 - 0.10	
%BASO =		

5/7/2015 C **B6** RADIOLOGY REPORT - FINAL 05/07/2015  
RADIOGRAPHIC REPORT

CHIEF COMPLAINT/HISTORY: 5/3/2015. **B6**

B6

FINDINGS: **B6**

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**B6**

## Patient History Report

<b>Client:</b> <b>Phone:</b> <b>Address:</b>	B6	<b>Patient:</b> <b>Species:</b> <b>Age:</b> <b>Color:</b>	<div style="border: 1px dashed black; padding: 2px; display: inline-block;">B6</div> Canine <div style="border: 1px dashed black; padding: 2px; display: inline-block;">B6</div> Blonde	<b>Breed:</b> Retriever, Golden <b>Sex:</b> Neutered Male
--	----	--	--	--

Date	Type	Staff	History
------	------	-------	---------

No significant abnormalities are present in the extra-thoracic soft tissues, skeletal structures, pleural and mediastinal spaces, pulmonary and cardiovascular structures, as well as in the visible cranial abdomen.

**SUMMARY/CONCLUSIONS:**

1. 

B6

5/7/2015	CK		B6
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5/6/2015	C	B6	COMMUNICATIONS WITH CLIENT 5/6/2015 11:48 <div style="border: 1px dashed black; padding: 10px; text-align: center; font-size: 2em; font-weight: bold;">B6</div>
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5/3/2015	C		IM TREATMENT NEW 5/3/2015 Internal Medicine Assessment <div style="border: 1px dashed black; padding: 2px; display: inline-block; font-weight: bold; font-size: 0.8em;">B6</div> <div style="border: 1px dashed black; padding: 20px; text-align: center; font-size: 4em; font-weight: bold; margin-top: 10px;">B6</div>
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Treatment: no treatment implemented

Recommended Follow-up Care: to return Thursday for further evaluation - chemistry, CBC thoracic radiographs, oral exam and endoscopy

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# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

5/3/2015 C

**B6**

IM PHYSICAL EXAM  
Chief Complaint:

History: **B6**

**B6**

Significant Physical Exam Findings: Mentation **B6**

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

## Patient History Report

Client: Phone: Address:	B6	Patient: <span style="border: 1px solid black; padding: 2px;">B6</span> Species: Canine Age: <span style="border: 1px solid black; padding: 2px;">B6</span> Color: Blonde	Breed: Retriever, Golden Sex: Neutered Male
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Date	Type	Staff	History
------	------	-------	---------

# B6

Lab Work: none performed today

Radiographic Findings: none performed today

5/3/2015	CK		Reason for Visit: Recheck Date Patient Checked Out: 05/03/15 Practice TF
11/21/2014	C	B6	COMMUNICATIONS WITH CLIENT 11/21/2014 13:54 <div style="border: 1px dashed black; text-align: center; padding: 10px; margin-top: 5px;"> <span style="font-size: 2em; font-weight: bold;">B6</span> </div>
11/14/2014	CK	B6	<div style="border: 1px dashed black; text-align: center; padding: 10px; margin-top: 5px;"> <span style="font-size: 2em; font-weight: bold;">B6</span> </div>
5/31/2014	C	B6	IM TREATMENT NEW 5/31/2014  Internal Medicine Assessment: <span style="border: 1px solid black; padding: 2px;">B6</span> <div style="border: 1px dashed black; text-align: center; padding: 10px; margin-top: 5px;"> <span style="font-size: 2em; font-weight: bold;">B6</span> </div> <div style="border: 1px dashed black; text-align: center; padding: 10px; margin-top: 10px;"> <span style="font-size: 3em; font-weight: bold;">B6</span> </div>

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

B6

## Patient History Report

<b>Client:</b> <b>Phone:</b> <b>Address:</b>	B6	<b>Patient:</b> B6 <b>Species:</b> Canine <b>Age:</b> B6 <b>Color:</b> Blonde	<b>Breed:</b> Retriever, Golden <b>Sex:</b> Neutered Male
--	----	--	--

Date	Type	Staff	History
------	------	-------	---------

			Treatment: no treatment implemented at this time
			Recommended Follow-up Care: B6
			B6
5/31/2014	C	B6	COMMUNICATIONS WITH CLIENT 5/31/2014 11:29 <div style="text-align: center; font-size: 1.5em; font-weight: bold; border: 1px dashed black; padding: 5px;">B6</div>

5/31/2014	L		Hematology results from B6 Requisition ID: 315958 Posted <span style="border: 1px dashed black; padding: 2px;">FINAL</span> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Test</th> <th style="width: 30%;">Result</th> <th style="width: 40%;">Reference Range</th> </tr> </thead> <tbody> <tr><td>HCT</td><td></td><td>36 - 60</td></tr> <tr><td>HGB</td><td></td><td>12.1 - 20.3</td></tr> <tr><td>MCHC</td><td></td><td>30 - 38</td></tr> <tr><td>WBC</td><td></td><td>4.0 - 15.5</td></tr> <tr><td>Bands</td><td></td><td>0 - 3</td></tr> <tr><td>RBC</td><td></td><td>4.8 - 9.3</td></tr> <tr><td>MCV</td><td></td><td>58 - 79</td></tr> <tr><td>MCH</td><td></td><td>19 - 28</td></tr> <tr><td>Platelet C</td><td></td><td>170 - 400</td></tr> <tr><td>Platelet E</td><td></td><td>ADEQUATE -</td></tr> <tr><td>Neutrophil</td><td></td><td>60 - 77</td></tr> <tr><td>Lymphocyte</td><td></td><td>12 - 30</td></tr> <tr><td>Monocytes</td><td></td><td>3 - 10</td></tr> <tr><td>Eosinophil</td><td></td><td>2 - 10</td></tr> <tr><td>Basophils</td><td></td><td>0 - 1</td></tr> <tr><td>Absolute N</td><td></td><td>2060 - 10600</td></tr> <tr><td>Absolute B</td><td></td><td>0 - 150</td></tr> <tr><td>Absolute L</td><td></td><td>690 - 4500</td></tr> <tr><td>Absolute M</td><td></td><td>0 - 840</td></tr> <tr><td>Absolute E</td><td></td><td>0 - 1200</td></tr> </tbody> </table> Ascn: B6 Profile: CBC  Platelet count reflects the minimum number due to platelet clumping.	Test	Result	Reference Range	HCT		36 - 60	HGB		12.1 - 20.3	MCHC		30 - 38	WBC		4.0 - 15.5	Bands		0 - 3	RBC		4.8 - 9.3	MCV		58 - 79	MCH		19 - 28	Platelet C		170 - 400	Platelet E		ADEQUATE -	Neutrophil		60 - 77	Lymphocyte		12 - 30	Monocytes		3 - 10	Eosinophil		2 - 10	Basophils		0 - 1	Absolute N		2060 - 10600	Absolute B		0 - 150	Absolute L		690 - 4500	Absolute M		0 - 840	Absolute E		0 - 1200
Test	Result	Reference Range																																																																
HCT		36 - 60																																																																
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Platelet C		170 - 400																																																																
Platelet E		ADEQUATE -																																																																
Neutrophil		60 - 77																																																																
Lymphocyte		12 - 30																																																																
Monocytes		3 - 10																																																																
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Absolute M		0 - 840																																																																
Absolute E		0 - 1200																																																																

5/31/2014	L		Chemistry results from B6 Requisition
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B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

# Patient History Report

Client:  
Phone:  
Address:

B6

Patient: B6  
 Species: Canine  
 Age: B6  
 Color: Blonde

Breed: Retriever, Golden  
 Sex: Neutered Male

**Date Type Staff History**

ID: 315958	Posted	Final	Reference Range
Test	Result		
ALB	B6		2.7 - 4.4
ALKP			5 - 131
ALT			12 - 118
AMYL			290 - 1125
AST			15 - 66
BUN/UREA			6 - 31
Ca			8.9 - 11.4
Chloride			102 - 120
CHOL			92 - 324
CK			59 - 895
CREA			0.5 - 1.6
GGT			1 - 12
GLU			70 - 138
LIPA			77 - 695
Mg			1.5 - 2.5
PHOS			2.5 - 6.0
Potassium			3.6 - 5.5
Sodium			139 - 154
TBIL			0.1 - 0.3
TP			5.0 - 7.4
TRIG		29 - 291	
GLOB		1.6 - 3.6	
A/G Ratio		0.8 - 2.0	
B/C Ratio		4 - 27	

5/31/2014 L

Endocrinology results from B6  
B6 Requisition ID: 315958 B6 Posted Final  
 Test Result Reference Range  
 T4 B6 0.8 - 3.5  
 Asc: B6 Profile: Total T4

5/31/2014 L

Miscellaneous results from B6  
B6 Requisition ID: 315958 B6 Posted Final  
 Asc: B6 Profile: Superchem  

B6

5/30/2014 C

B6

ULTRASOUND REPORT NEW

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

B6

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient:  
Species:  
Age:  
Color:

**B6**

Canine

**B6**

BRONZE

Breed: Retriever, Golden

Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

Referring Vet: Hospital:

ULTRASONOGRAPHIC FINDING:

# of

Films:

Written: 5/30/2014

**B6**

5/30/2014 C

**B6**

IM TREATMENT NEW  
5/30/2014

Internal Medicine Assessment:

**B6**

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

Page 27 of 30

Date: 4/20/2018 5:17 PM

# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

**B6**

Treatment: no treatment implemented at this time

Recommended Follow-up Care: **B6**

5/30/2014 C

**B6**

IM PHYSICAL EXAM NEW  
5/30/2014 22:58

Presenting Complaint:

History: **B6**

**B6**

**B6**

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**



# Patient History Report

Client:  
Phone:  
Address:

**B6**

Patient: **B6**  
Species: Canine  
Age: **B6**  
Color: Blonde

Breed: Retriever, Golden  
Sex: Neutered Male

Date	Type	Staff	History
5/27/2014	C	<b>B6</b>	RECEPTION ACTIONS NOTE <b>B6</b>
5/27/2014	C	<b>B6</b>	RECEPTION ACTIONS NOTE ***ADDENDUM 5/27/2014 <b>B6</b>

B: Billing, C: Med note, CB: Call back, CK: Check-in, CM: Communications, D: Diagnosis, DH: Declined to history, E: Examination, ES: Estimates, I: Departing instr, L: Lab result, M: Image cases, P: Prescription, PA: PVL Accepted, PB: problems, PP: PVL Performed, PR: PVL Recommended, R: Correspondence, T: Images, TC: Tentative medl note, V: Vital signs

**B6**

Report Details - EON-351031	
ICSR:	2045676
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-04-12 13:26:01 EDT
Reported Problem:	<b>Problem Description:</b> Feb 23, 2018 Patient presented to the cardiology service at [B6] [B6] for tachypnea. He was diagnosed with dilated cardiomyopathy and left side congestive heart failure. Whole blood taurine level was [B6]. At the time, patient consuming Zignature Kangaroo Formula and was advised to change.
	<b>Date Problem Started:</b> 02/22/2018
	<b>Concurrent Medical Problem:</b> Yes
	<b>Pre Existing Conditions:</b> [B6]
	<b>Outcome to Date:</b> Stable
Product Information:	<b>Product Name:</b> Zignature Kangaroo Formula
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Package Type:</b> BAG
	<b>Possess Unopened Product:</b> No
	<b>Possess Opened Product:</b> No
	<b>Product Use Information:</b>
	<b>Description:</b> Owner feeding for 2-3 years prior to diagnosis.
	<b>Last Exposure Date:</b> 03/01/2018
	<b>Time Interval between Product Use and Adverse Event:</b> 3 Years
<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes	
<b>Perceived Relatedness to Adverse Event:</b> Possibly related	
<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes	
<b>Manufacturer /Distributor Information:</b>	
<b>Purchase Location Information:</b> Name: Chewy.com	
Animal Information:	<b>Name:</b> [B6]
	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> Retriever - Golden
	<b>Gender:</b> Male
	<b>Reproductive Status:</b> Neutered
<b>Weight:</b> 40 Kilogram	

	Age:	6 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>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:		Address:	B6		United States				
Owner Information provided:	Yes															
Contact: Name:	B6															
Phone:																
Address:	B6															
	United States															
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Referred veterinarian</td> </tr> <tr> <td>Date First Seen:</td> <td>02/23/2018</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:		Address:	B6		United States	Type of Veterinarian:	Referred veterinarian	Date First Seen:	02/23/2018
Practice Name:	B6															
Contact: Name:	B6															
Phone:																
Address:	B6															
	United States															
Type of Veterinarian:	Referred veterinarian															
Date First Seen:	02/23/2018															
Sender Information:	Name:															
	Address:	B6														
		United States														
	Contact: Phone:															
	Email:	B6														
	Reporter Wants to Remain Anonymous:	No														
	Permission To Contact Sender:	Yes														
	Preferred Method Of Contact:	Email														
	Reported to Other Parties:	None														
Additional Documents:																

**From:** 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:** 6/10/2019 4:39:12 PM  
**Subject:** couple more related DCM- PFRs-FW: Zignature trout & salmon dry: Lisa Freeman - EON-390034 + Pure VitaVenison and Red Lentisl  
**Attachments:** 2067994-report.pdf; PureVita Venison & Red Lentils Grain-Free Dry Dog Food: [B6] EON-386301; PureVita Venison & Red Lentils Grain-Free Dry Dog Food: [B6] EON-390031; Zignature trout & salmon dry: Lisa Freeman - EON-370715; 2067994-attachments.zip

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

[B6]



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**From:** Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  
**Sent:** Monday, June 10, 2019 11:13 AM  
**To:** Rotstein, David <David.Rotstein@fda.hhs.gov>; Cleary, Michael \* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [B6]  
**Subject:** Zignature trout & salmon dry: Lisa Freeman - EON-390034

A PFR Report has been received and Related PFR Event [EON-390034] has been created in the EON System.

A "PDF" report by name "2067994-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 "2067994-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390034  
**ICSR #:** 2067994  
**EON Title:** Related PFR Event created for Zignature trout & salmon dry; 2067994

<b>AE Date</b>	11/07/2018	<b>Number Fed/Exposed</b>	3
<b>Best By Date</b>		<b>Number Reacted</b>	2

<b>Animal Species</b>	Dog	<b>Outcome to Date</b>	Better/Improved/Recovering
<b>Breed</b>	Retriever - Labrador		
<b>Age</b>	3 Years		
<b>District Involved</b>	PFR-New England DO		

**Product information**

**Individual Case Safety Report Number:** 2067994

**Product Group:** Pet Food

**Product Name:** Zignature trout & salmon dry

**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

**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:** 3

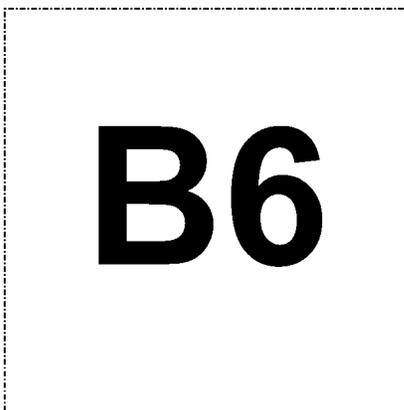
**Number of Animals Reacted With Product:** 2

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

This report is linked to:

**Initial EON Event Key:** EON-370715

**Initial ICSR:** 2058683



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

<https://eon.fda.gov/eon//browse/EON-390034>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issuelid=407306&parentIssueTypelid=12>

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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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](mailto:FDAReportableFoods@fda.hhs.gov) immediately.

# B4, B6

Owner:

B6

Accession Number:

B6

Reference Number:

B6

Case Coordinator: LAB, COMP. HEMATOLOGY

Received: 02/27/2018

Finalized: 02/27/2018

Species: DOG

Sex: FEMALE

Animal ID: B6

Specimen: SERUM

Sampled: 02/09/2018

Clinic:

NORTH CAROLINA ST UNIV- CLIN PATH LAB  
ROOM C269  
1060 WILLIAM MOORE DR  
RALEIGH, NC 27607

## FINAL REPORT

*This report supercedes all previous reports for this case*

### Clinical Pathology

#### PROFILE, IRON & TIBC

Animal Id:

B6

Sample Date:

Feb 9, 2018

Specimen Desc:

SERUM

B6

B6 H ug/dL

73 - 245

02/27/2018 05:14 PM

TIBC Comment

UNABLE TO CALCULATE TIBC. UIBC IS BELOW THE ANALYZER TECHNICAL LIMIT.

Gross appearance of

NORMAL

serum:

Chemistry assays

B6

MT, CLIN PATH LAB

reported by:

Accession Number:

B6

Status: Finalized

Tuesday, 27 Feb 2018 5:14 PM

Page 1 of 2

NC State University  
Veterinary Hospital  
1052 William Moore Drive  
Raleigh, NC 27607  
Discharge Comments

Fax: Admin  
Fax: Referral

Small Animal (919) 513-6500  
Large Animal (919) 513-6630

<b>Client</b> B6	<b>Patient</b> B6 SCHNAUZER MC BLACK CANINE	Case # 212267  8.2 kg	Attending DVM Student Discharging DVM Referring DVM	B6 B6 B6
---------------------	--	-----------------------------	--	----------------

Admission Date/Time: B6 Discharge Date/Time: B6 Discharge Status:

\*\*\*\*\*NOTICE OF EUTHANSIA\*\*\*\*\*

Case Summary

Diagnosis:

- 1) Biventricular congestive heart failure (left significantly worse than right)
- 2) Cardiomyopathy (suspect secondary) vs. myocarditis vs. tachycardia-induced cardiomyopathy vs. other

History:

B6 is a 2 and 1/2 year old male castrated Miniature Schnauzer who presented the NCSU ER on B6 for labored breathing and was subsequently transferred to NCSU Cardiology. B6 initially developed a cough three weeks ago; B6 describes the cough as a wheezing-type cough that occurred more frequently at night. When B6 showed no signs of improvement, B6 presented to his primary veterinarian on Thursday (1/26). Kennel cough was suspected as the underlying cause. On Monday, B6 B6 became uninterested in his food and began vomiting. The following day B6 continued vomiting and developed labored breathing and subsequently re-presented to the rDVM for evaluation. Bloodwork and thoracic radiographs were performed. Bloodwork was reportedly unremarkable at this time and there B6

B6 While in-hospital, B6 regurgitated. On Wednesday, B6 had improvement in respiratory effort but he still was not eating; B6

B6 The day of presentation, B6 syringe fed B6 but as she attempted he B6 developed marked labored breathing following this and was presented to an emergency hospital. Thoracic radiographs were performed (uploaded in eFilm) and revealed cardiomegaly; a diffuse, severe mixed interstitial to alveolar pattern that is most severe caudodorsally; hepatomegaly; and decreased abdominal serosal contrast. B6 was referred to NCSU for further care and ventilation if indicated.

B6

B6 lives with one other dog (not a relative) who is healthy and is currently up to date on his vaccinations. B6 is not current on any flea/tick prevention but receives heartworm prevention. B6 is fed California Natural dog food.

Physical Exam Findings (on presentation):

B6

B6

**B6**

Brief Daily Summary:

**B6** presented late in the evening on **B6** to the ER and after a TFAST was performed showing severe cardiomegaly with hypocontractility of the ventricles in addition to reviewing the rDVM radiographs, **B6** and **B6** were given. An

echocardiogram was then performed (performed sternally cage-side given patient status) and a diagnosis of severe cardiomyopathy (primary vs. secondary DCM vs. myocarditis, vs. pacing-induced cardiomyopathy vs. other) and he was quickly given another dose of

B6

B6 After the second B6 was given he was immediately placed on a B6 and B6 at

B6

B6 Immediately after B6 (approximately 1:30AM) which showed a marked improvement in terms of B6 significantly improved. He was maintained on B6

B6 He handled this quite well and while B6 as the B6 he clinically was markedly improved from presentation. His B6

B6

B6

I am sorry for the loss of your patient. Both B6 were absolutely wonderful to work with. If you have any questions at all, please do not hesitate to call us at B6

B6

NC State University  
Veterinary Hospital  
1052 William Moore Drive  
Raleigh, NC 27607  
Discharge Comments

Fax: Admin  
Fax: Referral

Small Animal (919) 513-6500  
Large Animal (919) 513-6630

<b>Client</b> <b>B6</b>	<b>Patient</b> <b>B6</b> SCHNAUZER MC GRAY&WHITE CANINE	Case # 216605  9.9 kg	Attending DVM Student Discharging DVM Referring DVM	<b>B6</b>  <b>B6</b>
----------------------------	--	-----------------------------	--	----------------------------

Admission Date/Time: JUN 22, 2017 10:46 AM

Discharge Date/Time: JUN 22, 2017 06:25 PM

Discharge Status: UNDETERM  
NED

CASE SUMMARY:

HISTORY:

**B6**

PHYSICAL EXAM FINDINGS:

**B6**

DIAGNOSTIC TESTS:

**B6**

Pending Lab Results:

**B6**

**B6**

ASSESSMENT:

**B6**

**B6** Unfortunately, **B6** echocardiogram revealed evidence of mild mitral valve endocardiosis (i.e. chronic mitral valve disease) and suspected dilated cardiomyopathy. Mitral valve endocardiosis is a chronic, progressive condition in which the valve leaflets become progressively thickened and no longer close appropriately allowing mitral regurgitation. Over time, the left atrium will enlarge and this can lead to congestive heart failure. Typically, in patients with mitral valve disease, the systolic heart function/contractility is maintained until late stages of the disease. Unfortunately, **B6** systolic function was significantly decreased, and he showed abnormal dilation of his left atrium and ventricle. These findings were most consistent with a condition called dilated cardiomyopathy (DCM). DCM is a disease of unknown etiology affecting the muscle of the heart and is most commonly seen in large breed dogs (such as Dobermans, Great Danes, and Labrador Retrievers), but there is a small case report of this disease occurring in Standard Schnauzers. Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics, infectious diseases, and toxins have all been linked to DCM. In order to assess for some of these possible causes, we have submitted testing for multiple nutritional deficiencies and infectious diseases. The NCSU Cardiology Service will call you as these tests become available. DCM leads to poor contractility and low cardiac output, and we suspect that **B6** episodes of collapse are most likely due to his low cardiac output during exertion. DCM can also lead to fibrosis and remodeling of the myocardium, which can lead to secondary arrhythmias. Fortunately, we saw no evidence of arrhythmias on **B6** ECG today. We performed chest radiographs to evaluate **B6** heart and lungs, and **B6** had evidence of left-sided congestive heart failure on his radiographs and impending right-sided congestive heart failure on his echocardiogram today. We are starting him on three medications to treat his heart disease and congestive heart failure today, and we may consider adding additional medications and supplements in the future. **B6**

**B6**

INSTRUCTIONS FOR CARE OF YOUR PET:

Medications:

**B6**

**B6**

**B6**

SMALL ANIMAL EMERGENCY SERVICE TEAM:

Faculty:

**B6**

Date: 6/22/17

CASE SUMMARY:

Thank you for entrusting us with the care of your companion. The Discharge Summary will be emailed to you and faxed to your RDVM within 24 hours of release/discharge from our facility at: **B6** If you or your veterinarian do not receive this, please contact the: **B6** to request a copy. The following will briefly outline the care your companion should receive at home and was explained by our staff at the time of discharge:

DIAGNOSIS (ES):

- 1. Left-sided congestive heart failure
- 2. Mitral valve endocardiosis with left atrial enlargement
- 3. Dilated cardiomyopathy

TREATMENTS:

**B6**

**B6**

INSTRUCTIONS FOR CARE OF YOUR PET:

Medications:

**B6**

IF YOU HAVE ANY QUESTIONS OR PROBLEMS, PLEASE CALL THE SMALL ANIMAL EMERGENCY SERVICE AT (919) 513-6911.

PLEASE CALL TO MAKE YOUR FOLLOW UP APPOINTMENT AS RECOMMENDED

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Owner/Agent Signature                      Clinician's Signature                      Student's Signature

Copy to: Owner / Medical Record / Fax to RDVM

NC State University  
Veterinary Hospital  
1052 William Moore Drive  
Raleigh, NC 27607  
Discharge Comments

Fax: Admin  
Fax: Referral

Small Animal (919) 513-6500  
Large Animal (919) 513-6630

<b>Client</b> B6	<b>Patient</b> B6 SCHNAUZER MC GRAY&WHITE CANINE	Case # 216605  9.9 kg	<b>Attending DVM</b> Student <b>Discharging DVM</b> <b>Referring DVM</b>	B6  B6
---------------------	---	-----------------------------	---	--------------

Admission Date/Time: JUL 10, 2017 10:59 AM      Discharge Date/Time: JUL 10, 2017 03:16 PM      Discharge Status:

CASE SUMMARY

DIAGNOSIS:  
Dilated Cardiomyopathy (DCM)  
Mitral valve endocardiosis and regurgitation

HISTORY: B6 a 7 year old neutered male miniature Schnauzer, was presented to the NCSU cardiology service for re-evaluation of dilated cardiomyopathy. At his prior visit, B6 presented to our Small Animal Emergency on 6/22/17 for episodes of collapse. B6 had his first two collapse episodes in mid February; he was described to fall over for ~6 seconds with no loss of consciousness, and he immediately returned to normal after. He later has several more collapsing episodes in June 2017, which prompted his presentation to NCSU SAES. Collapse episodes were preceded by excitement or exertion. He was discharged 6/22/17 with B6 house mate, B6 unfortunately passed away from DCM and CHF in February 2017. Infectious disease testing and amino acid testing did not identify a cause for the DCM. Histopathology was relatively unremarkable, however, findings could have been consistent with a toxic insult.

Since 6/22/17 B6 reports B6 is doing much better. He has not had any more collapsing episodes, excepting one moment where he stumbled but did not fall when excited 7/4/17. He is tolerating the medications and eating well. No coughing, sneezing, vomiting or diarrhea. His RR has been very normal since starting medications. His diet has been changed to Science Diet adult small breed from California Naturals.

The tests results from B6 6/22 visit were normal, including vector borne testing (IFA, PCR) and taurine and carnitine analysis. A full amino acid profile did not reveal significant abnormalities, however, consultation with UCD is pending for a full interpretation.

PHYSICAL EXAM FINDINGS:

B6

B6

RESULTS OF DIAGNOSTIC TESTS:

BLOOD PRESSURE- 110 mmHg systolic  
CHEST RADIOGRAPHS- Moderate left sided cardiomegally with no signs of congestive heart failure. Moderate hepamegaly.  
RENAL PANEL: B6

ASSESSMENT:

B6 was presented today for a recheck of his recently diagnosed dilated cardiomyopathy (DCM). DCM is a disease of unknown cause affecting the muscle of the heart and is most commonly seen in large breed dogs (such as Dobermans, Great Danes, and Labrador Retrievers). Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics and toxins have all been linked to DCM. Infectious and nutritional causes of DCM have been ruled out to the best of our ability to test for B6. The overall effect of DCM is a decrease in the contractility (pumping ability) of the heart. Because the heart is unable to pump

with enough vigor to move blood adequately forward into circulation, a volume overload occurs and the heart dilates to accommodate it. As a result, the chambers of the heart become very large, and the walls of the heart become very thin. Ultimately, the heart is unable to accommodate and dilate further, the result is back-up of blood from the heart and into the lungs, known as congestive heart failure. It is important to know that this disease is progressive, and ultimately those patients affected with it will experience congestive heart failure.

Given the unusual timing of [B6] and [B6] both developing dilated cardiomyopathy within the same time frame, their different ages, unrelatedness, same environment and lack of an identifiable cause, we are continuing to hunt for an environmental explanation for [B6] DCM. We will keep you up to date as we pursue toxin testing in the food and treats you have brought us. However, negative toxin testing may not completely rule out a toxin since we do not have samples representative of the onset of cardiac signs in both dogs. We have changed [B6] food to address this possibility.

We are glad to see that [B6] is doing well clinically. His chest xrays showed resolution of congestive heart failure and his renal panel was normal indicating that he is tolerating the medications well. We would like to add [B6] to his regime because his [B6] while normal, is at the low end of the range, and because this may have some long term benefit through [B6]. We have also listed doses for supplements, that while unproven in their benefit, are not harmful and may help his myocardial function. Taurine and carnitine supplementation are unlikely to be helpful since his plasma and whole blood concentrations are normal.

MEDICATIONS:

Please continue the following medications:

**B6**

Please start the following medication:

**B6**

ACTIVITY:

Please avoid strenuous exercise or situations which place undue stress on your pet. In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capability.

Please continue to monitor [B6] respiratory rate and call if this increases. Please also call if he begins coughing or collapse episodes recur.

DIET:

A diet that is moderately restricted in salt is ideal for cardiac patients, as excessive salt load can cause fluid accumulation. A commercial "Senior" diet is formulated with an appropriate amount of salt for your pet. Please also avoid salty treats, such as hot dogs or jerky treats.

NEXT APPOINTMENT:

[B6] should have a recheck appointment with NCSU Cardiology in 3-4 months to evaluate chest X-rays, blood pressure, kidney values, echocardiogram, and troponin. If he begins to show signs of heart failure prior to your next recheck, please call NCSU Cardiology so that we can recheck your pet sooner.

CLINICIANS:

[B6]

RESIDENTS:

[B6]

CLINICAL TECHNICIANS:

**B6**

RESEARCH TECHNICIAN:

**B6**

CLIENT SERVICES:

**B6**

In order to help expedite medication refills, please visit us online at [www.ncstatevets.org](http://www.ncstatevets.org) and select Pet Owners, Pharmacy Refills.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pet's medical condition.

Owner -

**B6**

Clinician - Darcy Adin, DVM

Student -

**B6**

Referring Veterinarians - please visit us online at [www.ncstatevets.org/veterinarians](http://www.ncstatevets.org/veterinarians) and fill out our RDVM Feedback Survey!

Report Details - EON-308715		
ICSR:	1064844	
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:	2017-03-30 15:52:14 EDT	
Reported Problem:	<b>Problem Description:</b> Presented to local veterinarian for gagging cough. Regular veterinarian concerned about new heart murmur and large heart on ultrasound and referred to Emergency and Cardiology services at <b>B6</b> . Cardiac workup showed degenerative valvular disease, but also very depressed cardiac contractility and early congestive heart failure. Taurine level (plasma) was checked to rule out taurine deficiency as cause of depressed cardiac contractility and level was extremely low - 5.3 nmol/mL (normal is 60-120 nmol/mL; critical is < 40 nmol/mL). Concerned that diet may not have sufficient precursors to taurine.	
	<b>Date Problem Started:</b> 03/09/2017	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>UPC:</b> 769949653905	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 25.3 Pound	
	<b>Possess Unopened Product:</b> Unknown	
	<b>Possess Opened Product:</b> Yes	
	<b>Storage Conditions:</b> Stored in original bag	
	<b>Product Use Information:</b>	<b>Description:</b> Fed 1 and 1/4 cup twice daily for several years according to pet owner
		<b>Last Exposure Date:</b> 03/09/2017
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes
		<b>Adverse Event Abate After Product Stop:</b> Unknown
		<b>Product Use Started Again:</b> No
<b>Perceived Relatedness to Adverse Event:</b> Possibly related		
<b>Other Foods or Products Given to the Animal During This Time Period:</b> Unknown		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>		
Animal Information:	<b>Name:</b> <b>B6</b>	

	<b>Type Of Species:</b> Dog
	<b>Type Of Breed:</b> Retriever - Golden
	<b>Gender:</b> Male
	<b>Reproductive Status:</b> Neutered
	<b>Weight:</b> 66 Pound
	<b>Age:</b> 8.5 Years
	<b>Assessment of Prior Health:</b> Excellent
	<b>Number of Animals Given the Product:</b> 1
	<b>Number of Animals Reacted:</b> 1
	<b>Owner Information:</b>
	<b>Owner Information provided:</b> Yes
	<b>Contact:</b>
	<b>Name:</b> B6
	<b>Phone:</b> B6
	<b>Other Phone:</b> B6
	<b>Email:</b> B6
	<b>Address:</b> B6
	United States
	<b>Healthcare Professional Information:</b>
<b>Sender Information:</b>	<b>Name:</b> B6
	<b>Address:</b> B6
	United States
	<b>Contact:</b>
	<b>Phone:</b> B6
	<b>Other Phone:</b> B6
	<b>Email:</b> B6
	<b>Reporter Wants to Remain Anonymous:</b> No
	<b>Permission To Contact Sender:</b> Yes
	<b>Preferred Method Of Contact:</b> Email
	<b>Reported to Other Parties:</b> None
<b>Additional Documents:</b>	

Report Details - EON-360238		
ICSR:	2052688	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-07-24 19:15:00 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> 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 (LVIDD 5.13cm today, 4.14cm previous July 2016)." He prescribed increasing the taurine and l-carnitine supplements and return for repeat echo in 3-4 months.	
	<b>Date Problem Started:</b> 05/08/2017	
	<b>Concurrent Medical Problem:</b> Yes	
	<b>Pre Existing Conditions:</b> She had inherited Mitral Valve Displasia that was diagnosed by a board certified cardiologist when she was one year of age. I was told that it was mild and she should live a normal life. He also diagnosed SAS, which was later listed as equivocal.	
	<b>Outcome to Date:</b> Better/Improved/Recovering	
Product Information:	<b>Product Name:</b> Taste of the Wild Pine Forrest, Venison and Legumes	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 28 Pound	
	<b>Purchase Date:</b> 04/01/2016	
	<b>Possess Unopened Product:</b> No	
	<b>Possess Opened Product:</b> No	
	<b>Storage Conditions:</b> In the bag it came in until it was gone.	
	<b>Product Use Information:</b>	<b>Description:</b> Kibble was fed in a stainless steel bowl with water and supplements twice a day
		<b>First Exposure Date:</b> 05/14/2016
		<b>Last Exposure Date:</b> 05/09/2017
		<b>Time Interval between Product Use and Adverse Event:</b> 1 Years
<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes		
<b>Adverse Event Abate After Product Stop:</b> Yes		
<b>Product Use:</b> No		

		<b>Started Again:</b>	
		<b>Perceived Relatedness to Adverse Event:</b>	Definitely related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>	<b>Name:</b>	Chewy.com
		<b>Address:</b>	1855 Griffin Road Dania Beach Florida 33004 United States
<b>Animal Information:</b>	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Retriever - Golden	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Intact	
	<b>Pregnancy Status:</b>	Not Pregnant	
	<b>Lactation Status:</b>	Not Applicable	
	<b>Weight:</b>	68.5 Pound	
	<b>Age:</b>	3 Years	
	<b>Assessment of Prior Health:</b>	Good	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	UCD VMTH Cardiology
		<b>Contact: Name:</b>	Joshua Stern
		<b>Phone:</b>	1-530-752-2475
		<b>Other Phone:</b>	9259899795
		<b>Address:</b>	1 Garrod Drive Davis California 95616 United States
		<b>Type of Veterinarian:</b>	Referred veterinarian
		<b>Date First Seen:</b>	07/06/2016
		<b>Permission to Release Records to FDA:</b>	Yes
<b>Sender Information:</b>	<b>Name:</b>	B6	
	<b>Address:</b>	B6 United States	
	<b>Contact:</b>	<b>Phone:</b>	B6
		<b>Other Phone:</b>	
		<b>Email:</b>	

<b>Permission To Contact Sender:</b>	Yes
<b>Preferred Method Of Contact:</b>	Email
<b>Reported to Other Parties:</b>	Other

**Additional Documents:**

<b>Attachment:</b>	[B6] ucd.7.6.17.pdf
<b>Description:</b>	[B6]
<b>Type:</b>	Echocardiogram
<b>Attachment:</b>	7.7.2016 [B6] results [B6].pdf
<b>Description:</b>	[B6] echo at 1 y/o by Dr. [B6] in 7/7 /2016
<b>Type:</b>	Echocardiogram
<b>Attachment:</b>	3.29.18 Dr. Stern Rept.pdf
<b>Description:</b>	[B6] third and most recent Echo at UCD 3/29/18
<b>Type:</b>	Echocardiogram
<b>Attachment:</b>	11.17.17 [B6] Dr. Stern UCD echo.pdf
<b>Description:</b>	[B6] second echo at UCD VMTH 11/17/17
<b>Type:</b>	Echocardiogram

Patient Name: **B6** Date of Exam: 7/6/2017  
 Medical Rec #: **B6** Breed: Golden Retriever  
 DOB: **B6** Weight: 66 lb  
 Age: 2 years BSA: 0.98 m<sup>2</sup>  
 Sex: Fi BP-sys: Not taken  
 Sonographer: **B6** DVM, Cardiology HR: 103  
 Resident

Cardiology Resident: **B6** DVM, Cardiology Resident  
 Diagnosis: Dilated Cardiomyopathy (suspect taurine responsive)

**CV Exam:**

**B6**

2D UCD LA sax UCD LA lax  
 LA d **B6** cm **B6** cm  
 Ao s **B6** cm **B6** cm  
 LA/Ao (<1.5) (<2.5)

LA 2d/LV mmode **B6**

<b>M-mode</b>	<u>Diastole</u>	<u>Systole</u>			LV EF	%
RV		cm	%FS	<b>B6</b>	LV SV	ml
IVS	<b>B6</b>	cm	MRSIm	<b>B6</b>	LV SI	ml/m <sup>2</sup>
LV		<b>B6</b> cm	MRSI	<b>B6</b>	LV CO	l/min
LVPW		<b>B6</b> cm	EDVI	<b>B6</b>	LV CI	l/min/m <sup>2</sup>
LA		cm	ESVI	<b>B6</b>	EPSS	<b>B6</b> cm

Normal Canine M-mode values (in cm) for 35 kg dogs.

LVIDd **B6** LVPWd **B6** IVSd **B6** LA **B6** AO **B6** %FS **B6**

**Aortic Valve:**  
 VMax **B6** m/s

**Mitral Valve:**  
 Mn Grad **B6** msec E Vmax **B6** m/s  
 P1/2T **B6** msec A Vmax **B6** m/s  
 MV Area **B6** cm<sup>2</sup> E/A **B6**  
 MV DT **B6** msec MV VTI **B6**

**Tricuspid valve:**  
 TV E Max **B6** m/s  
 TV Mn Grad **B6** mmHg  
 TV VTI **B6** mmHg

B6

7/6/2017

B6

Pulmonic valve:  
Vmax  
PV AT  
PV ET  
PV AT/ET

B6

CLINICIAN INTERPRETATION:

Mitral Valve: B6

Pulmonary Artery: B6

ECHO SUMMARY:

- Moderately dilated left ventricular chamber and LV systolic dysfunction - ddx: taurine responsive DCM vs idiopathic DCM.  
- LV chamber size has significantly increased in the recheck interim (LVIDD: B6 m today, B6 m previous July 2016).
- Mild left atrial enlargement (LA/Ao = B6)
- Mild mitral regurgitation is static in the recheck interim. This likely represents mild mitral valve dysplasia as previously noted, but may be secondary to annular deformation from chamber dilation (cannot determine accurately until reevaluation)
- Max Aortic / LVOT velocity is B6 m/s. This has improved in the recheck interim (previously: B6 m/s), however it is likely due to decreased systolic function.
- Trivial tricuspid regurgitation - can be seen in normal dogs.
- No other congenital heart diseases.

Recommendations:

B6

B6 DVM, Cardiology Resident

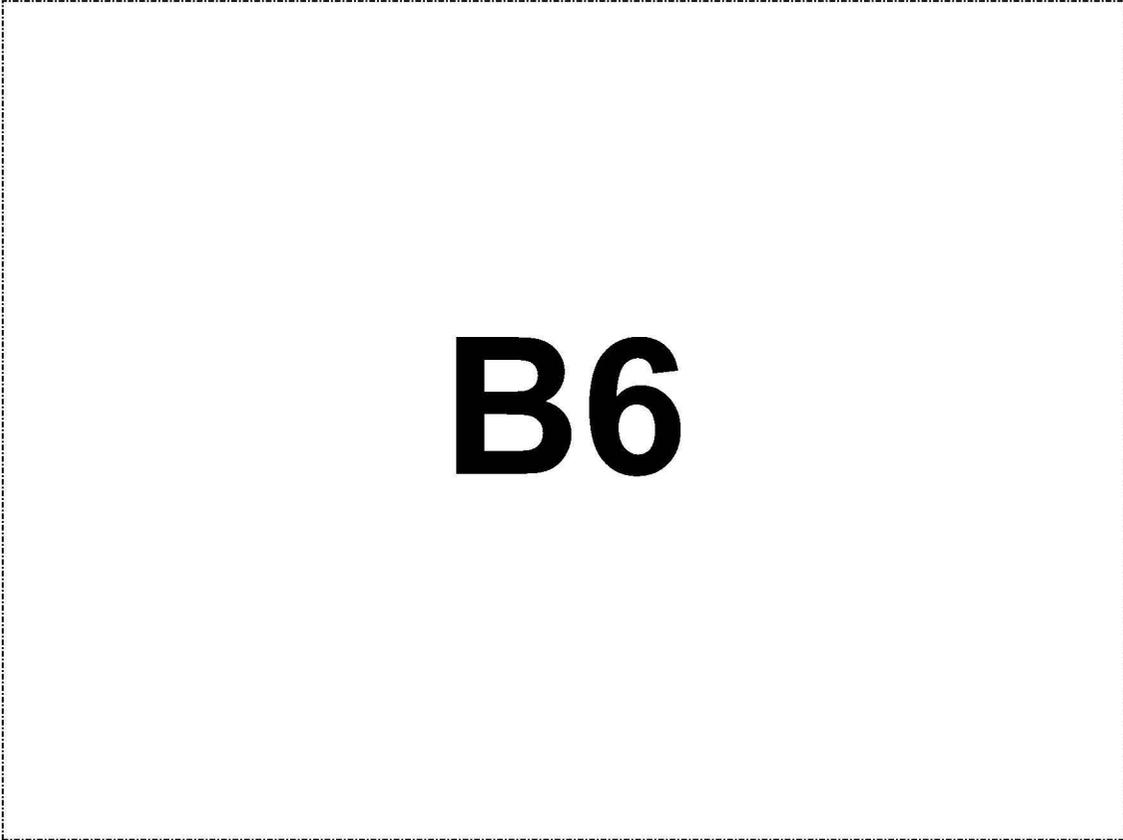
Joshua A Stern DVM, PhD, Diplomate ACVIM (Cardiology)  
Electronically signed on 7/6/2017 on 12:24:16 PM

B6

**B6**

7/6/2017

**B6**



**B6**



Discharge Instructions - Record Copy

Admission: <u>06Jul17</u>	<u>Small Animal Outpatient</u>	Visit#: <u>8042CV</u>
Discharge:		Status: <u>Open</u>

Client #: B6  
 Client: B6  
 Address: B6  
 City, St: B6

Clinician: B6  
 Patient #: B6 Birth: B6 Sex: F  
 Patient: B6  
 Species: K9  
 Breed: GOLDEN RETRIEVER

Discharge Instructions

- 1) Thank you for bringing B6 to the UC Davis Cardiology service for evaluation of her heart.
- 2) CLINICAL EXAMINATION
- 3) On physical exam, B6 was bright and alert. Her heart sounds were easily audible on physical exam and she has a Grade II/VI heart murmur. Her pulses match her heart beat. The remainder of her physical exam was unremarkable.
- 4) DIAGNOSTIC TESTS:
- 5) 1. Echocardiogram: The chambers of B6 heart are dilated. Her heart also has moderately decreased pumping function. This is due to a condition called dilated cardiomyopathy (DCM). She continues to have mild leak through her mitral valve, which may be mitral valve dysplasia, but can be due to her DCM. Her aortic velocity was normal today, but this may also be due to decreased pumping function of the heart.
- 6) ASSESSMENT:
- 7) Based on B6 previous labwork and taurine levels, we suspect that her DCM is caused by taurine deficiency. If her DCM is caused by a previous deficiency in taurine, we are hopeful that we can reverse her heart disease by supplementing her diet with taurine as you have already started to do.
- 8) B6 echo showed that her left atrium is mildly enlarged, which means there is low immediate risk to develop congestive heart failure (CHF) / fluid accumulation in the lungs.
- 9) B6 was noted to have mild mitral valve regurgitation in her previous echo report. This means that some blood from her left ventricle flows backwards into her left atrium when her heart pumps. This amount of mild mitral valve regurgitation is the same as was seen at her last echo. Her mitral valve regurgitation may be representative of mitral valve dysplasia, but it may also be due to her DCM.
- 10) B6 aortic velocity was normal today. We measure aortic velocity to assess the flow through the aortic valve. B6 was previously noted to have equivocal subaortic stenosis, though today we didn't appreciate any abnormalities of the blood flow through her aortic valve. B6 DCM may be masking her subaortic stenosis, so we would like to assess her aortic velocity flow when her heart is back to a normal size.
- 11) We would like to see if the taurine supplementation can reverse the DCM that we see now. Until we get B6 more stable, we would not advise anesthesia for her B6 or other elective procedures.
- 12) MONITORING
- 13) Please monitor B6 at home for any evidence that her heart disease is progressing. This includes exercise intolerance, increased coughing, collapse, weakness, lethargy, inappetence, abdominal distension, or trouble/difficulty breathing. Please call a veterinarian immediately if any of these signs are

observed.

14) MEDICATIONS

15) 1. Taurine:

16) Supplement B6 diet with 1500mg taurine twice a day. THIS IS A DOSE CHANGE from the amount of taurine B6 was previously getting.

17) 2. L-carnitine:

18) Supplement B6 diet with 2000 mg L-carnitine three times a day.

19) RECHECK

20) Please schedule an appointment in 3-4 months to reassess B6 heart. We will likely repeat an echocardiogram at this time to see how her heart chambers look after supplementing with taurine and carnitine.

21) Thank you again for bringing B6 to the UC Davis Cardiology service. She is SUCH a beautiful and well-behaved girl!

22) If you have any questions or concerns please do not hesitate to contact us at (530) 752-1393.

23) Senior Student: B6

24) Resident Clinician: Dr. B6

25) Faculty Veterinarian: Dr. Joshua Stern

I have read and understand the discharge instructions and I acknowledge receipt of the above animal.

Client Signature / Date

Form with checkboxes: Meds in Pharmacy, Meds in Ward, T.A., Please page: Clinician; or

Prepared by: ???

Prepared for: ???

Discharged by / Date & Time Clinician Signature / Date

**Report Details - EON-362010**

ICSR:	2053631
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-13 12:42:21 EDT
Initial Report Date:	07/24/2018
Reporter is the Animal Owner:	Yes
Parent ICSR:	2052688
Follow-up Report to FDA Request:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	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 at the [B6] at UC Davis 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 board certified 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 (LVID [B6] m today [B6] m previous July 2016)." He prescribed increasing the taurine and l-carnitine supplements and return for repeat echo in 3-4 months. She returned for additional echos in November 2017 and March 2018. Copies of all three visit reports and echos are attached. I'm going to try to attach a copy of her blood report of before and after supplementation.
	<b>Date Problem Started:</b>	05/08/2017
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	She had inherited Mitral Valve Displasia that was diagnosed by a board certified cardiologist when she was one year of age. I was told that it was mild and she should live a normal life. He also diagnosed SAS, which was later listed as equivocal. Her initial Echo was done by Dr. [B6] board certified Cardiologist, [B6] Report from visit attached.
	<b>Outcome to Date:</b>	Better/Improved/Recovering

<b>Product Information:</b>	<b>Product Name:</b>	Taste of the Wild Pine Forrest, Venison and Legumes
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Package Type:</b>	BAG
	<b>Package Size:</b>	28 Pound
	<b>Purchase Date:</b>	04/01/2016
	<b>Possess Unopened Product:</b>	No
	<b>Possess Opened Product:</b>	No
	<b>Storage Conditions:</b>	In the bag it came in until it was gone.
	<b>Product Use Information:</b>	<b>Description:</b> Kibble was fed in a stainless steel bowl with water and supplements twice a day
	<b>First Exposure Date:</b> 05/14/2016	
	<b>Last Exposure Date:</b> 05/09/2017	
	<b>Time Interval between Product</b> 1 Years	

		<b>Use and Adverse Event:</b>	
		<b>Product Use Stopped After the Onset of the Adverse Event:</b>	Yes
		<b>Adverse Event Abate After Product Stop:</b>	Yes
		<b>Product Use Started Again:</b>	No
		<b>Perceived Relatedness to Adverse Event:</b>	Definitely related
		<b>Other Foods or Products Given to the Animal During This Time Period:</b>	No
	<b>Manufacturer /Distributor Information:</b>		
	<b>Purchase Location Information:</b>	<b>Name:</b>	Chewy.com
		<b>Address:</b>	1855 Griffin Road Dania Beach Florida 33004 United States
<b>Animal Information:</b>	<b>Name:</b>	B6	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Retriever - Golden	
	<b>Gender:</b>	Female	
	<b>Reproductive Status:</b>	Intact	
	<b>Pregnancy Status:</b>	Not Pregnant	
	<b>Lactation Status:</b>	Not Applicable	
	<b>Weight:</b>	68.5 Pound	
	<b>Age:</b>	3 Years	
	<b>Assessment of Prior Health:</b>	Good	
	<b>Number of Animals Reacted:</b>	1	
	<b>Owner Information:</b>		
	<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	UCD VMTH Cardiology
		<b>Contact:</b>	<b>Name:</b> Joshua Stern
			<b>Phone:</b> 1-530-752-2475
			<b>Other Phone:</b> 9259899795
		<b>Address:</b>	1 Garrod Drive Davis California 95616 United States
		<b>Type of Veterinarian:</b>	Referred veterinarian
		<b>Date First Seen:</b>	07/06/2016
		<b>Permission to Release Records to FDA:</b>	Yes

<b>Sender Information:</b>	<b>Name:</b>	
	<b>Address:</b>	<b>B6</b> United States
	<b>Contact:</b>	<b>Phone:</b>
		<b>Other Phone:</b>
		<b>Email:</b>
	<b>Permission To Contact Sender:</b>	Yes
<b>Preferred Method Of Contact:</b>	Phone	
<b>Reported to Other Parties:</b>	Other	

<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b> 2017-06-27-0207.pdf
	<b>Description:</b>	This is a copy of two blood runs for <b>B6</b> . The first led to her visit to Dr. Stern at UCD. The second was after supplementation with taurine and L-carnitine had started and just before our first appoint at UCD. I have no other documentation.
	<b>Type:</b>	Laboratory Report



**B6**

PET OWNER: **B6**  
SPECIES: Canine  
BREED: Golden Retriever  
GENDER: Female  
AGE: **B6**  
PATIENT ID: **B6**

**B6**

ACCOUNT #: **B6**  
ATTENDING VET: **B6**

LAB ID: **B6**  
ORDER ID:  
COLLECTION DATE: **6/25/17**  
DATE OF RECEIPT: **6/27/17**  
DATE OF RESULT: **6/27/17**

IDEXX Services: **Taurine (Plasma)**<sup>t</sup>

## Therapeutics/Toxicology



**6/27/17** (Order Received)  
**6/29/17 6:25 PM** (Last Updated)

**5/8/17**

TEST  
**Taurine (Plasma)**      a **B6**      REFERENCE VALUE  
**60 - 120 NMOL/ML**      H  **B6**

<sup>a</sup> Testing performed at University of California, Davis

Report Details - EON-362973	
ICSR:	2054024
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:	2018-08-21 15:36:51 EDT
Reported Problem:	<b>Problem Description:</b> Presented to NCSU ER [B6] for lethargy, coughing and a terminal wretch for 4 days. He was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine [B6] nmol/ml. Slowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown significant improvement. Still not sure at this point if the DCM is breed or diet related, or both. Owner has another Mastiff which also was on Zignature Kangaroo Grain Free.
	<b>Date Problem Started:</b> [B6]
	<b>Concurrent Medical Problem:</b> No
	<b>Outcome to Date:</b> Better/Improved/Recovering
Product Information:	<b>Product Name:</b> Earthborne Naturals Lamb Grain Free
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Package Type:</b> BAG
	<b>Storage Conditions:</b> Please contact owner
	<b>Product Use Information:</b>
	<b>Description:</b> Used as a primary source of food 2013-2015
	<b>First Exposure Date:</b> 01/01/2013
	<b>Last Exposure Date:</b> 01/01/2015
	<b>Time Interval between Product Use and Adverse Event:</b> 5 Years
	<b>Perceived Relatedness to Adverse Event:</b> Possibly related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes
	<b>Manufacturer /Distributor Information:</b>
	<b>Purchase Location Information:</b>
<b>Product Name:</b> Zignature Kangaroo Grain Free Formula	
<b>Product Type:</b> Pet Food	
<b>Lot Number:</b>	
<b>Package Type:</b> BAG	
<b>Possess Unopened Product:</b> No	
<b>Possess Opened Product:</b> Unknown	
<b>Storage Conditions:</b> Please contact owner	
<b>Product Use Information:</b>	
<b>Description:</b> Used as a primary source for food 2015 -May 2018	
<b>First Exposure</b> 01/01/2015	

Date:	
Last Exposure Date:	05/10/2018
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 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:	Mastiff		
Gender:	Male		
Reproductive Status:	Neutered		
Weight:	96.4 Kilogram		
Age:	6 Years		
Assessment of Prior Health:	Excellent		
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:	NC State College of Veterinary Medicine	
	Contact:	Name:	B6
		Phone:	
		Email:	
Address:	1060 William Moore Dr Raleigh North Carolina		

		27607 United States
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Permission to Release Records to FDA:</b>	Yes

<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>	
	<b>Address:</b>		
		United States	
	<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>
		<b>Email:</b>	
	<b>Permission To Contact Sender:</b>	Yes	
	<b>Preferred Method Of Contact:</b>	Email	
<b>Reported to Other Parties:</b>	None		

<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b>	11 May 2018.pdf
	<b>Description:</b>		7 to 10 day recheck
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	<b>B6</b>	7 Aug 2018.pdf
	<b>Description:</b>		3 to 4 month recheck
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	<b>B6</b>	<b>B6</b>
	<b>Description:</b>		1st visit
	<b>Type:</b>	Medical Records	

Report Details - EON-364808		
ICSR:	2054800	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-09-10 15:30:53 EDT	
Reported Problem:	<b>Problem Description:</b> Other mastiff in the house [B6] was presented in congestive heart failure, possibly due to a grain free diet. [B6] was presented on 5/23/18 for occult DCM screening. [B6] has been doing well at home and not showing any signs of heart disease. He had been eating the same grain free diet as [B6] and was transitioned to a diet containing grains 3 weeks prior to this visit. Whole blood taurine basically normal. Echo revealed moderate to severe left ventricular enlargement, mild MR, mildly decreased LV ejection fraction. No arrhythmias detected. [B6] was placed on taurine supplementation. [B6] returned for a 3 month recheck 8/31/18. His echo showed considerable improvement in size, although still enlarged.	
	<b>Date Problem Started:</b> 05/23/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Better/Improved/Recovering	
Product Information:	<b>Product Name:</b> Earthborn Naturals Lamb Grain Free for 1 year Zignature Kangaroo Grain Free for 2 years	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Possess Unopened Product:</b> No	
	<b>Possess Opened Product:</b> No	
	<b>Storage Conditions:</b> Unknown	
	<b>Product Use Information:</b>	<b>Description:</b> Orally administered
		<b>Time Interval between Product Use and Adverse Event:</b> 3 Years
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes
		<b>Adverse Event Abate After Product Stop:</b> Unknown
		<b>Product Use Started Again:</b> No
		<b>Perceived Relatedness to Adverse Event:</b> Possibly related
<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes		
<b>Manufacturer /Distributor Information:</b>		
<b>Purchase Location Information:</b>		

<b>Animal Information:</b>	<b>Name:</b>	Has a housemate: <b>B6</b> reported on 8/21/18	
	<b>Type Of Species:</b>	Dog	
	<b>Type Of Breed:</b>	Mastiff	
	<b>Gender:</b>	Male	
	<b>Reproductive Status:</b>	Neutered	
	<b>Weight:</b>	84.5 Kilogram	
	<b>Age:</b>	6 Years	
	<b>Assessment of Prior Health:</b>	Excellent	
	<b>Number of Animals Given the Product:</b>	2	
	<b>Number of Animals Reacted:</b>	2	
	<b>Owner Information:</b>	<b>Owner Information provided:</b>	Yes
		<b>Contact:</b>	<b>Name:</b> <b>B6</b>
			<b>Phone:</b> <b>B6</b>
			<b>Email:</b> <b>B6</b>
		<b>Address:</b>	<b>B6</b>
United States			
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	NCSU CVM Cardiology Service	
	<b>Contact:</b>	<b>Name:</b> <b>B6</b>	
		<b>Phone:</b> <b>B6</b>	
	<b>Address:</b>	<b>B6</b>	
		United States	
	<b>Date First Seen:</b>	05/23/2018	
	<b>Permission to Release Records to FDA:</b>	Yes	
	<b>Practice Name:</b>	<b>B6</b>	
		<b>Contact:</b>	<b>Name:</b> <b>B6</b>
	<b>Phone:</b> <b>B6</b>		
<b>Email:</b> <b>B6</b>			
<b>Address:</b>	<b>B6</b>		
	United States		
<b>Type of Veterinarian:</b>	Primary/regular veterinarian		
<b>Permission to Release Records to FDA:</b>	Yes		
<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>	
	<b>Address:</b>	<b>B6</b>	

		<b>B6</b>
	United States	
<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>
	<b>Email:</b>	
<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email	
<b>Reported to Other Parties:</b>	None	
<b>Additional Documents:</b>		
	<b>Attachment:</b>	<b>B6</b> 225633.pdf
	<b>Description:</b>	NC State medical records (we do not have the rDVM medical records).
	<b>Type:</b>	Medical Records

Report Details - EON-362973	
ICSR:	2054024
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:	2018-08-21 15:36:51 EDT
Reported Problem:	<b>Problem Description:</b> Presented to NCSU ER <b>B6</b> for lethargy, coughing and a terminal wretch for 4 days. He was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine <b>B6</b> nmol/ml. Slowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown significant improvement. Still not sure at this point if the DCM is breed or diet related, or both. Owner has another Mastiff which also was on Zignature Kangaroo Grain Free.
	<b>Date Problem Started:</b> <b>B6</b>
	<b>Concurrent Medical Problem:</b> No
	<b>Outcome to Date:</b> Better/Improved/Recovering
Product Information:	<b>Product Name:</b> Earthborne Naturals Lamb Grain Free
	<b>Product Type:</b> Pet Food
	<b>Lot Number:</b>
	<b>Package Type:</b> BAG
	<b>Storage Conditions:</b> Please contact owner
	<b>Product Use Information:</b>
	<b>Description:</b> Used as a primary source of food 2013-2015
	<b>First Exposure Date:</b> 01/01/2013
	<b>Last Exposure Date:</b> 01/01/2015
	<b>Time Interval between Product Use and Adverse Event:</b> 5 Years
	<b>Perceived Relatedness to Adverse Event:</b> Possibly related
	<b>Other Foods or Products Given to the Animal During This Time Period:</b> Yes
	<b>Manufacturer /Distributor Information:</b>
	<b>Purchase Location Information:</b>
<b>Product Name:</b> Zignature Kangaroo Grain Free Formula	
<b>Product Type:</b> Pet Food	
<b>Lot Number:</b>	
<b>Package Type:</b> BAG	
<b>Possess Unopened Product:</b> No	
<b>Possess Opened Product:</b> Unknown	
<b>Storage Conditions:</b> Please contact owner	
<b>Product Use Information:</b>	
<b>Description:</b> Used as a primary source for food 2015 -May 2018	
<b>First Exposure</b> 01/01/2015	

Date:	
Last Exposure Date:	05/10/2018
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 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:	<b>B6</b> 9359														
Type Of Species:	Dog														
Type Of Breed:	Mastiff														
Gender:	Male														
Reproductive Status:	Neutered														
Weight:	96.4 Kilogram														
Age:	6 Years														
Assessment of Prior Health:	Excellent														
Number of Animals Reacted:	1														
Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td><b>B6</b></td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	Owner Information provided:	Yes	Contact:	<table border="1"> <tr> <td>Name:</td> <td><b>B6</b></td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	<b>B6</b>	Phone:		Email:		Address:	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States
Owner Information provided:	Yes														
Contact:	<table border="1"> <tr> <td>Name:</td> <td><b>B6</b></td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	<b>B6</b>	Phone:		Email:									
Name:	<b>B6</b>														
Phone:															
Email:															
Address:	<table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>	<b>B6</b>	United States												
<b>B6</b>															
United States															
Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>NC State College of Veterinary Medicine</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td><b>B6</b></td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td>1060 William Moore Dr Raleigh North Carolina</td> </tr> </table>	Practice Name:	NC State College of Veterinary Medicine	Contact:	<table border="1"> <tr> <td>Name:</td> <td><b>B6</b></td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	<b>B6</b>	Phone:		Email:		Address:	1060 William Moore Dr Raleigh North Carolina		
Practice Name:	NC State College of Veterinary Medicine														
Contact:	<table border="1"> <tr> <td>Name:</td> <td><b>B6</b></td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	<b>B6</b>	Phone:		Email:									
Name:	<b>B6</b>														
Phone:															
Email:															
Address:	1060 William Moore Dr Raleigh North Carolina														

		27607 United States
	<b>Type of Veterinarian:</b>	Referred veterinarian
	<b>Permission to Release Records to FDA:</b>	Yes

<b>Sender Information:</b>	<b>Name:</b>	<b>B6</b>		
	<b>Address:</b>			
		United States		
	<b>Contact:</b>	<b>Phone:</b>	<b>B6</b>	
		<b>Email:</b>		
	<b>Permission To Contact Sender:</b>	Yes		
	<b>Preferred Method Of Contact:</b>	Email		
<b>Reported to Other Parties:</b>	None			

<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b>	11 May 2018.pdf
	<b>Description:</b>		7 to 10 day recheck
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	<b>B6</b>	7 Aug 2018.pdf
	<b>Description:</b>		3 to 4 month recheck
	<b>Type:</b>	Medical Records	
	<b>Attachment:</b>	<b>B6</b>	<b>B6</b> .pdf
	<b>Description:</b>		1st visit
	<b>Type:</b>	Medical Records	

EMILED  
5/7/18

NC State University  
Veterinary Hospital  
1052 William Moore Drive  
Raleigh, NC 27607  
Discharge Comments

Fax: Admin  
Fax: Referral

Small Animal (919) 513-6500  
Large Animal (919) 513-6630

<b>Client</b> B6	<b>Patient</b> B6 MASTIFF MC FAWN CANINE	Case # B6 95.3 kg	Attending DVM Student Discharging DVM Referring DVM	B6 B6
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Admission Date/Time: MAY 03, 2018 03:42 PM Discharge Date/Time: MAY 04, 2018 03:30 PM Discharge Status:

CASE SUMMARY

DIAGNOSIS

1. Dilated cardiomyopathy - r/o primary vs diet induced
2. Atrial fibrillation
3. Congestive heart failure - pulmonary edema, abdominal effusion, pleural effusion

HISTORY

B6 is a 5 year old male castrated English Mastiff, who was presented to the NCSU B6 for lethargy and coughing with a terminal retch for four days. He was hospitalized and transferred to the NCSU Cardiology Service for further care.

B6 has been more lethargic at home for the past couple of weeks. Approximately 1 week ago he also began coughing with a terminal retch. He was taken to his primary veterinarian three days ago where bloodwork and a urinalysis were submitted for B6 B6

B6 B6 Over the past few days the coughing has progressed, and he is currently coughing 5-6 times per hour. He also refused to eat the morning of presentation, which is abnormal. Due to his progressive decline, he was presented to NCSU for further evaluation.

B6 is otherwise eating, drinking, urinating, and defecating normally. He has a history of allergies, and was started on benedryl and famotidine by his primary veterinarian at his visit a couple of days ago. He also has a history of frequent ear infections, light bulb foreign body, and naproxen toxicity. Murphy has been seen by the NCSU B6

B6 Both events resolved without hospitalization or intervention. He eats Zignature kangaroo diet (grain-free; for another dog's allergic skin disease). To supplement B6 diet, raw liver was added about 5-6 weeks ago to supply additional taurine. He is on no current medications, apart from preventative B6

B6

CV/RESP: rapid irregularly irregular tachyarrhythmia, variable and weak femoral pulses, increased lung sounds bilaterally

B6

DIAGNOSTICS

1. Big 4: PCV B6 TS B6 BC B6 Azo B6
2. Doppler blood pressure on admission: B6 mmHg
3. ECG: Atrial fibrillation with a rate of B6 bpm and infrequent left sided VPC's

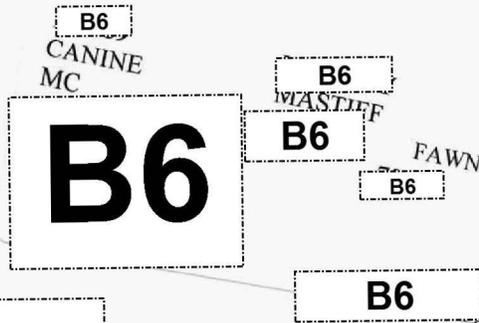
4. AFAST/TFAST - mild peritoneal effusion, no pleural or pericardial effusion

5. Echocardiogram

- a. Dilated cardiomyopathy - r/o primary vs diet induced
- b. Severely increased LV size
- c. Decreased ventricular wall thickness
- d. Moderately enlarged right ventricle
- e. Moderately reduced RV systolic function
- f. Severely dilated left atrium
- g. Moderate mitral valve regurgitation
- h. Mild to moderate tricuspid regurgitation

6. Thoracic radiographs \* final report pending \*

- a. Generalized cardiomegaly
- b. Mild pulmonary edema



**B6**

9. Whole blood taurine: pending

#### ASSESSMENT:

Thank you for bringing **B6** in to see us today. He is a sweet boy and was a pleasure to work with.

As you know, **B6** has been diagnosed with a heart condition known as dilated cardiomyopathy (DCM). DCM is a disease of unknown cause affecting the muscle of the heart and is most commonly seen in large breed dogs (such as Dobermans, Great Danes, and Labrador Retrievers). Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics and toxins have all been linked to DCM. The overall effect of DCM is a decrease in the contractility (pumping ability) of the heart. Because the heart is unable to pump with enough vigor to move blood adequately forward into circulation, a volume overload occurs and the heart dilates to accommodate it. As a result, the chambers of the heart become very large, and the walls of the heart become very thin. Ultimately, the heart is unable to accommodate and dilate further; the result is back-up of blood from the heart and into the lungs, known as congestive heart failure ("fluid on the lungs").

It is important to know that this disease is progressive, and ultimately those patients affected with it will experience congestive heart failure. Based on the results of **B6** diagnostics, it appears that he has experienced an episode of congestive heart failure secondary to DCM. This explains the clinical signs you observed at home - lethargy, panting, coughing. **B6** has responded well to heart failure medications in the hospital, and he is breathing comfortably. We will be sending him home on medications to help prevent further fluid accumulation, and improve the function of his heart. We will also recommend starting him on a supplement called taurine - that has been shown to improve heart function in DCM cases caused by nutritional deficiencies.

**B6** has also been diagnosed with an arrhythmia called atrial fibrillation (AF). Cardiac enlargement in dilated cardiomyopathy can result in this rhythm. AF arises due to an abnormality in the electrical system of the heart. In AF, the pacemaker cells' normal electrical impulses are overwhelmed by disorganized electrical impulses that originate in other areas of the atria. The result is an erratic, usually rapid, heart rhythm. Although in and of itself not life-threatening, AF may lead to the development of decreased exercise tolerance, fainting, lethargy and decreased appetite. If sustained for prolonged periods of time at very rapid rates, AF can also lead to the development of congestive heart failure, which was likely a contributing factor in **B6** episode of heart failure.

Changes in the muscle of the heart in dogs with DCM can lead to fibrosis and remodeling of the myocardium (heart muscle). This can lead to the development of ventricular arrhythmias. Intermittent ventricular arrhythmias are not dangerous, but if they occur in sequence and rapidly, they can result in sudden death. In the future we would like to place a holter monitor (24 hour ECG) to evaluate **B6** average heart rate at home, but also to evaluate for underlying ventricular arrhythmias. This can be performed at his next check appointment.

Although we cannot cure DCM, we hope to manage **B6** clinical signs with medical therapy as outlined below. The average survival for DCM patients after an episode of heart failure is 6-12 months. However, as we discussed, if **B6** DCM is secondary to a nutritional deficiency - his heart structure and function may show improvement with taurine supplementation and diet change. Please see below for diet recommendations.

Please monitor him for signs of worsening of heart failure such as increased exercise intolerance, labored breathing, increased coughing or fainting. Call NCSU Cardiology or your referring veterinarian if any of these signs occur. Also, please learn to take a respiratory (breathing) rate when your pet is resting. This can be done by counting the number of breaths your pet takes in 15 seconds and multiplying by 4 (to get the total breaths per minute). This number should remain less than 36-40 at rest.

#### INSTRUCTIONS FOR CARE

**B6**

**MONITORING:**

1. Please continue to monitor **B6** for signs of recurrent congestive heart failure. These would include exercise intolerance, increased respiratory rate, difficulty breathing, episodes of fainting/collapse, or decreased appetite. If you notice any of these signs, please contact us and have **B6** evaluated by a veterinarian.

2. Please also begin to monitor **B6** respiratory rate at home when you observe him sleeping. You can do this by counting the number of breaths he takes in 15 seconds, then multiplying this number by 4 to obtain the number of breaths per minute. A normal respiratory rate should be less than 36 breaths per minute. If you feel that **B6** respiratory rate is increasing - or if he is having more effort while breathing, please contact us.

**ACTIVITY:**

Please avoid strenuous exercise or situations which place undue stress on your **B6**. In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capability.

**DIET:**

As we discussed, we would like to change **B6** diet due to a concern for dietary induced DCM. We have seen an association between grain free diets and poor cardiac function recently. Although there is currently no scientific evidence, we have seen an increasing number of dogs with this problem. We would recommend transitioning him to a diet that contains grains. Some brands to consider include the major commercial brands (Purina, Hills, Royal Canin, Iams). There is a Royal Canin select protein adult KO diet that contains kangaroo as the protein source.

**RECOMMENDATIONS FOR FURTHER EVALUATION:**

**B6**

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pet's medical condition.

**B6**

**B6**

**B6**

Clinician

**B6**

Student - c/o 2018

Clinicians:  
Dr. Darcy Adin

**B6**

Residents:

**B6**

Clinical Technicians:

**B6**

Client Services:

**B6**

Research Technician

**B6**

In order to help expedite medication refills, please visit us online at [www.ncstatevets.org](http://www.ncstatevets.org) and select Pet Owners, Pharmacy Refills.

**B6**  
CANINE  
MC  
**B6**  
MASTIFF  
**B6**  
FAWN  
**B6**  
**B6**

**NC STATE VETERINARY HOSPITAL  
HISTORY & PHYSICAL**

**B6**  
CANINE  
MC

**B6**  
MASTIFF  
**B6** FAWN

**B6**

**B6**

Admission / Exam Date: 5/31/2018

Weight: \_\_\_\_\_  lbs  kgs \_\_\_\_\_

Temp: \_\_\_\_\_ Pulse: \_\_\_\_\_ Respiration: \_\_\_\_\_

Membrane Color: \_\_\_\_\_ Capillary Refill: \_\_\_\_\_

Body Condition: \_\_\_\_\_ Pain Score: \_\_\_\_\_

VACCINATION STATUS:			YES	NO	DATE		N	ABN	No Exam		N	ABN	No Exam
Rabies	<input type="checkbox"/>	<input type="checkbox"/>				General Appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Reproductive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Distemper or FVRCP	<input type="checkbox"/>	<input type="checkbox"/>				Integumentary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mammary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lepto or FeLV	<input type="checkbox"/>	<input type="checkbox"/>				Ophthalmic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Urinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tetanus	<input type="checkbox"/>	<input type="checkbox"/>				Otic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EEE / WEE / VEE	<input type="checkbox"/>	<input type="checkbox"/>				Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Alimentary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
West Nile Virus	<input type="checkbox"/>	<input type="checkbox"/>				Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Influenza	<input type="checkbox"/>	<input type="checkbox"/>				Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
Rhinopneumonitis	<input type="checkbox"/>	<input type="checkbox"/>											
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>				Lactating?	<input type="checkbox"/> Yes	<input type="checkbox"/> No		Pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

**CHIEF COMPLAINT:** \_\_\_\_\_

**B6**

- I. Present History
  - A. Onset / Duration
  - B. Progression
  - C. Prior Treatment
- II. Past History
  - A. Medical Illness
  - B. Surgical
  - C. Reproductive
  - D. Adverse Drug Reaction
  - E. Trauma
- III. Environment
  - IV. Preventative
  - V. Systems Review

Student Signature: \_\_\_\_\_

Clinician Signature: **B6** \_\_\_\_\_

**NCSU, COLLEGE OF VETERINARY MEDICINE  
NCSU DIAGNOSTIC LABORATORIES**

Client

Patient

Med Rec Case

**B6**

**B6**

**B6**  
MC 209.473 lbs  
TERRY CENTER TC-ICU ICU-XL

MASTIFF PAWN  
CANINE **B6**

Completed 17 of 17 Results

Request	Item	Priority	Status	Dates
<b>B6</b>	RENAL	ROUTINE	COMPLETE	Requested: 05/04/18 08:55 AM Collection: 05/04/18 08:55 AM Received: 05/04/18 09:05 AM Needed: 05/04/18 08:55 AM Status: 05/04/18 09:52 AM
Requesting DVM: Student: Comments:		<b>B6</b>		

**CHEMISTRY - RENAL PANEL**

TEST	RESULT	UNITS	REF RANGE	RESULT DATETIME
UREA NITROGEN	<b>B6</b>	MG/DL	6 - 26	05/04/2018 09:52 AM
CREATININE		MG/DL	.7 - 1.5	05/04/2018 09:52 AM
PHOSPHORUS		MG/DL	2.5 - 5.6	05/04/2018 09:52 AM
CALCIUM		MG/DL	9.4 - 11.4	05/04/2018 09:52 AM
PROTEIN- TOTAL		G/DL	5.2 - 7.3	05/04/2018 09:52 AM
ALBUMIN		G/DL	3 - 3.9	05/04/2018 09:52 AM
GLOBULIN		G/DL	1.7 - 3.8	05/04/2018 09:52 AM
ALB/GLOB RATIO			.9 - 1.8	05/04/2018 09:52 AM
SODIUM		MMOL/L	140 - 156	05/04/2018 09:52 AM
POTASSIUM		MMOL/L	4 - 5.3	05/04/2018 09:52 AM
CHLORIDE		MMOL/L	108 - 122	05/04/2018 09:52 AM
BICARBONATE		MMOL/L	18 - 26	05/04/2018 09:52 AM
ANION GAP			11.2 - 19.9	05/04/2018 09:52 AM
NA / K RATIO			27.7 - 35.9	05/04/2018 09:52 AM
ICTERIC INDEX				05/04/2018 09:52 AM
HEMOLYSIS INDEX				05/04/2018 09:52 AM
LIPEMIA INDEX				05/04/2018 09:52 AM

Comments:  
CHLORIDE

Containers  
1018-6103

**B6**

18742

B6

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

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

Vet/Tech Contact: B6
Company Name: North Carolina State University College of Veterinary Medicine
Address: Clinical Pathology Lab, Room C-269
1052 William Moore Drive
Raleigh, NC 27607
Email:
Tel: B6 Fax: 919 513-6556

Billing Contact: TAX ID:
Email: Tel:

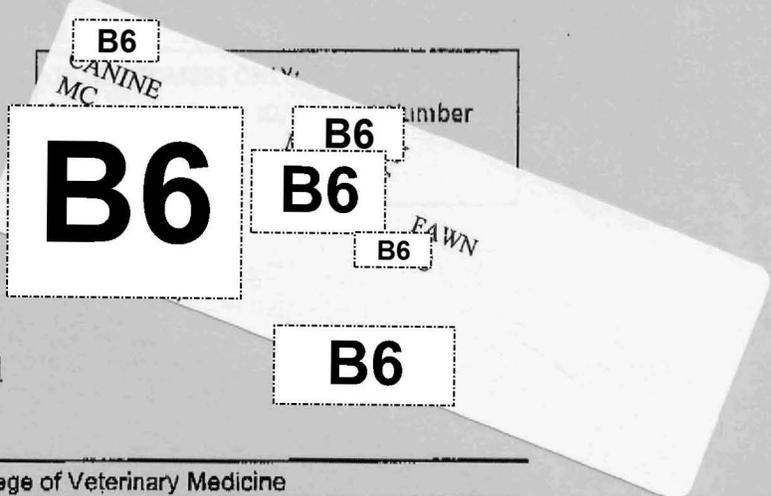
Patient Name: B6
Species: Canine
Owner's Name: B6

Sample Type: [ ] Plasma [x] Whole Blood [ ] Urine [ ] Food [ ] Other:
Test Items: [x] Taurine [ ] Complete Amino Acid [ ] Other:

Taurine Results (nmol/ml)
Plasma: Whole Blood: B6 Urine: Food:

Reference Ranges (nmol/ml)

Table with 4 columns: Species, Plasma Normal Range, Plasma No Known Risk for Taurine Deficiency, Whole Blood Normal Range, Whole Blood No Known Risk for Taurine Deficiency. Rows for Cat and Dog.



NCSU, COLLEGE OF VETERINARY MEDICINE  
NCSU DIAGNOSTIC LABORATORIES

Client

Patient

Med Rec Case **B6**

**B6**

**B6**

MC 209.475 lbs  
TERRY CENTER TC-ER ER-01

MASTIFF, FAWN  
CANINE **B6**

Completed 29 of 29 Results

Request	Item	Priority	Status	Dates
<b>B6</b>	SAF	ROUTINE	COMPLETE	Requested: 05/03/18 04:40 PM Collection: 05/03/18 04:39 PM Received: 05/03/18 04:46 PM Needed: 05/03/18 04:39 PM Status: 05/03/18 05:18 PM
Requesting DVM: <b>B6</b> Student: Comments:				

CHEMISTRY - SMALL ANIMAL CHEMISTRY PANEL

TEST	RESULT	UNITS	REF RANGE	RESULT DATETIME
GLUCOSE		MG/DL	70 - 131	05/03/2018 05:18 PM
UREA NITROGEN		MG/DL	6 - 26	05/03/2018 05:18 PM
CREATININE		MG/DL	.7 - 1.5	05/03/2018 05:18 PM
PHOSPHORUS		MG/DL	2.5 - 5.6	05/03/2018 05:18 PM
CALCIUM		MG/DL	9.4 - 11.4	05/03/2018 05:18 PM
MAGNESIUM		MG/DL	1.8 - 2.5	05/03/2018 05:18 PM
PROTEIN- TOTAL		G/DL	5.2 - 7.3	05/03/2018 05:18 PM
ALBUMIN		G/DL	3 - 3.9	05/03/2018 05:18 PM
GLOBULIN		G/DL	1.7 - 3.8	05/03/2018 05:18 PM
ALB/GLOB RATIO			.9 - 1.8	05/03/2018 05:18 PM
CHOLESTEROL		MG/DL	124 - 344	05/03/2018 05:18 PM
BILIRUBIN- TOTAL				05/03/2018 05:18 PM
ALKALINE PHOSPHATASE		IU/L	16 - 140	05/03/2018 05:18 PM
ALT		IU/L	12 - 54	05/03/2018 05:18 PM
AST	<b>B6</b>	IU/L	16 - 140	05/03/2018 05:18 PM
GGT				05/03/2018 05:18 PM
CK		IU/L	43 - 234	05/03/2018 05:18 PM
SODIUM		MMOL/L	140 - 156	05/03/2018 05:18 PM
POTASSIUM		MMOL/L	4 - 5.3	05/03/2018 05:18 PM
CHLORIDE		MMOL/L	108 - 122	05/03/2018 05:18 PM
BICARBONATE		MMOL/L	18 - 26	05/03/2018 05:18 PM
ANION GAP			11.2 - 19.9	05/03/2018 05:18 PM
NA / K RATIO			27.7 - 35.9	05/03/2018 05:18 PM
OSMOLALITY- CALC.		MOSM/KG	278.7 - 311.6	05/03/2018 05:18 PM
AMYLASE		IU/L	236 - 1337	05/03/2018 05:18 PM
LIPASE		IU/L	12 - 147	05/03/2018 05:18 PM
ICTERIC INDEX				05/03/2018 05:18 PM
HEMOLYSIS INDEX				05/03/2018 05:18 PM
LIPEMIA INDEX				05/03/2018 05:18 PM

Comments:  
CHLORIDE

Containers  
1018-6087

**B6**

Canine Echocardiography Report

Patient Name:  
Medical Rec #:  
DOB:  
Age:  
Sex:  
Sonographer:

**B6**  
Mc  
**B6**

Date of Exam: **B6**  
Breed: Mastiff  
Weight: 95 kg  
BSA: 2.10 m<sup>2</sup>  
HR:  
BP-sys:

Report Status: READ

Ref. Clinician: **B6**

Diagnosis: Dilated Cardiomyopathy w/ heart failure

Study Details: 2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The patient was awake.

2D  
IVS  
LV  
LVPW

2D  
LA Long Axis  
LA d  
Ao s  
LA/Ao

M-mode  
RV  
IVS  
LV  
LVPW  
LV normalized  
LA



Mitral Regurgitation:

MR Vmax  
MR Peak Gradient  
Est SBP by MR

**B6**

**B6**  
CANINE  
MC

**B6**

**B6**  
MASTIFF  
**B6** FAWN  
**B6**

Tricuspid valve:  
P 1/2 T

**B6**

**CLINICIAN INTERPRETATION:**

**Left Ventricle:** The left ventricular cavity size is severely increased. Ventricular wall thickness is decreased. LV basal fractional shortening is severely decreased.

**Left Atrium:** The left atrium is severely dilated.

**Right Atrium:** The right atrium is moderately dilated.

**Right Ventricle:** The right ventricular size is moderately enlarged. Global RV systolic function is

moderately reduced.

**Mitral Valve:** The E-point septal separation is increased. Moderate mitral valve regurgitation. The MR jet is centrally-directed.

**ECHO SUMMARY:**

1. The left ventricular cavity size is severely increased.
2. Ventricular wall thickness is decreased.
3. Moderately enlarged right ventricle.
4. Moderately reduced RV systolic function.
5. Severely dilated left atrium.
6. Moderately dilated right atrium.
7. Moderate mitral valve regurgitation.
8. Mild to moderate tricuspid regurgitation.

**CV Exam:**

Body condition was overweight. The animal was panting. The mucous membranes appeared pink, with a normal capillary refill time. Femoral pulse quality was difficult to assess.

**ECG:**

The heart rate measured at **B6** beats/minute. The ECG rhythm is atrial fibrillation.

**Recommendations:** The echocardiogram was limited due to patient size and stability.

This study shows evidence of dilated cardiomyopathy and atrial fibrillation. The LV is severely dilated with thin walls. The systolic function is severely reduced - with the septum moving more adequately than the LV free wall. The mitral regurgitation was difficult to quantify - but appears to be at least moderate. The left atrium is severely dilated.

The ECG shows evidence of atrial fibrillation with a ventricular response rate of **B6** bpm.

The patient eats a grain free diet (Zignature Kangaroo). Given the recent association with grain free diets and dilated cardiomyopathy - diet induced DCM is possible. However, given the breed and age idiopathic DCM is also considered.

There is a small volume of free fluid within the abdomen - consistent with R-CHF. Thoracic radiographs show mild pulmonary edema.

Treatment Recommendations

**B6**

**B6**

**B6**

Electronically signed on 5/3/2018 on 5:38:12 PM

**B6**

CANINE  
MC

**B6**

MASTIFF  
**B6**

FAWN  
**B6**

**B6**

**B6**

**Follow-up Case Information Uniform Data Entry Form  
Vet-LIRN**

Date (mm/dd/yy)

EON/CC Number:

**PATIENT INFORMATION**

Pet Name

Dog  Cat

Breed

Age in years (if < 6 months, put 0.5)

Gender:  
 M  MN  F  FS

This form serves as a Uniform Data Entry Form to capture additional case specific information not clear from the Consumer Complaint or Medical Records in a standardized manner. Because each follow-up interview made with owners features questions tailored specifically to the case, each box of information contained in this Uniform Data Entry Form may not be completed.

**HISTORY-Additional Comments from Owner**

Owner's Description of What Happened:

Any Health Problems Prior to the Event (e.g. allergies, surgeries):

Sensitive GI tract (e.g. stomach upset when switching foods, eats a lot of grass)  Yes

Changes to the pet's diet prior to illness  Yes

Date Diet Change:

**CLINICAL INFORMATION--Additional Comments from Owner on What Happened**

Appetite  Increased  Decreased

Vomiting  Yes

Diarrhea  Yes

Duration of Diarrhea (days)

Blood in Feces  Fresh,Red  
 Coffee Ground  
 Black,Tarry

Water Consumption  Increased  Decreased

Urination  Increased  Decreased

Lethargy  Yes

Other:

**MEDICATIONS-Taken Prior to the Event and Mentioned by Owner**

List medications mentioned by owner (e.g. NSAIDs, steroids, heartworm/flea prevention, antibiotics, etc.)

List probiotics, vitamins, or supplements mentioned by owner:

**Follow-up Case Information Uniform Data Entry Form  
Vet-LIRN**

EON/CC Number: 362,878

Owner:

B6

Pet's Name:

B6

DIET-Any other foods the owner mentions were given to the animal during this period. (check all that apply)

Commercial Dry Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name

fed Taste of the Wild until 1.5 to 2 yr ago, then switched to Acana Free Run Poultry-only variety, fed b/c mineral levels, first fed 1.5 to 2 year ago, 2 cups BID for each dog, measuring cup, last fed this food

Commercial Wet-Canned Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name

Commercial Wet-Pouch Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name:

Commercial-Raw Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name:

Grandma Lucy's Freeze Dried Raw (more of this than kibble)-Grain Free, 1 scoop for each dog BID, anywhere from 1/4 to 1/2 cup mixed with water, BID for each dog; Chicken flavor fed most often but

Homemade-Raw Product Use as Part of Diet:  Primary  Secondary  Occasional

Describe Product Type:

Homemade-Cooked Product Use as Part of Diet:  Primary  Secondary  Occasional

Describe Product Type:

chicken breast, green beans, carrots, long grain brown rice-sometimes in lieu of raw

Table Scraps/Human Food (as an occasional contribution to diet) Describe Product Type(s): frozen blueberries, organic pumpkin puree, peanut butter, apples,

Pet Treat Products Product Use as Part of Diet:  Primary  Secondary  Occasional

Commercial Product Label Name/Lot: Mother Hubbard tiny cookies Date first fed

How Product Administered: gotten occasionally, not handfuls daily Date last fed

Rawhides or Pig Ears Product Label Name/Lot: Bully sticks for B6 as a puppy but not recently Date first fed

How Product Administered: Date last fed

Marrow Bones Product Label Name/Lot: occ got knuckle bone but was 3 years ago Date first fed

How Product Administered: Date last fed

Chicken Jerky Product Label Name/Lot: Date first fed

How Product Administered: Date last fed

Duck Jerky Product Label Name/Lot: Date first fed

How Product Administered: Date last fed

Sweet Potato Jerky or Treats Product Label Name/Lot: Date first fed

How Product Administered: Date last fed

**Follow-up Case Information Uniform Data Entry Form  
Vet-LIRN**

EON/CC Number: 362,878

Owner:

B6

Pet's Name:

B6

DIET-continued-Any other foods the owner mentions were given to the animal during this period. (check all that apply)

Other Treats    Product Label Name/Lot: \_\_\_\_\_ Date first fed \_\_\_\_\_  
How Product Administered: \_\_\_\_\_ Date last fed \_\_\_\_\_

ENVIRONMENTAL EXPOSURES-Environmental Exposures Mentioned by the Owner Potentially Affecting the Animal's Overall State of Health Prior to the Event . (check all that apply)

- Indoor     Outdoor     Indoor & Outdoor     Carrion     Rodents     Grapes or Raisins     Nuts
- Plants     Trash     Hunt     Pet Shows     Sporting Events     Pet Recreation Facilities
- Livestock     Poultry     Reptiles     Pet Birds     Small Mammals     Untreated Surface Water
- Anti-freeze     Mushrooms     Heavy Metals     Ticks     Urban     Suburban     Rural

Comments: with owner 24/7, in and out all day long-owner: B6 outside supervised, big fenced in backyard, owner goes to barn often-exposure to whatever dog/cat/horse touched the clothing, dogs don't go to the barn with the owner;  
grape vines were growing along fence and became curious of them recently, trying to get them-owner cut them down; B6 will nibble grass; B6 will constantly try to eat mushrooms or acorns  
B6 used to do sporting events or dog social facilities until a little after they got; B6 will go hiking; see ticks crawling on them and last year both dogs were bitten once (unclear if attached)

HOUSEHOLD-Signalment of Additional Animals Given the Product mentioned by the owner.

Animal 1: B6 normal Taurine and Echocardiogram, had a minor sinus B6 does weird hacking cough: she will eat dust bunnies or  Reacted

Animal 2: \_\_\_\_\_  Reacted

Animal 3: \_\_\_\_\_  Reacted

Comments: \_\_\_\_\_

Submit

Report Details - EON-374786		
ICSR:	2060599	
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:	2018-12-27 10:09:22 EST	
Reported Problem:	<b>Problem Description:</b> Housemate was diagnosed with DCM ( <b>B6</b> ) - previously reported). <b>B6</b> 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. <b>B6</b>	
	<b>Date Problem Started:</b> 08/20/2018	
	<b>Concurrent Medical Problem:</b> Yes	
	<b>Pre Existing Conditions:</b> Hypothyroidism, incontinence, history of UTIs/crystalluria	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Acana Free Run Poultry dry	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b> <b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> <b>B6</b>	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Doberman Pinscher	
	<b>Gender:</b> Female	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 38.1 Kilogram	
	<b>Age:</b> 10 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 2	
	<b>Number of Animals Reacted:</b> 2	
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b> <b>Name:</b> <b>B6</b>
		<b>Phone:</b> <b>B6</b>
		<b>Email:</b> <b>B6</b>
	<b>Address:</b>	<b>B6</b>
United States		
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine	
	<b>Contact:</b> <b>Name:</b> Lisa Freeman	

			<b>Phone:</b> (508) 887-4523
			<b>Email:</b> lisa.freeman@tufts.edu
		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		
<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b>	medical records.pdf
	<b>Description:</b>	Medical records	
	<b>Type:</b>	Medical Records	

Client: **B6**  
Address: **B6**

Home Phone: **B6**  
Work Phone: **B6**  
Cell Phone: **B6**

**All Medical Records**

Patient: **B6**  
Breed: English Bulldog  
DOB: **B6**

Species: Canine  
Sex: Female  
(Spayed)

**Referring Information**

---

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

---

**Initial Complaint:**

New **B6** DCM study

SOAP Text Feb 20 2019 3:37PM **B6**

---

**Disposition/Recommendations**

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Client:

**B6**

Patient:

---

---

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:	<b>B6</b>
Veterinarian:	
Patient ID:	<b>B6</b>
Visit ID:	

Patient:	<b>B6</b>
Species:	Canine
Breed:	English Bulldog
Sex:	Female (Spayed)
Age:	<b>B6</b> Years Old

**Lab Results Report**

Accession ID:			
Test	Results	Reference Range	Units



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

**CBC/CHEM**



**Tufts Cummings School Of Veterinary Medicine**

200 Westboro Road  
North Grafton, MA 01536

**DUPLICATE**

Name/DOB: **B6**      Sex: SF      Provider: **B6**  
Patient ID: **B6**      Age: 8      Order Location: V3205597 Investigation into  
Phone number:      Species: Canine      Sample ID: 1902200170  
Collection Date: 2/20/2019 3:39 PM      Breed:  
Approval date: 2/20/2019 5:50 PM

**CBC, Comprehensive, Sm Animal (Research)**

02/20/19	5:50 PM	<b>B6</b>	
SMACHUNSKI			Ref. Range/Females
WBC (ADVIA)		<b>B6</b>	4.40-15.10 K/uL
RBC (Advia)		<b>B6</b>	5.80-8.50 M/uL
Hemoglobin (ADVIA)		<b>B6</b>	13.3-20.5 g/dL
Hematocrit (Advia)		<b>B6</b>	39-55 %
MCV (ADVIA)		<b>B6</b>	64.5-77.5 fL
MCH (ADVIA)		<b>B6</b>	21.3-25.9 pg
CHCM		<b>B6</b>	
MCHC (ADVIA)		<b>B6</b>	31.9-34.3 g/dL
RDW (ADVIA)		<b>B6</b>	11.9-15.2
Platelet Count (Advia)		<b>B6</b>	173-486 K/uL
Mean Platelet Volume (Advia)		<b>B6</b>	8.29-13.20 fl
02/20/19	3:56 PM	<b>B6</b>	
Platelet Crit		<b>B6</b>	0.129-0.403 %
02/20/19	3:56 PM	<b>B6</b>	
PDW		<b>B6</b>	
Reticulocyte Count (Advia)		<b>B6</b>	0.20-1.60 %
Absolute Reticulocyte Count (Advia)		<b>B6</b>	14.7-113.7 K/uL
CHr		<b>B6</b>	
MCVr		<b>B6</b>	

**Microscopic Exam of Blood Smear (Advia)**

SMACHUNSKI			Ref. Range/Females
Seg Neuts (%)		<b>B6</b>	43-86 %
Lymphocytes (%)		<b>B6</b>	7-47 %
Monocytes (%)		<b>B6</b>	1-15 %
Eosinophils (%)		<b>B6</b>	0-16 %
Seg Neutrophils (Abs) Advia		<b>B6</b>	2.800-11.500 K/uL
Lymphs (Abs) Advia		<b>B6</b>	1.00-4.80 K/uL
Mono (Abs) Advia		<b>B6</b>	0.10-1.50 K/uL
Eosinophils (Abs) Advia		<b>B6</b>	0.00-1.40 K/uL
WBC Morphology		<b>B6</b>	
RBC Morphology		<b>B6</b>	
Poikilocytosis		<b>B6</b>	

**Research Chemistry Profile - Small Animal (Cobas)**

Sample ID: 1902200170/1  
This report continues... (Final)

Reviewed by: \_\_\_\_\_

Client: **B6**  
Patient:

**CBC/CHEM**



**Tufts Cummings School Of Veterinary Medicine**

200 Westboro Road  
North Grafton, MA 01536

**DUPLICATE**

Name/DOB:	<b>B6</b>	Provider:	<b>B6</b>
Patient ID:		Order Location:	V320559: Investigation info
Phone number:		Age:	8
Collection Date:	2/20/2019 3:39 PM	Species:	Canine
Approval date:	2/20/2019 5:50 PM	Breed:	

**Research Chemistry Profile - Small Animal (Cobas) (cont'd)**

		Ref. Range/Females
DNOYES	<b>B6</b>	
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+		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		106-116 mEq/L
Potassium		3.7-5.4 mEq/L
tCO2(Bicarb)		14-28 mEq/L
AGAP		8.0-19.0
NA/K		29-40
Total Bilirubin		0.10-0.30 mg/dL
Alkaline Phosphatase		12-127 U/L
GGT		0-10 U/L
ALT	14-86 U/L	
AST	9-54 U/L	
Creatine Kinase	22-422 U/L	
Cholesterol	82-355 mg/dL	
Triglycerides	30-338 mg/dl	
Amylase	409-1250 U/L	
Osmolality (calculated)	291-315 mmol/L	

Sample ID: 1902200170/2  
REPRINT: Orig. printing on 2/20/2019 (Final)

Reviewed by: \_\_\_\_\_  
Page 2

Client: **B6**  
Patient:

**IDEXX BNP - 2/20/2019**

IDEXX Reference Laboratories

Client: **B6**

Client: **B6**  
Patient:  
Species: CANINE  
Breed: BULLDOG  
Gender: FEMALE S PAVED  
Age: 8Y

Date: 02/20/2019  
Requisition #: 1A  
Accession: **B6**  
Ordered by:

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 - CANINE	<b>B6</b>	0 - 900 pmol/L		<b>B6</b>	

**Comments**

1. **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.

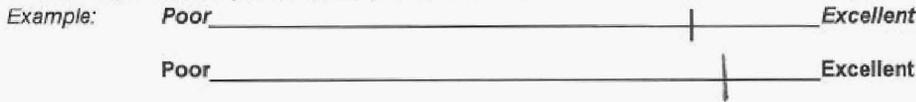
Client: **B6**  
 Patient: \_\_\_\_\_

**Diet history 2/20/19**

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

Pet's name: **B6** Owner's name: **B6** Today's date: 2/20/19

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



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

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

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

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 cup	2x/day	Jan 2016-present
85% lean hamburger	microwaved	3 oz	1x/week	June -Aug 2016
Pupperoni original beef flavor	treat	1/2	1x/day	Sept 2016-present
Rawhide	treat	6 inch twist	1x/week	Dec 2018-present
<u>SAME AS</u> <b>B6</b>				

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

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

	Brand/Concentration	Amount per day
Taurine <input type="checkbox"/> Yes <input 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
<u>Pro Biotic</u>	<u>Nature's Promise</u>	<u>50 billion</u>

3. How do you administer pills to your pet?  
 I do not give any medications  
 I put them directly in my pet's mouth without food  
 I put them in my pet's dog/cat food  
 I put them in a Pill Pocket or similar product  
 I put them in foods (list foods): \_\_\_\_\_

CHANGE TO  
RECRADINE

Client: B6  
Patient: B6

---

**Vitals Results**

---

2/20/2019 3:00:08 PM

Weight (kg)

B6

Client:  
Patient:

**B6**

---

**ECG from cardio**

---

**B6**

2/20/2019 4:05:01 PM

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

---

12 Lead: Standard Placement

**B6**

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

**ECG from cardio**

**B6**

2/20/2019 4:05:13 PM

Page 1 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

12-Lead Standard Placement

**B6**

Client: **B6**  
Patient:

---

**ECG from cardio**

---

**B6**

2/20/2019 4:05:13 PM

Page 2 of 2

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**B6**

Client: **B6**  
Patient:

**ECG from cardio**

**B6**

2/20/2019 4:05:43 PM

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Cardiology

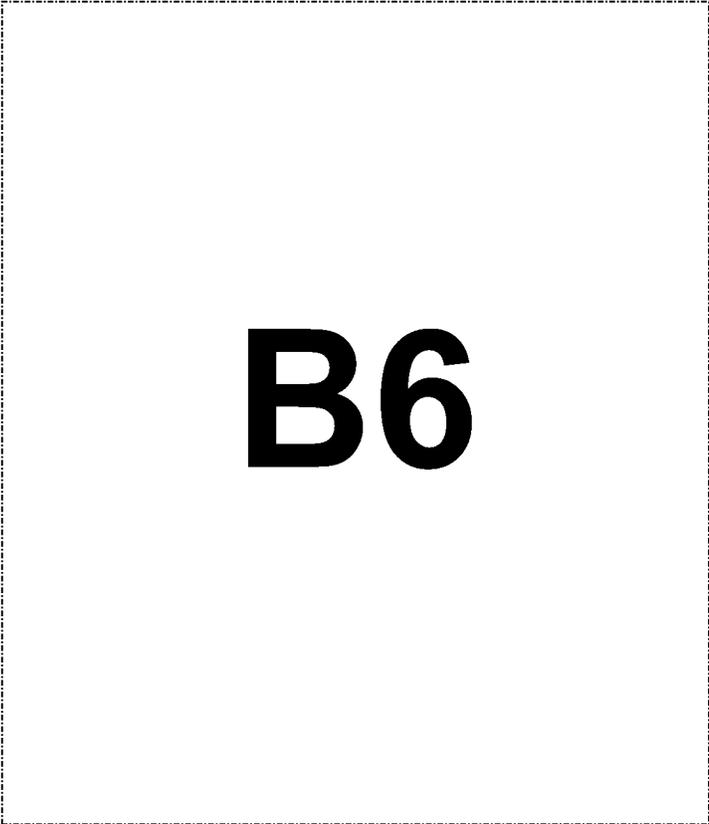
12 Lead: Standard Placement

**B6**

Client: **B6**  
Patient:

**Patient History**

02/08/2019 09:18 AM Appointment  
02/12/2019 10:57 AM Appointment  
02/13/2019 09:14 AM Appointment  
  
02/13/2019 10:56 AM Appointment  
  
02/20/2019 02:30 PM UserForm  
02/20/2019 02:56 PM Treatment  
02/20/2019 02:57 PM Treatment  
02/20/2019 03:00 PM Vitals  
02/20/2019 03:00 PM Purchase  
02/20/2019 03:19 PM Purchase  
02/20/2019 03:19 PM Purchase  
02/20/2019 03:47 PM UserForm  
  
02/20/2019 10:42 PM Email  
02/22/2019 05:15 PM Appointment



## Discharge Instructions

**Patient**

Name: B6

Species: Canine

Brown/White Female (Spayed) English

Bulldog

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 Intern:**

B6

Student: B6

Date: 2/20/2019

**Diagnoses:**

Mild cardiac changes that could be consistent with early arrhythmogenic right ventricular cardiomyopathy (ARVC) or a component of nutritional cardiomyopathy

**Clinical Findings:**

Thank you for bringing B6 to the Tufts cardiology service today for evaluation of her heart as part of a study on DOM. You report that other than an elevated BNP, there has been no indication that B6 has had any heart issues. Her breathing rate and activity levels at home have appeared normal.

To evaluate the health of her heart, we performed an echocardiogram (echo). We also evaluated B6 heart rhythm with an electrocardiogram (EKG). On echo B6 had mildly decreased contractile function of the left ventricle. Her left atrium was mildly enlarged. Her right heart, however, was more significantly enlarged, which is something we can see with ARVC. No arrhythmias were detected on the EKG today, but we cannot rule out intermittent arrhythmia. Overall B6 changes do not clearly require medication at this stage, but we will want to monitor for progression over time. It is unclear whether the changes to Bella's heart are related to ARVC, nutrition, or some combination of things.

A blood sample was also collected for bloodwork for the study, and we will contact you as the results come in.

At this time, we will only treat B6 with the taurine supplement. We do recommend periodic echo rechecks to make sure there have been no changes to her heart over time and for the DOM study that she has been enrolled in.

**Monitoring at Home:**

Please monitor [B6] at home for any concerning cardiac signs such as increased breathing rate or effort, exercise intolerance, or collapsing episodes. If she collapses, evaluate her gums for any darker coloration. If this occurs, please have [B6] seen by a veterinarian immediately.

Please obtain a Kardia/Alivecor ECG reading from [B6] at home once every few weeks. You can email this result to [cardiovet@tufts.edu](mailto:cardiovet@tufts.edu).

**Diet Suggestions:**

We recommend feeding [B6] a commercial dog food diet, as directed by Dr Freeman.

**Exercise Recommendations:**

[B6] may continue her regular exercise regimen.

**Recommended Medications:**

[B6]  
We may not need to continue this once we get [B6] taurine results back.

**Recheck Visits:** Please call to schedule an appointment for about 3 months for a recheck echocardiogram as part of the DOM study.

Thank you for entrusting us with [B6] care. She is such a sweet girl, and was an excellent patient to work with!

Please contact our Cardiology liaison at (508)-887-4696 or email us at [cardiovet@tufts.edu](mailto:cardiovet@tufts.edu) for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

<http://vet.tufts.edu/heartsmart/>

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**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](http://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: **B6**

**B6** Canine

**B6** years Old Female (Spayed) English Bulldog  
Brown/White

### Cardiology Appointment Report

Date: 2/20/2019

#### Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

**B6**

#### Cardiology Resident:

**B6**

#### Cardiology Technician:

**B6**

Student: **B6**

#### Presenting Complaint:

DCM Study

#### Concurrent Diseases:

None

#### General Medical History:

Elevated BNP: **B6**

Had surgery for **B6** finished pain meds about a week ago.

**B6**

**B6**

{O doesn't remember} - sx corrected as a puppy

**B6**

#### Diet and Supplements:

CORE Wellness grain-free diet (dry (fish) and wet (turkey and chicken)) - 3 ounces of wet food BID, 1/4 cup dry BID

Probiotic for **B6**

#### Cardiovascular History:

Prior CHF diagnosis? N

Prior heart murmur? N

Prior ATE? N

Prior arrhythmia? N

Monitoring respiratory rate and effort at home? Y, owner thinks no higher than 40 at rest, usually 20-30

Cough? N

Shortness of breath or difficulty breathing? Not when at rest

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? Yes, when taken for long walks

**Current Medications Pertinent to CV System:**

None at this time

**Cardiac Physical Examination:**

**B6**

**Muscle condition:**

- |  |  |
|--|--|
| <input type="checkbox"/> Normal  | <input type="checkbox"/> Moderate cachexia |
| <input checked="" type="checkbox"/> Mild muscle loss: mild wasting over epaxials | <input type="checkbox"/> Marked cachexia   |

**Cardiovascular Physical Exam:**

**Murmur Grade:**

- |  |                                |
|--|--------------------------------|
| <input checked="" 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 type="checkbox"/> III/VI          |                                |

**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 type="checkbox"/> Fair   | <input type="checkbox"/> Pulse deficits   |
| <input type="checkbox"/> Good   | <input type="checkbox"/> Pulsus paradoxus                                       |
| <input type="checkbox"/> Strong | <input checked="" type="checkbox"/> Other: difficult to assess due to trembling |

**Arrhythmia:**

- |  |                                      |
|--|--------------------------------------|
| <input type="checkbox"/> None                        | <input type="checkbox"/> Bradycardia |
| <input checked="" 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:**

- 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:**

No cardiac anomalies to report

**Diagnostic plan:**

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

**Echocardiogram Findings:**

General/2-D findings: B6

**B6**

**Doppler findings:**

**B6**

**Mitral inflow:**

- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

**ECG findings:**

B6

**Assessment and recommendations:**

Echocardiogram reveals structural changes that could be consistent with ARVC, but no arrhythmia was documented today. 24 hour Holter monitor could be considered to rule out intermittent arrhythmia. Owner has a Kardia at home and will obtain monthly readings. No cardiac medications are clearly indicated based on today's exam, but recommend supplementing with taurine until blood levels return from the lab. Patient was enrolled in the DCM study. Recheck echo in 3 and 6 months for the study.

**Final Diagnosis:**

Possible early ARVC; r/o nutrition related cardiomyopathy or a combination

**Heart Failure Classification Score:**

**ISACHC Classification:**

- Ia
- Ib
- IIIa
- IIIb

II

**ACVIM Classification:**

- A
- B1
- B2

- C
- D

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

EDV(Teich)

ESV(Teich)

EF(Teich)

%FS

SV(Teich)

Ao Diam

LA Diam

LA/Ao

Max LA

TAPSE

EPSS

**B6**

cm

cm

cm

cm

cm

cm

ml

ml

%

%

ml

cm

cm

cm

cm

cm

cm

M-Mode Normalized

IVSdN

LVIDdN

LVPWdN

IVSsN

LVIDsN

LVPWsN

Ao Diam N

LA Diam N

**B6**

(0.290 - 0.520)

(1.350 - 1.730)

(0.330 - 0.530)

(0.430 - 0.710)

(0.790 - 1.140)

(0.530 - 0.780)

(0.680 - 0.890) !

(0.640 - 0.900) !

2D

SA LA

Ao Diam

SA LA / Ao Diam

IVSd

LVIDd

**B6**

cm

cm

cm

cm

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		cm
LVEDV A-L LAX		ml
LVEDV MOD LAX		ml
LVLs LAX		cm
LVA <sub>s</sub> LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml
HR		BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min
<u>Doppler</u>		
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
S'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

B6

**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  
B6 Female (Spayed)  
Canine English Bulldog  
Brown/White  
B6

2/21/2019

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 (Cardiology)

**Report Details - EON-390205**

ICSR:	2068096
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:	2019-06-11 14:55:22 EDT
Initial Report Date:	02/25/2019
Parent ICSR:	2063134
Follow-up Report to FDA Request:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Housemate (half sister: [B6]) (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated) Patient DOA when owners arrived home on [B6] Suspected sudden death. Heart muscle samples were collected by rDVM and submitted to FDA for further evaluation.
	<b>Date Problem Started:</b>	02/01/2019
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	Spinal trauma as puppy
	<b>Outcome to Date:</b>	Died Other
	<b>Date of Death:</b>	[B6]

<b>Product Information:</b>	<b>Product Name:</b>	Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Product Use Information:</b>	<b>Description:</b> Please see diet history for more info (and refer to [B6] diet history for more complete info - all dogs eat same diets)
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

<b>Animal Information:</b>	<b>Name:</b>	[B6]
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Bulldog
	<b>Gender:</b>	Male
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	22.1 Kilogram
	<b>Age:</b>	8 Years
	<b>Assessment of Prior Health:</b>	Good
	<b>Number of Animals Given the Product:</b>	6
	<b>Number of Animals Reacted:</b>	4
<b>Owner Information:</b>	<b>Owner Information provided:</b>	Yes
	<b>Contact: Name:</b>	[B6]

			Phone:	<b>B6</b>	
			Email:		
		Address:	<b>B6</b>		
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine			
	<b>Contact:</b>	<b>Name:</b>	Lisa Freeman		
		<b>Phone:</b>	(508) 887-4523		
		<b>Email:</b>	lisa.freeman@tufts.edu		
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States				
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman			
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States			
		<b>Contact:</b>	<b>Phone:</b>	5088874523	
			<b>Email:</b>	lisa.freeman@tufts.edu	
		<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email				
<b>Additional Documents:</b>					

**Report Details - EON-390203**

ICSR:	2068095
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:	2019-06-11 14:43:13 EDT
Initial Report Date:	02/25/2019
Parent ICSR:	2063135
Follow-up Report to FDA Request:	Yes

<b>Reported Problem:</b>	<b>Problem Description:</b>	Eating BEG diet - 2 other dogs in household diagnosed with DCM [B6] and [B6] - already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts 2/20/19 Probable ARVC/diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Low plasma and whole blood taurine levels - started taurine supplement 3/1/2019 Troponin [B6]
	<b>Date Problem Started:</b>	02/20/2019
	<b>Concurrent Medical Problem:</b>	Yes
	<b>Pre Existing Conditions:</b>	<b>B6</b>
	<b>Outcome to Date:</b>	Stable

<b>Product Information:</b>	<b>Product Name:</b>	Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe
	<b>Product Type:</b>	Pet Food
	<b>Lot Number:</b>	
	<b>Product Use Information:</b>	<b>Description:</b> Please see diet history for more info (and also see [B6] diet history for exact diets)
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	

<b>Animal Information:</b>	<b>Name:</b>	[B6]
	<b>Type Of Species:</b>	Dog
	<b>Type Of Breed:</b>	Bulldog
	<b>Gender:</b>	Female
	<b>Reproductive Status:</b>	Neutered
	<b>Weight:</b>	24.2 Kilogram
	<b>Age:</b>	[B6] Years
	<b>Assessment of Prior Health:</b>	Good
	<b>Number of Animals Given the Product:</b>	6
	<b>Number of Animals Reacted:</b>	4
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
	<b>Contact:</b> <b>Name:</b> [B6]	
	<b>Phone:</b> [B6]	

		<b>Email:</b> B6
	<b>Address:</b>	B6
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b>	Tufts Cummings School of Veterinary Medicine
	<b>Contact:</b>	<b>Name:</b> Lisa Freeman
		<b>Phone:</b> (508) 887-4523
		<b>Email:</b> lisa.freeman@tufts.edu
<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
	<b>Contact:</b>	<b>Phone:</b> 5088874523
		<b>Email:</b> lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes
<b>Preferred Method Of Contact:</b>	Email	
<b>Additional Documents:</b>	<b>Attachment:</b>	Follow-up med records pt 2.pdf
	<b>Description:</b>	Med records
	<b>Type:</b>	Medical Records
	<b>Attachment:</b>	Follow-up med records pt 1.pdf
	<b>Description:</b>	Med records
	<b>Type:</b>	Medical Records

Report Details - EON-369322		
ICSR:	2057941	
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 07:21:15 EDT	
Reported Problem:	<b>Problem Description:</b> DCM and CHF Euthanized for worsening heart failure and arrhythmia in September	
	<b>Date Problem Started:</b> 02/09/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Died Euthanized	
	<b>Date of Death:</b> B6	
Product Information:	<b>Product Name:</b> Merrick LID Grain Free dry (salmon, duck, or chicken)	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b>	
	<b>Package Type:</b> BAG	
	<b>Product Use Information:</b> <b>Description:</b> Merrick for ~1 year Please see diet history for other foods and previous diets (Canidae LID grain free)	
	<b>Manufacturer /Distributor Information:</b>	
	<b>Purchase Location Information:</b>	
Animal Information:	<b>Name:</b> B6	
	<b>Type Of Species:</b> Dog	
	<b>Type Of Breed:</b> Retriever - Labrador	
	<b>Gender:</b> Male	
	<b>Reproductive Status:</b> Neutered	
	<b>Weight:</b> 47 Kilogram	
	<b>Age:</b> 9 Years	
	<b>Assessment of Prior Health:</b> Excellent	
	<b>Number of Animals Given the Product:</b> 1	
	<b>Number of Animals Reacted:</b> 1	
	<b>Owner Information:</b>	<b>Owner Information provided:</b> Yes
		<b>Contact:</b> <b>Name:</b> B6
		<b>Phone:</b> B6
		<b>Email:</b> B6
	<b>Address:</b>	B6
United States		
<b>Healthcare Professional Information:</b>	<b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine	
	<b>Contact:</b> <b>Name:</b> Lisa Freeman	
	<b>Phone:</b> (508) 887-4523	
	<b>Email:</b> lisa.freeman@tufts.edu	

		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States
--	--	-----------------	---

<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman	
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	<b>Contact:</b>	<b>Phone:</b>	5088874523
		<b>Email:</b>	lisa.freeman@tufts.edu
	<b>Permission To Contact Sender:</b>	Yes	
<b>Preferred Method Of Contact:</b>	Email		

<b>Additional Documents:</b>	<b>Attachment:</b>	<b>B6</b> compiled record.pdf
	<b>Description:</b>	Compiled medical record
	<b>Type:</b>	Medical Records

---

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L  
**CC:** Reimschuessel, Renate  
**Sent:** 7/20/2018 11:01:57 PM  
**Subject:** RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

PS – I have food samples for [B6] and [B6]

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](http://www.petfoodology.org)

**From:** Freeman, Lisa  
**Sent:** Friday, July 20, 2018 6:32 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Cc:** Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>  
**Subject:** RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

Hi Jen and Renate  
I'll get permission from all 3 owners and send records. I might wait another week before calling [B6] and [B6] owners based on updates below.  
Lisa

Updates:

For [B6], WB taurine was [B6]. On [B6] We talked to owner: [B6] was having trouble breathing, they were planning to pts today but he died at home yesterday.

For [B6], taurine came back normal (plasma = [B6] WB= [B6]). Owner left a message that [B6] died on [B6] so no repeat echo. We're calling the vet to see if we can find out any additional info.

For [B6] owner told us on [B6] He collapsed twice on [B6] once at home and again at [B6] where we had him put to sleep  
No autopsy done. Not sure if I sent before but his taurine was plasma [B6] and WB [B6]

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[www.petfoodology.org](http://www.petfoodology.org)

**From:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Sent:** Friday, July 20, 2018 8:47 AM  
**To:** Freeman, Lisa <lisa.freeman@tufts.edu>  
**Cc:** Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>  
**Subject:** RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

Good morning Lisa,

Yes, we got the reports you previously submitted and recorded the information for our database. Will you please forward any medical records for:

- [REDACTED] B6 are you able to send any updates on the Taurine testing or echocardiogram (if done?)
- [REDACTED] B6 - Also was an autopsy done?

Thank you in advance and for your time to report all the cases!

Jen

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



**From:** Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]  
**Sent:** Friday, July 20, 2018 8:06 AM  
**To:** Reimschuessel, Renate <[Renate.Reimschuessel@fda.hhs.gov](mailto:Renate.Reimschuessel@fda.hhs.gov)>  
**Cc:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Subject:** RE: 800.267-FDA Case Investigation for [REDACTED] B6 (EON-358523)

Dear Renata and Jennifer

That seems reasonable. I was never contacted about the other cases that I submitted. There was some confusion about the way I submitted them so I want to be sure you actually got them ([REDACTED] B6 [REDACTED] B6). I'm sure you're all getting slammed with reports (and there will probably be even more coming now) but just wanted to check to be sure they got recorded.

Thanks

Lisa

**From:** Reimschuessel, Renate [<mailto:Renate.Reimschuessel@fda.hhs.gov>]  
**Sent:** Friday, July 20, 2018 7:55 AM  
**To:** Freeman, Lisa <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)>  
**Cc:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Subject:** RE: 800.267-FDA Case Investigation for [REDACTED] B6 (EON-358523)

Dear Lisa

Thanks for gathering the information.

I think, since we are getting so many reports since our CVM update, we should pass on the [REDACTED] B6 case as it is not clear-cut.

I think Jen is more familiar with the [REDACTED] B6 case, so I'll let her respond regarding that one.

Thank you again for all your work on this investigation.

rr

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN

**Phone 1- 240-402-5404**

Fax 301-210-4685

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

**From:** Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]  
**Sent:** Thursday, July 19, 2018 5:59 PM  
**To:** Reimschuessel, Renate <[Renate.Reimschuessel@fda.hhs.gov](mailto:Renate.Reimschuessel@fda.hhs.gov)>  
**Subject:** RE: 800.267-FDA Case Investigation for [REDACTED] B6 (EON-358523)

Dear Renate

In looking back through this case, I'm not sure this is a completely clear-cut one. The dog has degenerative mitral valve disease and CHF but also has reduced cardiac contractility so might be a combination. Do you still want me to collect the info below?

Also, I have an update on [B6] who died at home last week. I do have food from the owner if you want that.

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](http://www.petfoodology.org)

**From:** Reimschuessel, Renate <[Renate.Reimschuessel@fda.hhs.gov](mailto:Renate.Reimschuessel@fda.hhs.gov)>  
**Sent:** Tuesday, July 17, 2018 11:48 AM  
**To:** Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>  
**Subject:** 800.267-FDA Case Investigation for [B6] (EON-358523)

Dear Dr. Freeman,

Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about [B6] illness. As part of our investigation, we'd like to request:

- **Full Medical Records**

- Please email (preferred) or fax (301-210-4685) a copy of [B6] **entire** medical history (not just this event), including any referral diagnostics.

- **Phone interview** about [B6] diet and environmental exposures

- Please confirm permission to contact the owner.
- The interview generally lasts 30 minutes.

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.

**Please respond to this email so that we can initiate our investigation.**

Thank you kindly, especially for submitting multiple cases,  
Dr. Reimschuessel

Renate Reimschuessel V.M.D. Ph.D.  
Director: Vet-LIRN

*(Veterinary Laboratory Investigation and Response Network)*

Center For Veterinary Medicine, FDA,  
8401 Muirkirk Road, Laurel, MD 20708

**Phone 1- 240-402-5404** Fax 301-210-4685

**EMAIL :** [renate.reimschuessel@fda.hhs.gov](mailto:renate.reimschuessel@fda.hhs.gov)

Vet-LIRN

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

Phish-Pharm

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/Phish-Pharm/default.htm>

Aquaculture

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm>

Client: B6  
Patient: B6  
Species: CANINE  
Breed: GREAT\_DANE  
Gender: MALE  
Age: 8Y

Date: 02/21/2018  
Requisition #: 366354  
Accession #: B6  
Ordered by: B6

IDEXX VetConnect 1-888-433-9987  
TUFTS UNIVERSITY  
200 WES TBORO RD  
NORTH GRAFTON, Massachusetts 01536-1828  
508-839-7936  
Account #80735

CARDIOPET proBNP - CANINE

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

Comments:

**B6**

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

**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 11/5/18. 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:** 11/05/2018  
**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 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

		<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States	
<b>Sender Information:</b>	<b>Name:</b>	Lisa Freeman		
	<b>Address:</b>	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	<b>Contact:</b>	<b>Phone:</b>	5088874523	
		<b>Email:</b>	lisa.freeman@tufts.edu	
	<b>Permission To Contact Sender:</b>	Yes		
<b>Preferred Method Of Contact:</b>	Email			
<b>Additional Documents:</b>	<b>Attachment:</b>	compiled medical record <b>B6</b> .pdf		
	<b>Description:</b>	Medical records		
	<b>Type:</b>	Medical Records		

**Medical Record for B6**

Client: **B6**  
Address: **B6**

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

Species: Canine  
Sex: Male  
(Neutered)

Home Phone: **B6**  
Work Phone: ( ) -  
Cell Phone: **B6**

**Referring Information**

**B6**

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

**Initial Complaint:**

Emergency

**SOAP Text Nov 5 2018 6:41PM - Clinician, Unassigned FHSA**

**Subjective**

NEW VISIT (ER)

Doctor: **B6**  
Student: **B6** V19  
Presenting complaint: CHF  
Referral visit? yes  
Diagnostics completed prior to visit: at rDVM 11/5  
Bloodwork: **B6**  
Chest x-rays: Marked cardiomegaly, pulmonary edema  
EKG: atrial fibrillation reported

**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

Client: **B6**  
Patient:

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** for 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**

C/V: no murmur, Tachycardic, atrial fibrillation, poor femoral pulses

**B6**

ASSESSMENT:

A1: CHF secondary to DCM

PLAN:

**B6**

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

**B6**

Enroll in DCM diet study

**B6**

Diagnostics completed:

ECG on intake-- Atrial fibrillation

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

NOVA-- no significant findings

PCV/TS: **B6**

Diagnostics pending:

BNP

Taurine

Troponin

Client communication:

**B6**

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

Deposit & estimate status: **B6**

Resuscitation code (if admitting to ICU): **B6**

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

**SOAP Text Nov 6 2018 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 11/5 at that time radiographs showed cardiomegaly and ECG indicated atrial fibrillation. Patient was given 2 doses of **B6** (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.

Overnight respiratory rate between 20-30 with normal slight effort. Given **B6** (1.7 mg/kg dose) at intake at 7 PM (2AM dose of **B6**). Started on **B6**. EKG monitoring

Client: **B6**  
Patient:

overnight showed persistent A-fib and tachycardia **B6** Had 2+ diarrhea overnight and vomited bile at 9 PM after quickly drinking water. Ate EN Proplan overnight. Interested in Dr. Freeman's study.

**B6**

Heart: No murmurs/gallops ausculted, irregularly irregular rhythm ausculted, femoral pulses weak

**B6**

Assessments [refined to the highest level; list Rule Outs if appropriate]

A1: Enlarged heart- R/O- DCM (Dobie occult DCM vs. taurine-deficiency vs. BEG diet induced)

A2: Atrial fibrillation- R/O- secondary to DCM

A3. Wide complex QRS- R/O- atrial fibrillation w ashman's vs. VPC's vs. R on T

A4. Mass on ventral neck- R/O- thyroid tumor (thymoma vs. carcinoma) vs. lipoma vs. soft tissue sarcoma

A5. Neutrophilia- R/O- stress leukogram

A6. Elevated ALT/ALP- R/O: hepatic congestion vs. less likely primary liver disease (Doberman chronic hepatitis)

Plan

**B6**

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

---

**B6**

SOAP completed by: **B6** V'19  
SOAP reviewed by: **B6**

SOAP Text Nov 7 2018 7:19AM - Clinician, Unassigned FHSA

---

**Subjective**

**B6**

**B6**

Client: **B6**  
Patient:

Heart: Grade III/VI left apical systolic murmur, jugular pulses bottom 1/3 of neck, irregularly irregular heart beat, femoral pulses variable,

**B6**

Assessments [refined to the highest level; list Rule Outs if appropriate]

- A1: Enlarged heart- R/O- DCM (Dobie occult DCM vs. taurine-deficiency vs. BEG diet induced)
- A2: Atrial fibrillation- R/O- secondary to DCM
- A3. Grade III/VI- R/O- DMVD
- A4. Wide complex QRS- R/O- atrial fibrillation w ashman's vs. VPC's vs. R on T
- A5. Mass on ventral neck- R/O- thyroid tumor (thymoma vs. carcinoma) vs. lipoma vs. soft tissue sarcoma
- A6. Neutrophila- R/O- stress leukogram
- A7. Elevated ALT/ALP- R/O: hepatic congestion vs. less likely primary liver disease (Doberman chronic hepatitis)

Plan

**B6**

SOAP completed by: **B6** V19

SOAP reviewed by:

**Disposition/Recommendations**

---

Client:  
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: Doberman Pinscher  
 Sex: Male (Neutered)  
 Age: **B6** Years Old

**Lab Results Report**

**CBC, Comprehensive, Sm Animal** 11/5/2018 8:12:13 PM **Accession ID: B6**

Test	Results	Reference Range	Units
MPV (ADVIA)	<b>B6</b>	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)** 11/5/2018 8:12:13 PM **Accession ID: B6**

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



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

SODIUM		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	<b>B6</b>	106 - 116	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
GGT		0 - 10	U/L
ALT		14 - 86	U/L
iCO2 (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		11/5/2018 8:12:13 PM	Accession ID: <b>B6</b>
Test	Results	Reference Range	Units
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
L YMPHS%		7 - 47	%
MONOS%	<b>B6</b>	1 - 15	%
SEGS%		43 - 86	%
L YMPHS (ABS)ADVIA		1 - 4.8	K/uL
WBC MORPHOLOGY		0 - 0	
No Morphologic Abnormalities			
SEGS (AB)ADVIA	<b>B6</b>	2.8 - 11.5	K/ul



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

POIKILOCYTOSIS **B6** 0 - 0

**Nova Full Panel-ICU** 11/5/2018 8:12:13 PM **Accession ID: B6**

Test	Results	Reference Range	Units
nMG	<b>B6</b>	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	
CAMG		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** 11/5/2018 8:12:13 PM **Accession ID: B6**

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



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

TS (FHSA) **B6** 0 - 0 g/dl

11/5/2018 8:12:13 PM Accession ID: **B6**

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

**Chemistry 21 (Cobas)** 11/5/2018 8:12:13 PM Accession ID: **B6**

Test	Results	Reference Range	Units
AST	<b>B6</b>	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** 11/5/2018 8:12:13 PM Accession ID: **B6**

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



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

**IDEXX BNP** **B6**

IDEXX Reference Laboratories

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

Client: **B6**  
Patient: **B6**  
Species: CANINE  
Breed: DOBERMAN\_PINSCH  
Gender: MALE  
Age: BY

Date: 11/06/2018  
Requisition #: 1A  
Accession #: **B6**  
Ordered by: **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	<b>B6</b>	0 - 900 pmol/L	HIGH		<b>B6</b>

**Comments:**

1: **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: **B6**  
Patient:

**Vitals Results**

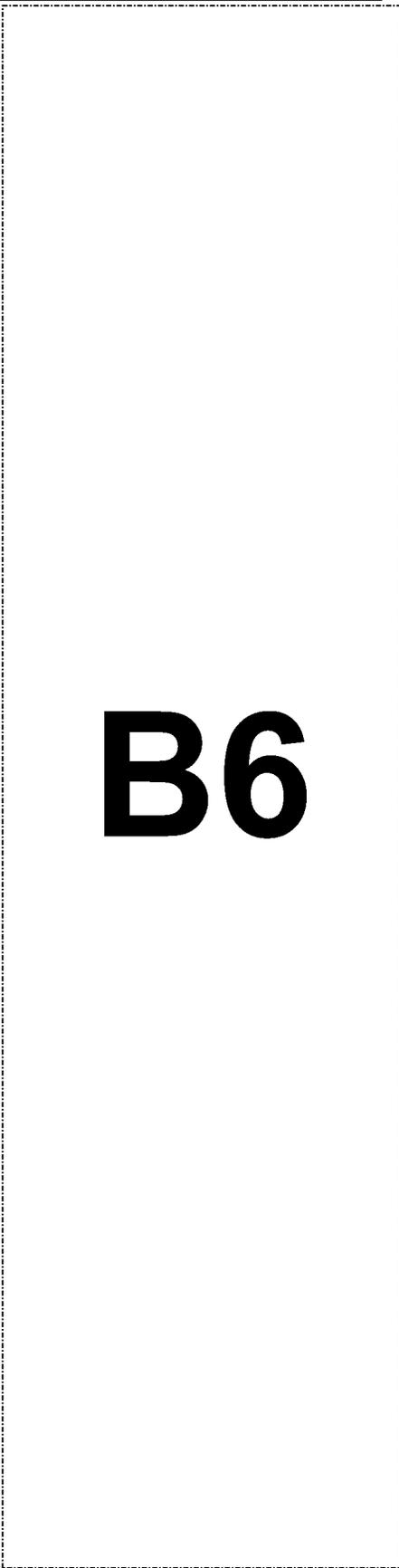
11/5/2018 7:10:41 PM	Lasix treatment note
11/5/2018 7:15:25 PM	Heart Rate (/min)
11/5/2018 7:15:26 PM	Respiratory Rate
11/5/2018 7:15:27 PM	Temperature (F)
11/5/2018 7:15:28 PM	Weight (kg)
11/5/2018 8:50:18 PM	Amount eaten
11/5/2018 8:59:52 PM	Respiratory Rate
11/5/2018 9:00:02 PM	Cardiac rhythm
11/5/2018 9:00:03 PM	Heart Rate (/min)
11/5/2018 9:00:07 PM	Nursing note
11/5/2018 9:04:11 PM	Respiratory Rate
11/5/2018 9:41:42 PM	Respiratory Rate
11/5/2018 9:42:35 PM	Cardiac rhythm
11/5/2018 9:42:36 PM	Heart Rate (/min)
11/5/2018 11:05:47 PM	Cardiac rhythm
11/5/2018 11:05:48 PM	Heart Rate (/min)
11/5/2018 11:05:58 PM	Respiratory Rate
11/5/2018 11:27:54 PM	Eliminations
11/5/2018 11:28:35 PM	Eliminations
11/5/2018 11:28:49 PM	Catheter Assessment
11/6/2018 12:16:11 AM	Heart Rate (/min)
11/6/2018 12:16:12 AM	Cardiac rhythm
11/6/2018 12:16:24 AM	Respiratory Rate
11/6/2018 12:25:01 AM	Nursing note
11/6/2018 1:03:51 AM	Cardiac rhythm
11/6/2018 1:03:52 AM	Heart Rate (/min)
11/6/2018 1:04:30 AM	Respiratory Rate
11/6/2018 1:57:40 AM	Respiratory Rate
11/6/2018 1:58:50 AM	Cardiac rhythm
11/6/2018 1:58:51 AM	Heart Rate (/min)
11/6/2018 1:59:44 AM	Nursing note
11/6/2018 3:04:07 AM	Cardiac rhythm
11/6/2018 3:04:08 AM	Heart Rate (/min)
11/6/2018 3:06:27 AM	Respiratory Rate
11/6/2018 3:32:24 AM	Catheter Assessment
11/6/2018 3:34:43 AM	Amount eaten
11/6/2018 4:06:30 AM	Cardiac rhythm
11/6/2018 4:06:31 AM	Heart Rate (/min)
11/6/2018 4:06:49 AM	Respiratory Rate
11/6/2018 5:00:14 AM	Eliminations

**B6**

Client: B6  
Patient:

**Vitals Results**

11/6/2018 5:24:57 AM	Cardiac rhythm
11/6/2018 5:24:58 AM	Heart Rate (/min)
11/6/2018 5:25:15 AM	Respiratory Rate
11/6/2018 5:46:22 AM	Respiratory Rate
11/6/2018 5:46:49 AM	Cardiac rhythm
11/6/2018 5:46:50 AM	Heart Rate (/min)
11/6/2018 6:31:20 AM	Cardiac rhythm
11/6/2018 6:31:21 AM	Heart Rate (/min)
11/6/2018 6:31:40 AM	Respiratory Rate
11/6/2018 7:12:38 AM	Respiratory Rate
11/6/2018 7:12:54 AM	Temperature (F)
11/6/2018 7:13:08 AM	Cardiac rhythm
11/6/2018 7:13:09 AM	Heart Rate (/min)
11/6/2018 7:13:51 AM	Weight (kg)
11/6/2018 7:13:59 AM	Catheter Assessment
11/6/2018 7:16:21 AM	Body Condition Score (BCS)
11/6/2018 7:16:22 AM	Muscle Condition Score (MCS)
11/6/2018 7:16:23 AM	Pain assessment
11/6/2018 9:19:06 AM	Respiratory Rate
11/6/2018 9:36:24 AM	Cardiac rhythm
11/6/2018 9:36:25 AM	Heart Rate (/min)
11/6/2018 9:58:09 AM	Cardiac rhythm
11/6/2018 9:58:10 AM	Heart Rate (/min)
11/6/2018 10:06:41 AM	Lasix treatment note
11/6/2018 10:07:04 AM	Catheter Assessment
11/6/2018 10:15:59 AM	Eliminations
11/6/2018 10:16:39 AM	Respiratory Rate
11/6/2018 11:31:33 AM	Cardiac rhythm
11/6/2018 11:31:34 AM	Heart Rate (/min)
11/6/2018 11:33:55 AM	Respiratory Rate
11/6/2018 11:37:52 AM	Eliminations
11/6/2018 12:02:52 PM	Cardiac rhythm
11/6/2018 12:02:53 PM	Heart Rate (/min)
11/6/2018 12:03:56 PM	Respiratory Rate
11/6/2018 1:11:16 PM	Respiratory Rate
11/6/2018 1:13:44 PM	Cardiac rhythm
11/6/2018 1:13:45 PM	Heart Rate (/min)
11/6/2018 1:16:08 PM	Eliminations
11/6/2018 1:38:13 PM	Respiratory Rate
11/6/2018 1:51:30 PM	Cardiac rhythm
11/6/2018 1:51:31 PM	Heart Rate (/min)



Client: **B6**  
Patient:

**Vitals Results**

11/6/2018 3:03:10 PM	Respiratory Rate
11/6/2018 3:10:58 PM	Cardiac rhythm
11/6/2018 3:10:59 PM	Heart Rate (/min)
11/6/2018 3:36:48 PM	Lasix treatment note
11/6/2018 3:37:03 PM	Catheter Assessment
11/6/2018 4:33:09 PM	Respiratory Rate
11/6/2018 4:33:31 PM	Cardiac rhythm
11/6/2018 4:33:32 PM	Heart Rate (/min)
11/6/2018 5:08:41 PM	Cardiac rhythm
11/6/2018 5:08:42 PM	Heart Rate (/min)
11/6/2018 5:18:43 PM	Respiratory Rate
11/6/2018 6:31:11 PM	Amount eaten
11/6/2018 6:31:46 PM	Cardiac rhythm
11/6/2018 6:31:47 PM	Heart Rate (/min)
11/6/2018 6:31:55 PM	Respiratory Rate
11/6/2018 6:32:03 PM	Eliminations
11/6/2018 9:01:47 PM	Respiratory Rate
11/6/2018 9:02:04 PM	Heart Rate (/min)
11/6/2018 9:02:15 PM	Cardiac rhythm
11/6/2018 9:32:43 PM	Catheter Assessment
11/6/2018 9:32:57 PM	Respiratory Rate
11/6/2018 9:33:11 PM	Cardiac rhythm
11/6/2018 9:33:12 PM	Heart Rate (/min)
11/6/2018 9:45:07 PM	Eliminations
11/6/2018 11:17:03 PM	Respiratory Rate
11/6/2018 11:18:05 PM	Cardiac rhythm
11/6/2018 11:18:06 PM	Heart Rate (/min)
11/6/2018 11:58:17 PM	Cardiac rhythm
11/6/2018 11:58:18 PM	Heart Rate (/min)
11/6/2018 11:59:06 PM	Respiratory Rate
11/7/2018 12:45:06 AM	Respiratory Rate
11/7/2018 12:45:29 AM	Cardiac rhythm
11/7/2018 12:45:30 AM	Heart Rate (/min)
11/7/2018 1:53:36 AM	Eliminations
11/7/2018 1:53:49 AM	Respiratory Rate
11/7/2018 1:54:14 AM	Cardiac rhythm
11/7/2018 1:54:15 AM	Heart Rate (/min)
11/7/2018 2:49:27 AM	Cardiac rhythm
11/7/2018 2:49:28 AM	Heart Rate (/min)
11/7/2018 2:50:03 AM	Respiratory Rate
11/7/2018 3:26:42 AM	Catheter Assessment

**B6**

Client: **B6**  
Patient:

**Vitals Results**

11/7/2018 4:00:38 AM	Cardiac rhythm
11/7/2018 4:00:39 AM	Heart Rate (/min)
11/7/2018 4:01:06 AM	Respiratory Rate
11/7/2018 5:12:19 AM	Cardiac rhythm
11/7/2018 5:12:20 AM	Heart Rate (/min)
11/7/2018 5:12:33 AM	Respiratory Rate
11/7/2018 5:19:34 AM	Nursing note
11/7/2018 5:21:05 AM	Amount eaten
11/7/2018 5:34:53 AM	Weight (kg)
11/7/2018 5:35:01 AM	Eliminations
11/7/2018 5:54:55 AM	Respiratory Rate
11/7/2018 5:55:09 AM	Cardiac rhythm
11/7/2018 5:55:10 AM	Heart Rate (/min)
11/7/2018 6:27:18 AM	Cardiac rhythm
11/7/2018 6:27:19 AM	Heart Rate (/min)
11/7/2018 6:27:52 AM	Respiratory Rate
11/7/2018 7:18:19 AM	Respiratory Rate
11/7/2018 7:18:32 AM	Heart Rate (/min)
11/7/2018 7:18:33 AM	Cardiac rhythm
11/7/2018 7:19:29 AM	Temperature (F)
11/7/2018 7:19:30 AM	Body Condition Score (BCS)
11/7/2018 7:19:31 AM	Muscle Condition Score (MCS)
11/7/2018 7:19:32 AM	Pain assessment
11/7/2018 7:42:35 AM	Lasix treatment note
11/7/2018 8:47:36 AM	Cardiac rhythm
11/7/2018 8:47:37 AM	Heart Rate (/min)
11/7/2018 8:47:47 AM	Respiratory Rate
11/7/2018 8:50:11 AM	Catheter Assessment
11/7/2018 9:09:21 AM	Respiratory Rate
11/7/2018 11:08:26 AM	Cardiac rhythm
11/7/2018 11:08:27 AM	Heart Rate (/min)
11/7/2018 11:20:51 AM	Respiratory Rate
11/7/2018 11:21:02 AM	Eliminations
11/7/2018 12:06:15 PM	Cardiac rhythm
11/7/2018 12:06:16 PM	Heart Rate (/min)
11/7/2018 12:06:28 PM	Respiratory Rate
11/7/2018 12:39:17 PM	Nursing note
11/7/2018 1:03:57 PM	Cardiac rhythm
11/7/2018 1:03:58 PM	Heart Rate (/min)
11/7/2018 1:04:22 PM	Respiratory Rate
11/7/2018 1:20:21 PM	Cardiac rhythm

**B6**

Client: **B6**  
Patient:

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**Vitals Results**

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11/7/2018 1:20:22 PM	Heart Rate (/min)
11/7/2018 1:20:59 PM	Respiratory Rate
11/7/2018 1:21:06 PM	Eliminations
11/7/2018 3:15:43 PM	Cardiac rhythm
11/7/2018 3:15:44 PM	Heart Rate (/min)
11/7/2018 3:16:26 PM	Respiratory Rate
11/7/2018 3:48:16 PM	Respiratory Rate
11/7/2018 3:48:26 PM	Cardiac rhythm
11/7/2018 3:48:27 PM	Heart Rate (/min)
11/7/2018 3:48:41 PM	Catheter Assessment
11/7/2018 5:47:11 PM	Nursing note

**B6**

Client: **B6**  
Patient:

**ECG from Cardio**

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**B6**

11/6/2018 11:06:07 AM

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

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**B6**

Client:  
Patient:

**B6**

**ECG from Cardio**

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**B6**

11/6/2018 11:06:48 AM

Page 1 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

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**B6**

Client:  
Patient:

**B6**

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**ECG from Cardio**

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**B6**

11/6/2018 11:06:48 AM

Page 2 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

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**B6**

Client:  
Patient:

**B6**

**ECG from Cardio**

**B6**

11/6/2018 11:07:04 AM

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

12 Lead: Standard Placement

**B6**

Client: **B6**  
Patient:

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**ECG from Cardio**

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**B6**

11/6/2018 11:07:15 AM

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

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Client: **B6**  
Patient:

**Patient History**

11/05/2018 07:05 PM Prescription  
11/05/2018 07:07 PM Prescription  
11/05/2018 07:10 PM Vitals  
11/05/2018 07:15 PM Vitals  
11/05/2018 07:15 PM Vitals  
11/05/2018 07:15 PM Vitals  
11/05/2018 07:15 PM Vitals  
11/05/2018 07:23 PM Purchase  
11/05/2018 07:23 PM Purchase  
11/05/2018 07:23 PM Purchase  
11/05/2018 08:12 PM Purchase  
11/05/2018 08:12 PM Purchase  
11/05/2018 08:13 PM Purchase  
11/05/2018 08:36 PM Labwork  
11/05/2018 08:38 PM Treatment  
11/05/2018 08:50 PM Treatment  
  
11/05/2018 08:50 PM Treatment  
  
11/05/2018 08:50 PM Vitals  
11/05/2018 08:59 PM Treatment  
11/05/2018 08:59 PM Vitals  
11/05/2018 09:00 PM Treatment  
  
11/05/2018 09:00 PM Vitals  
11/05/2018 09:00 PM Vitals  
11/05/2018 09:00 PM Vitals  
11/05/2018 09:04 PM Treatment  
11/05/2018 09:04 PM Vitals  
11/05/2018 09:19 PM Purchase  
11/05/2018 09:41 PM Treatment  
11/05/2018 09:41 PM Vitals  
11/05/2018 09:42 PM Treatment  
  
11/05/2018 09:42 PM Vitals  
11/05/2018 09:42 PM Vitals  
11/05/2018 09:42 PM Vitals  
11/05/2018 11:05 PM Treatment  
  
11/05/2018 11:05 PM Vitals  
11/05/2018 11:05 PM Vitals  
11/05/2018 11:05 PM Treatment  
11/05/2018 11:05 PM Vitals  
11/05/2018 11:27 PM Vitals  
11/05/2018 11:28 PM Treatment  
11/05/2018 11:28 PM Treatment

**B6**

Client: **B6**  
Patient:

**Patient History**

11/05/2018 11:28 PM	Vitals
11/05/2018 11:28 PM	Treatment
11/05/2018 11:28 PM	Vitals
11/06/2018 12:16 AM	Treatment
11/06/2018 12:16 AM	Vitals
11/06/2018 12:16 AM	Vitals
11/06/2018 12:16 AM	Treatment
11/06/2018 12:16 AM	Vitals
11/06/2018 12:25 AM	Vitals
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11/06/2018 01:03 AM	Vitals
11/06/2018 01:03 AM	Vitals
11/06/2018 01:04 AM	Treatment
11/06/2018 01:04 AM	Vitals
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11/06/2018 01:57 AM	Vitals
11/06/2018 01:58 AM	Treatment
11/06/2018 01:58 AM	Vitals
11/06/2018 01:58 AM	Vitals
11/06/2018 01:59 AM	Vitals
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11/06/2018 03:04 AM	Vitals
11/06/2018 03:04 AM	Vitals
11/06/2018 03:06 AM	Treatment
11/06/2018 03:06 AM	Vitals
11/06/2018 03:31 AM	Treatment
11/06/2018 03:32 AM	Treatment
11/06/2018 03:32 AM	Vitals
11/06/2018 03:34 AM	Treatment
11/06/2018 03:34 AM	Vitals
11/06/2018 03:34 AM	Vitals
11/06/2018 04:06 AM	Treatment
11/06/2018 04:06 AM	Vitals
11/06/2018 04:06 AM	Vitals
11/06/2018 04:06 AM	Treatment
11/06/2018 04:06 AM	Vitals
11/06/2018 05:00 AM	Treatment
11/06/2018 05:00 AM	Vitals
11/06/2018 05:24 AM	Treatment
11/06/2018 05:24 AM	Vitals
11/06/2018 05:24 AM	Vitals
11/06/2018 05:25 AM	Treatment
11/06/2018 05:25 AM	Vitals

**B6**

Client: **B6**  
Patient:

**Patient History**

11/06/2018 05:46 AM	Treatment
11/06/2018 05:46 AM	Vitals
11/06/2018 05:46 AM	Treatment
11/06/2018 05:46 AM	Vitals
11/06/2018 05:46 AM	Vitals
11/06/2018 06:31 AM	Treatment
11/06/2018 06:31 AM	Vitals
11/06/2018 06:31 AM	Vitals
11/06/2018 06:31 AM	Treatment
11/06/2018 06:31 AM	Vitals
11/06/2018 07:12 AM	Treatment
11/06/2018 07:12 AM	Vitals
11/06/2018 07:12 AM	Treatment
11/06/2018 07:12 AM	Vitals
11/06/2018 07:13 AM	Treatment
11/06/2018 07:13 AM	Treatment
11/06/2018 07:13 AM	Vitals
11/06/2018 07:13 AM	Vitals
11/06/2018 07:13 AM	Treatment
11/06/2018 07:13 AM	Treatment
11/06/2018 07:13 AM	Vitals
11/06/2018 07:13 AM	Treatment
11/06/2018 07:13 AM	Vitals
11/06/2018 07:14 AM	Treatment
11/06/2018 07:16 AM	Vitals
11/06/2018 07:16 AM	Vitals
11/06/2018 07:16 AM	Vitals
11/06/2018 08:10 AM	Purchase
11/06/2018 08:38 AM	Purchase
11/06/2018 08:44 AM	Purchase
11/06/2018 08:44 AM	Purchase
11/06/2018 09:19 AM	Treatment
11/06/2018 09:19 AM	Vitals
11/06/2018 09:33 AM	Deleted Reason
11/06/2018 09:36 AM	Treatment
11/06/2018 09:36 AM	Vitals
11/06/2018 09:36 AM	Vitals
11/06/2018 09:44 AM	Purchase
11/06/2018 09:57 AM	Treatment

**B6**

Client: **B6**  
Patient:

**Patient History**

11/06/2018 09:58 AM	Treatment
11/06/2018 09:58 AM	Vitals
11/06/2018 09:58 AM	Vitals
11/06/2018 10:06 AM	Vitals
11/06/2018 10:07 AM	Treatment
11/06/2018 10:07 AM	Treatment
11/06/2018 10:07 AM	Vitals
11/06/2018 10:15 AM	Treatment
11/06/2018 10:15 AM	Vitals
11/06/2018 10:16 AM	Treatment
11/06/2018 10:16 AM	Vitals
11/06/2018 10:19 AM	Purchase
11/06/2018 10:43 AM	Prescription
11/06/2018 11:03 AM	Purchase
11/06/2018 11:25 AM	Purchase
11/06/2018 11:31 AM	Treatment
11/06/2018 11:31 AM	Vitals
11/06/2018 11:31 AM	Vitals
11/06/2018 11:33 AM	Treatment
11/06/2018 11:33 AM	Vitals
11/06/2018 11:37 AM	Treatment
11/06/2018 11:37 AM	Vitals
11/06/2018 12:02 PM	Treatment
11/06/2018 12:02 PM	Vitals
11/06/2018 12:02 PM	Vitals
11/06/2018 12:03 PM	Treatment
11/06/2018 12:03 PM	Vitals
11/06/2018 12:55 PM	UserForm
11/06/2018 12:57 PM	UserForm
11/06/2018 12:58 PM	Treatment
11/06/2018 01:10 PM	Treatment
11/06/2018 01:11 PM	Treatment
11/06/2018 01:11 PM	Vitals
11/06/2018 01:13 PM	Treatment
11/06/2018 01:13 PM	Vitals
11/06/2018 01:13 PM	Vitals
11/06/2018 01:16 PM	Treatment
11/06/2018 01:16 PM	Vitals

**B6**

Client: **B6**  
Patient:

**Patient History**

11/06/2018 01:30 PM Treatment  
11/06/2018 01:30 PM Treatment  
11/06/2018 01:38 PM Treatment  
11/06/2018 01:38 PM Vitals  
11/06/2018 01:43 PM UserForm  
  
11/06/2018 01:51 PM Treatment  
  
11/06/2018 01:51 PM Vitals  
11/06/2018 01:51 PM Vitals  
11/06/2018 03:03 PM Treatment  
11/06/2018 03:03 PM Vitals  
11/06/2018 03:10 PM Treatment  
  
11/06/2018 03:10 PM Vitals  
11/06/2018 03:10 PM Vitals  
11/06/2018 03:36 PM Vitals  
11/06/2018 03:37 PM Treatment  
11/06/2018 03:37 PM Treatment  
11/06/2018 03:37 PM Vitals  
  
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11/06/2018 04:33 PM Vitals  
11/06/2018 04:33 PM Treatment  
  
11/06/2018 04:33 PM Vitals  
11/06/2018 04:33 PM Vitals  
11/06/2018 05:08 PM Treatment  
  
11/06/2018 05:08 PM Vitals  
11/06/2018 05:08 PM Vitals  
11/06/2018 05:18 PM Treatment  
11/06/2018 05:18 PM Vitals  
11/06/2018 06:29 PM Prescription  
11/06/2018 06:31 PM Treatment  
  
11/06/2018 06:31 PM Treatment  
  
11/06/2018 06:31 PM Treatment  
  
11/06/2018 06:31 PM Vitals  
11/06/2018 06:31 PM Treatment  
11/06/2018 06:31 PM Treatment  
  
11/06/2018 06:31 PM Vitals  
11/06/2018 06:31 PM Vitals  
11/06/2018 06:31 PM Treatment  
11/06/2018 06:31 PM Vitals  
11/06/2018 06:32 PM Treatment  
11/06/2018 06:32 PM Vitals  
11/06/2018 09:01 PM Treatment

**B6**

Client: B6  
Patient:

**Patient History**

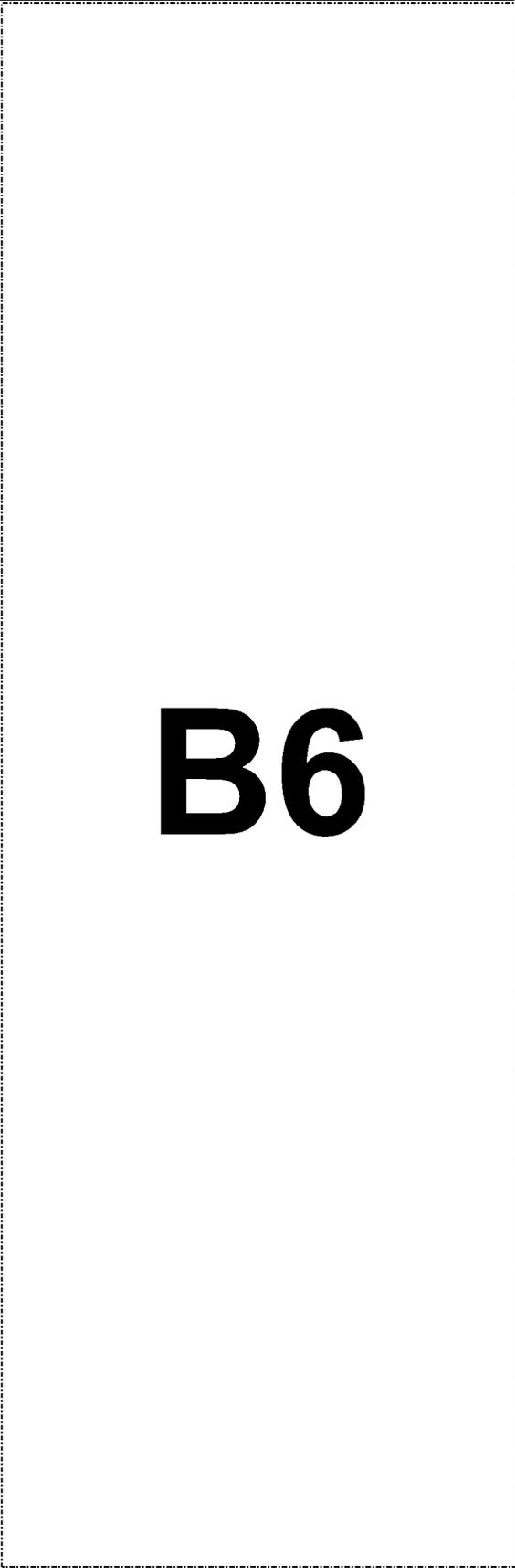
11/06/2018 09:01 PM	Treatment
11/06/2018 09:01 PM	Vitals
11/06/2018 09:02 PM	Vitals
11/06/2018 09:02 PM	Vitals
11/06/2018 09:32 PM	Treatment
11/06/2018 09:32 PM	Treatment
11/06/2018 09:32 PM	Treatment
11/06/2018 09:32 PM	Vitals
11/06/2018 09:32 PM	Treatment
11/06/2018 09:32 PM	Vitals
11/06/2018 09:33 PM	Treatment
11/06/2018 09:33 PM	Vitals
11/06/2018 09:33 PM	Vitals
11/06/2018 09:44 PM	Treatment
11/06/2018 09:45 PM	Treatment
11/06/2018 09:45 PM	Vitals
11/06/2018 11:17 PM	Treatment
11/06/2018 11:17 PM	Vitals
11/06/2018 11:18 PM	Treatment
11/06/2018 11:18 PM	Vitals
11/06/2018 11:18 PM	Vitals
11/06/2018 11:58 PM	Treatment
11/06/2018 11:58 PM	Vitals
11/06/2018 11:58 PM	Vitals
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11/06/2018 11:59 PM	Vitals
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11/07/2018 12:45 AM	Vitals
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11/07/2018 12:45 AM	Vitals
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11/07/2018 01:11 AM	Treatment
11/07/2018 01:53 AM	Treatment
11/07/2018 01:53 AM	Vitals
11/07/2018 01:53 AM	Treatment
11/07/2018 01:53 AM	Vitals
11/07/2018 01:53 AM	Treatment
11/07/2018 01:54 AM	Treatment
11/07/2018 01:54 AM	Vitals
11/07/2018 01:54 AM	Vitals
11/07/2018 02:49 AM	Treatment
11/07/2018 02:49 AM	Vitals

**B6**

Client: **B6**  
Patient:

**Patient History**

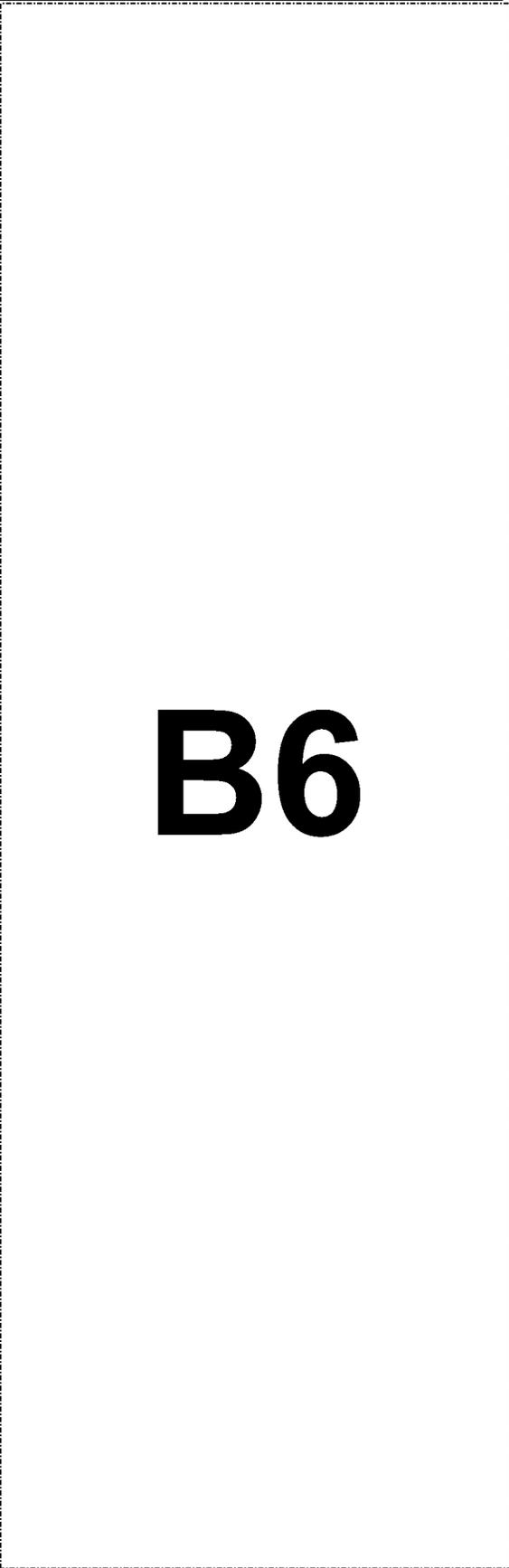
11/07/2018 02:49 AM Vitals  
11/07/2018 02:50 AM Treatment  
11/07/2018 02:50 AM Vitals  
11/07/2018 03:26 AM Treatment  
11/07/2018 03:26 AM Vitals  
11/07/2018 04:00 AM Treatment  
  
11/07/2018 04:00 AM Vitals  
11/07/2018 04:00 AM Vitals  
11/07/2018 04:01 AM Treatment  
11/07/2018 04:01 AM Vitals  
11/07/2018 05:12 AM Treatment  
  
11/07/2018 05:12 AM Vitals  
11/07/2018 05:12 AM Vitals  
11/07/2018 05:12 AM Treatment  
11/07/2018 05:12 AM Vitals  
11/07/2018 05:19 AM Treatment  
11/07/2018 05:19 AM Treatment  
  
11/07/2018 05:19 AM Vitals  
11/07/2018 05:20 AM Treatment  
  
11/07/2018 05:21 AM Treatment  
  
11/07/2018 05:21 AM Vitals  
11/07/2018 05:34 AM Treatment  
11/07/2018 05:34 AM Vitals  
11/07/2018 05:35 AM Treatment  
11/07/2018 05:35 AM Vitals  
11/07/2018 05:54 AM Treatment  
11/07/2018 05:54 AM Vitals  
11/07/2018 05:55 AM Treatment  
  
11/07/2018 05:55 AM Vitals  
11/07/2018 05:55 AM Vitals  
11/07/2018 06:27 AM Treatment  
  
11/07/2018 06:27 AM Vitals  
11/07/2018 06:27 AM Vitals  
11/07/2018 06:27 AM Treatment  
11/07/2018 06:27 AM Vitals  
11/07/2018 06:59 AM Purchase  
11/07/2018 07:18 AM Treatment  
11/07/2018 07:18 AM Vitals  
11/07/2018 07:18 AM Treatment  
  
11/07/2018 07:18 AM Vitals  
11/07/2018 07:18 AM Vitals  
11/07/2018 07:19 AM Vitals



Client: **B6**  
Patient:

**Patient History**

11/07/2018 07:19 AM Vitals  
11/07/2018 07:19 AM Vitals  
11/07/2018 07:19 AM Vitals  
11/07/2018 07:42 AM Vitals  
11/07/2018 07:42 AM Treatment  
11/07/2018 08:47 AM Treatment  
  
11/07/2018 08:47 AM Vitals  
11/07/2018 08:47 AM Vitals  
11/07/2018 08:47 AM Treatment  
11/07/2018 08:47 AM Vitals  
11/07/2018 08:48 AM Treatment  
11/07/2018 08:50 AM Treatment  
11/07/2018 08:50 AM Vitals  
11/07/2018 08:56 AM Treatment  
  
11/07/2018 09:09 AM Treatment  
11/07/2018 09:09 AM Vitals  
11/07/2018 11:08 AM Treatment  
  
11/07/2018 11:08 AM Vitals  
11/07/2018 11:08 AM Vitals  
11/07/2018 11:20 AM Treatment  
11/07/2018 11:20 AM Vitals  
11/07/2018 11:21 AM Treatment  
11/07/2018 11:21 AM Vitals  
11/07/2018 12:06 PM Treatment  
  
11/07/2018 12:06 PM Vitals  
11/07/2018 12:06 PM Vitals  
11/07/2018 12:06 PM Treatment  
11/07/2018 12:06 PM Vitals  
11/07/2018 12:39 PM Vitals  
11/07/2018 01:03 PM Treatment  
  
11/07/2018 01:03 PM Vitals  
11/07/2018 01:03 PM Vitals  
11/07/2018 01:04 PM Treatment  
11/07/2018 01:04 PM Vitals  
11/07/2018 01:04 PM Treatment  
11/07/2018 01:20 PM Treatment  
  
11/07/2018 01:20 PM Vitals  
11/07/2018 01:20 PM Vitals  
11/07/2018 01:20 PM Treatment  
11/07/2018 01:20 PM Vitals  
11/07/2018 01:21 PM Treatment  
11/07/2018 01:21 PM Vitals  
11/07/2018 02:53 PM Purchase  
11/07/2018 03:15 PM Treatment



Client: **B6**  
Patient:

**Patient History**

11/07/2018 03:15 PM	Vitals
11/07/2018 03:15 PM	Vitals
11/07/2018 03:16 PM	Treatment
11/07/2018 03:16 PM	Vitals
11/07/2018 03:40 PM	Labwork
11/07/2018 03:48 PM	Treatment
11/07/2018 03:48 PM	Vitals
11/07/2018 03:48 PM	Treatment
11/07/2018 03:48 PM	Vitals
11/07/2018 03:48 PM	Vitals
11/07/2018 03:48 PM	Treatment
11/07/2018 03:48 PM	Vitals
11/07/2018 04:45 PM	Prescription
11/07/2018 04:45 PM	Prescription
11/07/2018 04:47 PM	Prescription
11/07/2018 04:47 PM	Prescription
11/07/2018 04:48 PM	Prescription
11/07/2018 05:47 PM	Treatment
11/07/2018 05:47 PM	Treatment
11/07/2018 05:47 PM	Treatment
11/07/2018 05:47 PM	Vitals

**B6**







**Radiology Request & Report**

**Patient**

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

**Owner**

Name: B6  
Address: B6

Patient ID: B6  
Date of request: B6

Attending Clinician: B6 DVM (Resident - Cardiology)

Student:

Date of exam: 11/7/18

Patient Location: Ward/Cage:

Weight (kg) 45.20

**Sedation**

- Inpatient
- Outpatient Time:
- Waiting
- Emergency

- 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 B6 and referred here. 1 dose of B6 overnight.

**Findings:**

THORAX, SINGLE LATERAL VIEW, TWO IMAGES (compared to RDVM study dated 11/5/18 in SS): Evaluation of the cardiac silhouette is slightly limited due to superimposed thoracic limb and collimation of the ventral portion of the thorax. The cardiac silhouette remains enlarged in height with straightening of the caudal cardiac border. The pulmonary vessels are within normal limits. The previously seen marked perihilar interstitial pattern appears markedly improved, however the lung fields are not completely evaluated. A small amount of gas is seen within the thoracic esophagus. The imaged cranial abdomen is within normal limits. No osseous abnormalities are detected.

**Conclusions:**

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

**Radiologists**

Primary: B6 DVM

Reviewing: B6 DVM, DACVR

**Dates**

Reported: 11/6/18

Finalized: 11/7/18

### Discharge Instructions

**Patient**

Name: B6

Species: Canine

Black/Tan Male (Neutered) Doberman

Pinscher

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

Student: B6 V19

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Admit Date: 11/5/2018 6:19:57 PM

Discharge Date: 11/6/2018

**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, B6 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.

An echocardiogram (ultrasound of the heart) revealed dilation and thinning of the walls of his heart consistent with a disease called dilated cardiomyopathy (DCM). On his EKG in addition to his atrial fibrillation, he had ventricular beats (presented as couplets and triplets) which can be concerning as they can lead to life-threatening arrhythmias. We also repeated chest x-rays on B6 which showed improvement in the congestion in his lung. His bloodwork showed normal kidney value but slightly elevated liver enzymes. We suspect this is secondary to his heart disease but is something we will monitor through bloodwork in the future. His ventricular arrhythmia improved overnight and he continued to breathe well. We feel he is ready to go home with you for continued care and monitoring.

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.

**Monitor at home:**

**B6**

**Recommended Medications:**

**B6**

# 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 (<http://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. As you have been trying to reduce B6 weight, we recommend Purina Pro Plan Adult Weight Management as it is a good weight management diet that is low in sodium. If you would like to put a small amount of wet food to entice him to eat, there are canned food recommendations below as well.

- 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 Bode 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/uom613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Pet Foodology 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.

## Dry Food Options:

**Purina Pro Plan Adult Weight Management.**

## 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+

## 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 visit is recommended in 1-2 weeks after any medication adjustments are made. At this visit we will check your dog's breathing effort and heart function, do a blood test to recheck kidney and liver values. A recheck echocardiogram is recommended in 3-4 months.

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/>

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**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](http://vet.tufts.edu/cvmc/clinical-studies)*

---

Case: B6

Owner: B6

Discharge Instructions

### **AliveCor/Kardia Handout**

If you have an iPhone or Android, you may want to explore the option of purchasing an AliveCor/Kardia ECG monitor which will allow you to record and email your pet's heart rate and rhythm at home.

The device (Kardia) can be purchased at [www.alivecor.com](http://www.alivecor.com) or [www.amazon.com](http://www.amazon.com). The app for your phone is free.

#### **If you have an iPhone:**

- Search for 'Veterinary AliveECG' app in the Apple Store
- You will need to sign-up for an account
- Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker port, say **'OK/allow'**

#### **If you have an Android:**

- Search for 'Kardia' app in the Google Playstore
- You will need to sign-up for an account.
- Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker port, say **'OK/allow'**
- Once downloaded, it will require you to send a "test ECG" for activation of the app. Just place your fingers on the silver sensors and let it record
- If the test ECG is unable to record, try again, with less movement. If it still fails, then your phone is not compatible with the device

#### **Recording an ECG:**

- Apply rubbing alcohol (soaked cotton ball will work) to the chest region behind your pet's elbow (where you can feel the heartbeat)
- Enough to wet the regions where both silver boxes will touch the animal
- If your pet is fluffy, you may have to clip a small patch of fur to allow for better contact
- Hold the device against your pet's chest with the silver areas being up and down (vertical) in contact with the animal
- With the app open, hold your phone near (within a few inches) the device.
- There is a signal bar in the upper left corner of the app to show whether it detects the device. If there are no bars then move your phone around/get closer to the device until they appear.
- Once you see a recording, hold everything in place for at least 30 seconds if possible.
- *The human Kardia app will attempt to interpret the ECG; just ignore this as it is not always accurate.*
- *The heart rate that the apps report is also not always accurate.*

**Saving an ECG:**

- The app will automatically save the ECG as long as the recording is long enough (>20seconds)
- You can click on the ID (box with pencil icon) in the Veterinary AliveECG app to add your pet's name

**Emailing an ECG:**

- If you are in the recording screen on the Veterinary AliveECG app, click on "ECGs" to see the list of saved ECGs
- If you are in the home screen on the Kardia app, click "History".
- Select the ECG you wish to send. Go to "Share". Select "Email PDF". **SKIP** the Password protect feature and select the email app you wish to send it by (Gmail, outlook, yahoo, etc). **You must have a working email on your phone for this to work.**
- Select an ECG that you wish to send
- Click the mail icon (either a box with arrow or a letter symbol), and select "Email"
- Email to: [cardiovet@tufts.edu](mailto:cardiovet@tufts.edu) (only monitored Monday-Friday 9AM-5PM)

# Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY  
Cardiology Liaison: 508-887-4696

**B6**

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

## Cardiology Inpatient

Date: 11/6/2018

Weight: Weight (kg) 45.20

### Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

**B6**

### Cardiology Resident:

**B6**

### Thoracic radiographs available for review?

- Yes - in SS  
 Yes - in PACS  
 No

### Presenting complaint and important concurrent diseases:

DCM, CHF, a-fib

**\*STOP - remainder of form to be filled out by Cardiology\***

### Physical Examination

**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

- 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

**B6**

**Doppler findings:**

**Mitral inflow:**

- Summated
- Normal
- Delayed relaxation

- Pseudonormal
- Restrictive

**Blood Pressure (mmHg):**

Cuff size:

Limb:

**B6**

# B6

**Assessment and recommendations:** Findings consistent with active congestive heart failure due to dilated cardiomyopathy (DCM) and atrial fibrillation. Considering breed predisposition, unclear whether DCM is a primary cause or this is diet induced (patient has been on grain free diet for years). Patients on DCM with CHF demands lifelong treatment in order to improve systolic function and avoid fluid accumulation. However, recommend Taurine supplementation as some patients can benefit from it. Atrial fibrillation with fast ventricular rate worsens systolic function, which makes prognosis and life expectancy lower than in animals without the arrhythmia. Thus decrease HR is necessary and B6 is recommended. Patient should be under telemetry monitoring during hospitalization and as B6 doses were administered over the past 24 hours, kidney and electrolytes values should be monitored during hospitalization. Recommend switch diet to a normal large breed diet, such as Pro Plan Weight Management. Echocardiogram should be repeated in 3 months or sooner in case patient develops clinical signs consistent with worsening of the disease.

**Treatment plan:**

# B6

**Addendum**

11/7/2018 - Patient improved respiratory rate overnight but had frequent ventricular arrhythmias (multimorphic VPCs, couplets and triplets) that can potentially be life threatening. B6 BID for 7 days and then SID is recommended. Blood work revealed normal kidney function and mild elevation on liver enzymes and hypokalemia B6 /L. Recommend B6 D and supplement potassium 2mEq orally BID.

B6 - Respiratory rate is within normal limits with slight effort. Ventricular arrhythmias are less frequent and rare episodes of couplets and no triplets was visualized. Blood work stable and potassium levels improved B6 /L. Patient was discharged from the hospital.

**Final Diagnosis:**

- Dilated cardiomyopathy - r/o primary vs. diet induced.
- Congestive heart failure
- Atrial fibrillation
- Ventricular arrhythmias.

**Heart Failure Classification Score:**

ISACH Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM CHF Classification:

- A
- C

B1  
 B2

D

**Notice of Patient Admit**

**Date:** 11/5/2018 6:19:57 PM

**Case No:** B6

**Referring Doctor:** B6

**Client Name:** B6

**Patient Name:** 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, Afib

If you have any questions regarding this particular case, please call 508-887-4988 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

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

**B6**

**B6**

Male (Neutered)

Canine Doberman Pinscher

Black/Tan

**B6**

**Daily Update From the Cardiology Service**

Today's date: 11/8/2018

Dear **B6**

Thank you for referring patients to the Foster Hospital for Small Animals 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 11/7/2018

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](mailto:cardiovet@tufts.edu) if you have any questions.

Thank you!

Attending Clinician: **B6** DVM (Resident - Cardiology)

Faculty Clinician: **B6** DVM, DACVIM

Senior student:



Report Details - EON-370776		
ICSR:	2058702	
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 21:21:30 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	<b>Problem Description:</b> Diagnosed and treated for DCM at Cummings Medical Center at Tufts. Have fed Earthborn Holistic Weight Management Grain Free diet for about 5 years. Read FDA Study Report and decided to report experience. I wrote a comprehensive description of what happened twice and got timed out both times. Call if I can be of further help.	
	<b>Date Problem Started:</b> 11/04/2018	
	<b>Concurrent Medical Problem:</b> No	
	<b>Outcome to Date:</b> Stable	
Product Information:	<b>Product Name:</b> Earthborn Holistic Weight Control (Grain Free)	
	<b>Product Type:</b> Pet Food	
	<b>Lot Number:</b> <b>Expiration Date:</b> 11/09/2019	
	<b>UPC:</b> 3484671932	
	<b>Package Type:</b> BAG	
	<b>Package Size:</b> 28 Pound	
	<b>Purchase Date:</b> 09/14/2018	
	<b>Number Purchased:</b> 1	
	<b>Possess Unopened Product:</b> No	
	<b>Possess Opened Product:</b> Yes	
	<b>Storage Conditions:</b> In sealable bag that it came in in dry room	
	<b>Product Use Information:</b>	<b>Description:</b> Kibbles fed along with Wellness wet food
		<b>First Exposure Date:</b> 10/01/2018
		<b>Last Exposure Date:</b> 11/05/2018
		<b>Time Interval between Product Use and Adverse Event:</b> 6 Hours
		<b>Product Use Stopped After the Onset of the Adverse Event:</b> Yes
<b>Adverse Event Abate After Product Stop:</b> No		
<b>Product Use Started Again:</b> Unknown		
<b>Perceived Relatedness to Adverse Event:</b> Possibly related		
<b>Other Foods or Products Given:</b> Yes		

to the Animal  
During This Time  
Period:

**Manufacturer  
/Distributor Information:**

**Name:** Earborn Holistic  
**Type(s):** Manufacturer  
**Address:** United States  
**Contact:**  
**Possess One or More Labels from This Product:** Yes

**Purchase Location  
Information:**

**Name:** Amazon  
**Address:** United States

**Animal Information:**

**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Doberman Pinscher  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Weight:** 100 Pound  
**Age:** 9 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  
**Other Phone:** B6  
**Address:** B6  
United States  
**Type of Veterinarian:** Primary/regular veterinarian  
**Date First Seen:** 11/05/2018  
**Permission to Release Records to FDA:** Yes  
**Practice Name:** Cummings Veterinary Medical Center at Tufts University  
**Contact:** **Name:** B6  
**Phone:** B6  
**Other Phone:**  
**Address:** 55 Willard St  
North Grafton  
Massachusetts  
01536  
United States  
**Type of Veterinarian:** Referred veterinarian  
**Date First Seen:** 11/05/2018

Permission to Release Records to FDA: Yes

**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

**Additional Documents:**

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**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** [REDACTED] B6  
**Sent:** 8/23/2018 3:50:49 PM  
**Subject:** 800.267-FDA Case Investigation for [REDACTED] B6 and [REDACTED] B6 (EON-308715)  
**Attachments:** 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf

Good morning Dr. [REDACTED] B6

Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about [REDACTED] B6 illness.

As part of our investigation, we'd like to request:

- **Full Medical Records**

- Please email (preferred) or fax (301-210-4685) a copy of [REDACTED] B6 entire medical history (not just this event), including any referral diagnostics.

- **Have you submitted a report for [REDACTED] B6** I was forwarded the medical records and told from Dr. Lisa Freeman that you may have submitted a complaint. I cannot seem to locate it within our system.

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.

**Please respond to this email so that we can initiate our investigation.**

Thank you kindly,

Dr. Jones

**Jennifer L. A. Jones, DVM**

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





## Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

### Network Procedures for Owners

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

The following items are explained below:

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

#### 1. General Introduction:

##### 1.1. What is the goal of the case investigation?

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

##### 1.2. What is the focus of a case investigation?

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

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

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

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

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



## Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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

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

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

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

## **2. Billing:**

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

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

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

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

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

No, we cannot pay for treatment or cremation.



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

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

### **3. Step by Step Process:**

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

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

**Vet-LIRN requests that:**

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

### **4. Types of Services and Tests:**

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

A veterinary examination may include:

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

#### **4.2. Will your animal be tested more than once?**



## Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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

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

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

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

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

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

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

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

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

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