

Vet-LIRN Case Summary Document

Vet-LIRN Case Number:	800.218
EON/CC #:	EON-323515-323519
Vet-LIRN Initiation Date:	7/13/2017
MedRec: Requested:	7/12/2017
MedRec: Received:	7/13/2017
MedRec: Significant finding:	Cardiogenic heart failure clinically but less supported histologically
Vet-LIRN Tests (planned):	B5
Vet-LIRN Test Results:	
Result Interpretation:	NCSU: iron wnl, Ferritin elevated 3x URL
IF NFA, justification:	

COMPLAINT Narrative:

B6 housemat **B6** (separate report submitted) was diagnosed with DCM and CHF 2/17 and was euthanized after aggressive treatment of CHF. At that time **B6** had 2 syncopal events closely related to each other. His appetite for dog food declined but he would eat it if tempted with treats mixed in. He was presented 6/22/17 for more syncopal events and was similarly diagnosed with severe DCM and CHF. He was able to be successfully treated however and is clinically doing well on CHF medications as of 7/10/17. A re-review of the myocardial histopathology for **B6** housemat **B6** was requested at this time because of the unusual diagnosis of DCM in a small breed dog living in the same house as another dog similarly diagnosed a few months ago. **B5**

B6

B6. Lik **B6** unrelated, younger miniature schnauzer. **B6** had been fed California Naturals Adult - both kangaroo with lentils and venison with lentils along with Milo's kitchen treats. We have samples of these foods from 6/17 but not

the original bags from when he was presented 2/17. These samples were provided at the time **B6** also presented with severe DCM and CHF. Like **B6** had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation, we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure. We have plasma, serum, urine and myocardial tissue samples (latter only for **B6** stored at -80 Celsius in addition to food and treat samples.

3 week history of cough treated unsuccessfully with **B6** 3 day history of inappetence and vomiting prior to presentation to **B6** emergency service for dyspnea. Radiographs showed severe pulmonary edema and echocardiogram showed severe Dilated Cardiomyopathy. There was an initial response to diuretic therapy however, he declined and was placed on the ventilator for respiratory support and continued CHF treatment. Attempts to wean off the ventilator were unsuccessful and aquaphoresis was performed. He continued to decline despite aggressive therapy and was euthanized. Infectious disease testing was negative and taurine and carnitine analysis showed adequate levels. Necropsy initially did not reveal a cause for DCM and supported alveolar injury (possibly ventilator related). **B6**

B6

B6 had been fed California Naturals Adult - both kangaroo with lentils and venison with lentils along with Milo's kitchen treats. We have samples of these foods from 6/17 but not the original bags from when he was presented 2/17. These samples were provided at the time his housemate **B6** (unrelated, older miniature schnauzer) also presented with severe DCM and CHF. I will enter this dog as a separate affected patient. Both dogs had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation **B6** had clinical signs at the time **B6** was treated, but didn't present with CHF for several months), we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure.

Signalment:

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

Signs: syncopal episodes, dyspnea, cough, heart failure

Food: Alternated feedings between:

- California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils Recipe Dog Food
- "" Kangaroo and Lentils

Vet-LIRN PLAN OF ACTION:

- MRx review

B5

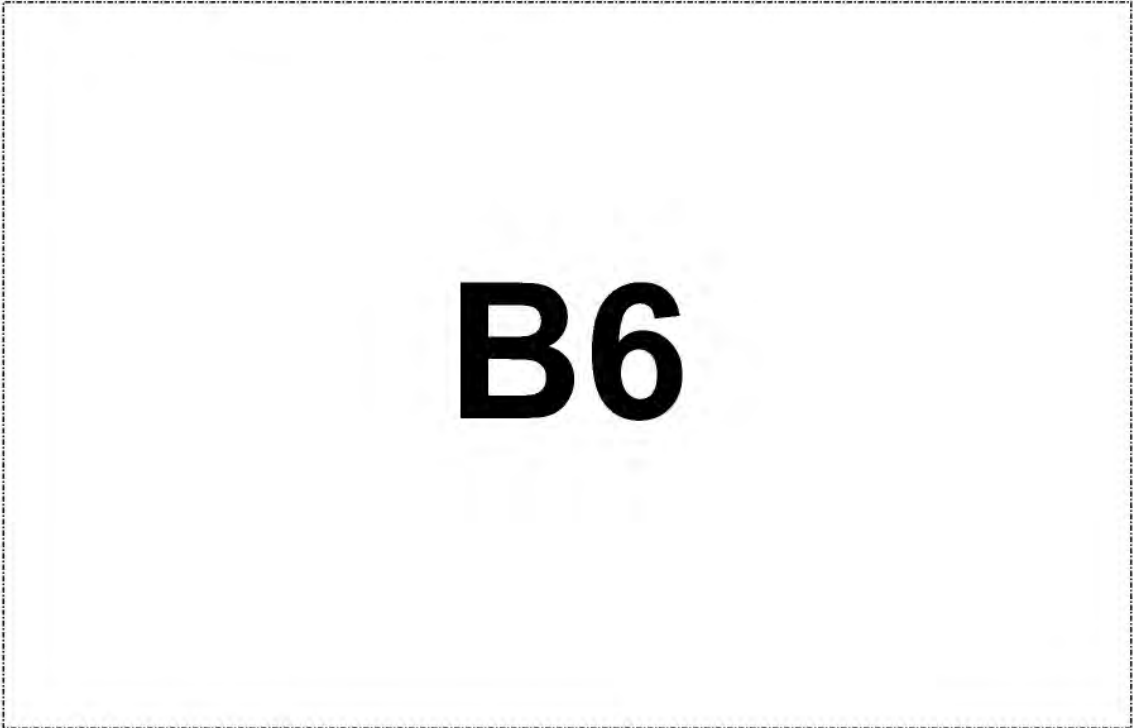
Medical Record Review:

B6

Presenting complain: B6 dyspnea, cough of 3 week duration-wheezing type more frequent at night → rDVM, treated w/ prednisone and doxycycline for kennel cough → B6 inappetance, vomiting B6 dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated → B6 treated as outpatient, B6 as syring feeding, dog regurgitated and had marked dyspnea → ER → refer to B6 → B6 put on mechanical ventilator → B6 euthanized

PE: B6 P 160 bpm, R 64 rpm, pale pink mm, Gr I-II/VI left apical systolic murmur, femoral pulse hypokinetic but synchronous, jugular venous distention

Labwork:



Rads: B6 concern for aspiration pneumonia

cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudo-dorsally, hepatomegaly, dec abdominal serosal contrast
severe generalized cardiomegaly with biventricular heart failure, improved vs rDVM rads
worsening cardiogenic pulmonary edema, cannot exclude lung induced injury

B6 pneumonia

post ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to hy alveolar

improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia
markedly progressive alveolar pattern with significantly worse cardiogenic edema

tFAS: B6 severe cardiomegaly with ventricular hypocontractility

Echo: B6 cm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

B6

B6

Presented **B6** episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousness → immediately return to normal → 2 weeks later again collapse, then on → 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February; → recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6 **PE:** P 130 bpm, R pant, mild increased breath sounds in all lung fields

B6 99.7F, P 136 bpm, R 36 rpm, equivocal mild dehydration <5%, Gr II/VI left apical systolic murmur

Labs:

B6

Rads: left sided congestive heart failure

B6

B6 moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

B5

7/18/2017

B5

7/19/2017

JJ-TAMU can do the testing at TVMDL. Vet sent product weight and dimensions. **Vet confirms, neither dog received anchovies, sardines, or seafood in February or Chronically.**

7/22/2017

JJ-Vet did not receive a return shipping label. Will make PO for shipping to Vet-LIRN.

7/26/17

JG – AT received dog food in a container on 7/26/17. JJ received it.

Note: JG took pictures on 1/17/18

7/28/2017

JJ-Vet sent info-she's had 2 other cases of DCM with dogs eating the California Naturals diet. Info below:

I don't know if there is anything to this but I have treated 2 other dogs in the last 2 weeks with DCM and CHF that are being fed California natural food (one kangaroo and lentil, and we are trying to find out about the other one which is in our ER now). One is mixed breed and we'll recommend testing for taurine deficiency. The other was a golden and taurine was a bit low but not super low so although we supplemented, I wasn't totally convinced it was the cause. Unfortunately she died a week later.

*I don't have a sense for how widely fed this diet is but I don't see it on the top selling lists I can find by google, so seeing 4 DCM dogs recently eating this particular food is interesting to say the least. I thought this might be of interest to you as you start to look at the California natural food sample from the **B6** dogs.*

Vet also sent journal article about **B5**

Found Eurofins can test for **B5** in pet food.

Sent info to group, and DR thinks testing for taurine, carnitine **B5** worth it. I can send an email to Eurofins to request testing cost/method info/shipping info/amount needed for testing.

8/3/2017

JJ-Prepared pet food on 8/2 and lab submission forms. Make boxes today and send for testing.

JG – Shipped samples to Covance and TAMU

8/4/2017

JJ-Eurofins responded **B5** testing would require method development and be quite costly. Will not pursue at this time.

8/7/2017

JJ-TAMU sent final results **B5** Will send all product test results to vet when received.

8/9/2017

JJ-DR suggested-**B5**

8/22/2017

JJ-Received Covance results for Taurine **B5** Filed. Vet asked about results **B5** results and taurine/carnitine in progress until we interpret. Plan to send those after interpretation finalized. Asked vet which dry food we were sent.

B5

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and B5 levels. Based on the dogs' blood taurine B5 levels and the dry dog food test results, it is unlikely that B5 taurine, or B5 caused the dogs' illness.

Vet responded-flavor is Kangaroo. Let her know B5 not available as a test unless she wants to pursue method development with Eurofins.

DR agrees-sent final interpretation to vet. NFA.

10/16/2017

B5

1/3/2018

JJ-Received an email from Dr. Aden-

I'm hoping that you recall our communications over the summer regarding food testing for unrelated housemate dogs that developed DCM. These dogs were eating California Naturals Kangaroo and Lentil diet and we were not able to identify a cause of the DCM, dietary or infectious or toxic. (**800.218**)

I wanted to reach out again because we continue to see DCM in non-genetically predisposed breeds and it seems that this diet is a relatively common theme. We have been increasingly better about recording a diet history in dogs that are presented to cardiology or ER at our hospital with DCM in the last 6 months. Most of the dogs have been tested

for taurine and carnitine deficiency and have been within the reference range. About half of them are alive and half died close to the time of diagnosis.

I also searched our records for this diet (knowing that recording of diet in the MR history has been spotty at best) and found another pair of unrelated housemate dogs eating California naturals kangaroo and lentil that were diagnosed with DCM 6 months apart.

We will continue to record the cases we see but since last june we have seen 7 dogs eating California Naturals diet (5 kangaroo and lentil) in addition to the pair of housemates from 2016 (so total of 9). We also have 4 dogs eating Acana (3/4 are dobermans though) and 1 each of 4Health and Iams - so maybe these are not necessarily related.

Discussed during the weekly PFO meeting-DR suggested we test for Selenium since it has been associated with White Muscle Disease. We have leftover food and can send for testing. Based on my search-Lentils can have varying Se content based on soil concentrations (Thavarajah et al 2008). DR requested an article "Nutritional and micronutrient determinants of idiopathic dilated cardiomyopathy: diagnostic and therapeutic implications" by Marinescu et al.

Will ask vet if any of them had selenium testing done, and mention we will test the leftover food from this case for Selenium. Also ask if any histopath on the other dogs.

Did not find any references that list the selenium content of kangaroo.

1/9/2018

JJ-DR sent an article-V. Marinescu & P. McCullough- Nutritional and micronutrient determinants of idiopathic dilated cardiomyopathy: diagnostic and therapeutic implications: Expert Rev. Cardiovasc. Ther. 9(9), 1161-1170 (2011)

Type	Cardiomyopathy
Toxic	Alcohol Cobalt
Metabolic	Hypocalcemia Hypophosphatemia Hypomagnesemia
Nutritional	Carnitine Copper Iron Magnesium Selenium Thiamine Vitamin B12 Zinc

Plan to test for Co, Ca, P, Mg, Cu, Fe, Mg, Se, Zn

Vet replied: "We have **not tested for selenium** in any of the dogs. We have **stored blood samples** from several dogs and have an inpatient right now that we can submit blood from [B4] (runs this). We will probably start with looking at blood samples from 2 dogs as a screening. We also have frozen myocardium from one dog - do you think this should also be evaluated?"

I clarified-the frozen myocardium is from 800.218 case-Yes "The myocardium is from [B6] Maybe we will wait to see what the blood levels show."

B5
B5

B5

Vet also has food from the current case. We discussed the case this morning-plan to test archived/current case from vet/1 lot (several bags) storebought.

Will email vet to collect food. Make PO for new bags of food (same lot).

1/10/2018

JJ-Vet sent the weight and picture of the subsample of food. Asked JG to send a box for collection.

Vet sent 2 dog blood samples for Se testing. One in RR, 1 high.

JG – Shipped the food collection kit to NCSU

1/11/2018

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues in **B6** posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume CN but not sure) in the last year - 2 were housemates but related.”

1/12/2018

JJ-DR mentioned Kogia whales get DCM of unknown origin: “I didn’t get the articles for you, but there is an issue in Kogia (pygmy sperm whales) involving a cardiomyopathy of unknown etiology. There was some work up done on some muscle markers. Not sure if NCSU would be interested in that info or not.”

DR provided the articles-will share this information with NCSU.

1/16/18

JG – Received treat sub 2 and 3

Store purchased samples. Both are California Natural, Grain free ingredient diet, Kangaroo and Red lentils recipe

1/17/2018

JJ-Vet cannot find package. Will resend.

JG – reshipped the food sample collection kit and provided shipping tracking information

1/23/2018

JJ-

B5

B5

B5

. I cannot give advice one way or the other.

The food she is sending us shipped today-

- Fromm Grain Free
- Ca Naturals Chicken and Lentil

We received an additional set of reports with DCM and California Naturals food. This case we'll start with MRx. I made a separate case folder within this folder.

JJ-Adding testing of **B5** to the plan based on the **B6** case cluster we received.

B5

1/25/18

JG – Received a treat sample from Dr. Adin (NC state univ). Logged it in as Sub-4

JG – Received a treat sample from Dr. Adin (NC state univ). Vet wrote down “California Naturaksm Kangaroo +Lentil”. JJ informed this is not Kangaroo but chicken flavor. Wrote down “Chicken + Lentil” and logged it in as Sub-5

2/2/2018

JJ-Preparing the lab submission forms and emailing ID re: testing. For the Fromm-will email vet to ask what flavor.

The veterinarian replied with the Fromm ingredient list. There are various proteins but also lentils and chickpeas.



B5

replied the testing for the case samples is pending.

JG – Received a treat sample from 'EON-Multi **B6** case'. Log in the treat as 800.218-Treat-sub-6

2/5/2018

JJ-Prepared all samples for ID and Covance testing. Package for shipping.

2/6/18

JG – Shipped the dry dog food to ID and provided shipping tracking information

2/20/2018

JJ-I emailed Covance to request a testing update.

2/22/2018

JJ-We received the results from Idaho and Covance. The only significant finding was all products contained inadequate Fe content, below the AAFCO claim. Fe has been associated with idiopathic DCM (Marinescu and McCullough 2011) in people. According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure.

Looking at our cases, a CBC was done for 3 dogs according to their discharge summaries. One dog had a non/pre-regenerative anemia, and the other two had no mention of RBC abnormalities; **B5**

B5

Dr. Adin at NCSU emailed additional theories. She continues to see more cases.

B5

The Vet Cardiology Community is discussing this quite a bit.

2/23/2018

B5

B5

Send feed test results to NCSU and [B6] I'll ask Dr. Adin if an iron panel has been done on any of the dogs. If not, we can request a full iron panel for one dog at NCSU and one from [B6] Will get estimates for the test from each lab. If the dogs are low Fe, we can test a myocardial sample from the [B6] case.

2/26/2018

JJ-Dr. Adin replied-

We have not looked at iron panels in any of the dogs. I just went through their CBCs (most but not all had them done). Only 2 of 23 were anemic and these were normocytic normochromic (although for one the MCH and MCHC were at the low end of the normal range). One anemia was mild (37) and the other was more severe and unexplained (5 yr Lab, 27%, this dog died after a week just recently).

One issue is that we had a freezer failure about a month ago - devastating.... I refroze the samples but I am uncertain if these are still OK to test. She is calling the company because the dog that ate the California natural chicken food you sampled was one of them [B6] The dog that ate Fromm is no longer with us and his samples were not only thawed but older (company states they should be less than 28 days). And [B6] samples fall in that category as well.

If the company tells us that testing serum that has been thawed will not give us accurate results. we have saved serum from a few recent cases that were eating:

1. California Natural Salmon and peas (I also bought a bag of this off amazon when I heard they had discontinued the CN line) - this dog is clinically doing well but only 2 weeks out
2. Blue Buffalo grain free bison (this is the dog with the unexplained HCT of [B6] and died after a week)
3. Zignature grain free lamb and peas (had been eating California natural kangaroo and lentil the year before) - this dog did not make it out of the hospital

I know this latter scenario is less than ideal and not sure how long it would take to test a few more diets for just iron if we wanted to pair these with the serum samples. The other issue to consider is that if we tested the additional diets, they would not be from the bag the dog was eating (however, this was not necessarily the case for [B5] the owners brought in the food but from a different bag).

B5

We will be proactive about getting the actual food and doing some iron testing on our end if new cases come it.

She got an estimate for the Iron Testing: "I think it would be best to send off serum that was not inadvertently thawed. Since it is not too expensive, I was thinking I'd send off 2 sample [B6] our anemic dog that ate Blue buffalo and [B6] a dog that ate CN salmon) - I can cover the cost of the 2nd one."

We will cover the cost of 1 dog as initially planned. Will make a PO.

Dr. Adin sent an article: Higgings et al 2017. This study involved children w/ DCM and Heart Failure: 96.4% of patients had Fe deficiency, only 39.3% had anemia, and only 2/11 with anemia had a microcytic anemia.

3/5/2018

JJ-Dr. Adin sent the invoice and requested a check. [B6] This dog was eating California Natural Salmon and peas. I will submit the invoice and am waiting on the Tax ID for the check.

Dr. Adin asked how other cardiologists should submit the complaints. Last week, I responded, individual PFRs.

Dr. Adin sent the Fe level testing. "They are relatively normal."

[B6] Iron [B6] (ref range 73-245 ug/dl), TIBC could not be determined because her total iron was a bit high so unsaturated binding was low - I talked to the clinical pathologist at the lab who felt this was not clinically significant and just a result of her slightly high iron)

[B6] Iron [B6] (73-245), TIBC [B6] (270-530)

They are going to run ferritin levels on the blood too as an indication of total body scores - may or may not be helpful.

B5

3/13/2018

JJ-The veterinarian emailed back, asking if the phosphorous we reported was the same as [B5] replied no. The ferritin results in these dogs was 3x the upper reference range. Ferritin is an acute phase protein. She's meeting with a clinical pathologist to discuss the significance of these findings. I requested a copy of the blood work results.

I recommend NFA.

3/14/2018

JJ-DR agrees to NFA the case. He mentioned the elevated ferritin could be related to the cardiac disease as a consequence, not a cause.

3/19/2018

JJ-The vet sent a copy of the Fe panel results, and I filed.

3/28/2018

JJ-Vet asked if the
species and not speciate. I emailed ID to confirm.

B5

3/29/2018

JJ-ID confirms-the panel measures total Fe and does not speciate.

4/12/18

JG – Shipped samples to MSU (iodine)

4/23/2018

JJ-MSU sent the iodine results. All subs tested were less than 10 ppm. NFA.

4/27/2018

JJ-Sent copy of Iodine results for sub 4 & 5 to vet.

Document properties

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Company: US FDA
Template: Normal.dotm
Page count: 2
Paragraph count: 269
Line count: 595
Word count: 5310
Character count (spaces excluded): 26966
Character count (spaces included): 32358

Report Details - EON-323519

ICSR: 2023230
 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: 2017-07-11 17:32:14 EDT

Reported Problem:

Problem Description: Please note: Dr. Jennifer Jones was consulted prior to submission of this report. She would like to be involved in the case review [B6] housemate, [B6] (separate report submitted) was diagnosed with DCM and CHF. [B6] had 2 syncopal events closely related to each other. His appetite for dog food declined but he would eat it if tempted with treats mixed in. He was presented [B6] for more syncopal events and was similarly diagnosed with severe DCM and CHF. He was able to be successfully treated however and is clinically doing well on CHF medications as of 7/10/17. A re-review of the myocardial histopathology for [B6] housemate [B6] was requested at this time because of the unusual diagnosis of DCM in a small breed dog living in the same house as another dog similarly diagnosed a few months ago. [B6]

B6

[B6] (unrelated, younger miniature schnauzer), [B6] had been fed California Naturals Adult - both kangaroo with lentils and venison with lentils along with Milo's kitchen treats. We have samples of these foods from 6/17 but not the original bags from when he was presented [B6]. These samples were provided at the time [B6] also presented with severe DCM and CHF. Like [B6] had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation, we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure. We have plasma, serum, urine and myocardial tissue samples (latter only for [B6]) stored at -80 Celsius in addition to food and treat samples.

Date Problem Started: [B6]
Date of Recovery: 07/10/2017
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:

Product Name: Alternated feedings between [B6]: California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and Lentils

Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 26 Pound
Storage Conditions: In the bag in a cabinet

Product Use Information:

Description: the Venison and Kangaroo types were alternated depending on store availability and were fed twice daily along with Milo's kitchen treats

Perceived Relatedness to Adverse Event: Possibly related

Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information: **Name:** [B6]

	Type Of Species:	Dog												
	Type Of Breed:	Schnauzer - Miniature												
	Gender:	Male												
	Reproductive Status:	Neutered												
	Weight:	9.6 Kilogram												
	Age:	7 Years												
	Assessment of Prior Health:	Excellent												
	Number of Animals Given the Product:	2												
	Number of Animals Reacted:	2												
	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>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> </table>	Owner Information provided:	Yes	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:		Address:	B6
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Healthcare Professional Information:	Practice Name:	North Carolina State University, College of Veterinary Medicine												
	Contact:	<table border="1"> <tr> <td>Name:</td> <td>Darcy Adin</td> </tr> <tr> <td>Phone:</td> <td>(919) 513-6694</td> </tr> <tr> <td>Other Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td>dbadin@ncsu.edu</td> </tr> </table>	Name:	Darcy Adin	Phone:	(919) 513-6694	Other Phone:	B6	Email:	dbadin@ncsu.edu				
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Address:	1060 William Moore Dr Raleigh New York 27607 United States													
Practice Name:	North Carolina State University, College of Veterinary Medic													
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Sender Information:	Name:	Darcy Adin												
	Address:	1060 William Moore Dr Raleigh New York 27607 United States												
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td>9195136694</td> </tr> <tr> <td>Other Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td>dbadin@ncsu.edu</td> </tr> </table>	Phone:	9195136694	Other Phone:	B6	Email:	dbadin@ncsu.edu						
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Other Phone:	B6													
Email:	dbadin@ncsu.edu													
	Permission To Contact Sender:	Yes												

Preferred Method Of Contact:	Email
Reported to Other Parties:	Manufacturer

Additional Documents:

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

Client B6	Patient B6 SCHNAUZER MC GRAY&WHITE CANINE	Case # B6 9.9 kg	Attending DVM ADIN, DARCY Student B6 Discharging DVM Referring DVM B6
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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 B6 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 B6 with B6 mg PO BID, B6 mg PO BID and B6 mg PO BID. B6 house mate, B6 unfortunately passed away from DCM and CHF in B6. 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 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 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

CV/R: Grade 2/6 left apical systolic murmur, no arrhythmias auscultated, femoral pulses strong and synchronous, normal bronchovesicular lung sounds noted on bilateral auscultation- no crackles or wheezes, eupneic

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 potassium, while normal, is at the low end of the range, and because this may have some long term benefit through anti-[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

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] Dr. Darcy Adin [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 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 and fill out our RDVM Feedback Survey!



Texas A&M Veterinary Medical Diagnostic Laboratory
 483 Agronomy Road
 College Station TX 77840
 Phone: (979) 845-3414 Fax: (979) 845-1794

Report Date: 8/4/2017

Final Report

Date Received: 8/4/2017

Case Coordinator: [B6]

Accession No: [B6]

JENNIFER JONES, DVM
 8401 MUIRKIRK RD.
 LAUREL MD 20708

Phone: (240) 402-5421
 Fax: (301) 210-4685
 Email: jennifer.jones@fda.hhs.gov

Associated Parties

Vet Practice	TAMU Veterinary Pathobiology	Account #: A02336	Attn: [B6] [B6]
	Jennifer Jones, DVM		8401 Muirkirk Rd. Laurel, MD 20708 (240) 402-5421

Customer Requests

Specimens Submitted: 1 bag,
 Customer Test Request: Please test dog food product fo [B5]

History

Please see previous email.

Lab Findings

Toxicology

Specimen	Test Name	Method	Basis	Toxicology Result	Units
Dog food - 800.218 - 1	[B5]	ELISA	As received basis	None Detected, < 5	ppm
[B5] was not detected in this sample at the detection limit of 5 ppm. -- [B6] DABT, Veterinary Toxicologist /kk					

Client Report History

Report Type	Delivery Method	Sent To	Date Sent
Final	Email	jennifer.jones@fda.hhs.gov	8/4/2017 3:59 PM

Accession Number: [B6]

Final (8/4/2017)

Page 1 of 1

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

Client [B6]	Patient [B6] SCHNAUZER MC GRAY&WHITE CANINE	Case # [B6] 9.9 kg	Attending DVM Student [B6] Discharging DVM Referring DVM [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 of [B6] 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 [B6] with [B6] mg PO BID, [B6] mg PO BID and [B6] mg PO BID. [B6] house mate, [B6], unfortunately passed away from DCM and CHF in [B6]. 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] 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]

CV/R: Grade 2/6 left apical systolic murmur, no arrhythmias auscultated, femoral pulses strong and synchronous, normal bronchovesicular lung sounds noted on bilateral auscultation- no crackles or wheezes, eupneic
GI/GU: Soft, non-painful, slightly distended abdomen on palpation, no fluid wave present, no organomegaly detected.
MSK: Ambulatory on all four limbs with no observed lameness.

[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: all normal (BUN [B6], creat [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] 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 potassium, while normal, is at the low end of the range, and because this may have some long term benefit through anti-aldosteronism. 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:



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 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 and fill out our RDVM Feedback Survey!

B6

B6

Patient Information

Patient: **B6** Age: 5 years Referring Veterinarian: **B6**
 Patient Number: 211495 Weight:(kg) 25.60 Cardiologist: **B6**
 Breed: Labrador Retriever Sex: FS Client Number: 138074
 Exam Date: 08/24/2017 08:19 BSA: 0.88

History: **B6** was presented to **B6** today for evaluation of a new heart murmur and evaluation after being diagnosed with congestive heart failure on 8/18/17. **B6** was evaluated by her regular vet on 8/18/17 for heavy breathing and coughing. Radiographs and blood work were done at the time and **B6** was diagnosed with an enlarged heart and congestive heart failure at that time. **B6** was started on **B6** by her regular vet. **B6** was seen through **B6** ER of **B6** for reevaluation of congestive heart failure. The clients report that **B6** had improved some but had not improved a lot. Medications were adjusted based on recommendations from Dr. **B6** for **B6** until **B6** could get an appointment to be seen by **B6**. The clients report that since the medications were increased **B6** has improved, however they do still feel that she is breathing faster than normal at home and she is still panting a lot at home. **B6** is still eating very well at home and is currently on a low sodium kibble and lentil diet. The clients also report

B6

initiation of treatment. The clients report that **B6** was not well controlled on **B6** tablets: 1 tablet by mouth once daily so **B6** tablets. Give 1/2 tablet by mouth every 12 hours was added in. They are unsure if **B6** **B6**
B6 The client feel that **B6** is less social and less active at home.
B6 is currently receiving **B6**

B6

Physical Examination:

B6

Diagnostic Tests:

Thoracic Radiographs: Persistent cardiomegaly with mild decrease in severity. No evidence of cardiac decompensation.
 Renal Panel: **B6**
 Echo: See Below. Sinus rhythm on ECG.

Echocardiographic Report

2D ECHO

LA Systolic Diameter LX

B6

Aortic Root Diameter

DOPPLER

AV Peak Velocity
AV Peak Gradient
Mitral E Point Velocity
Mitral E to A Ratio
MR Peak Velocity

PV Peak Velocity
PV Peak Gradient
TR Peak Velocity
TR Peak Gradient

M-MODE

LV Diastolic Diameter MM
LV Systolic Diameter MM
LV Fractional Shortening MM
LV Diastolic Volume Cube
LV Systolic Volume Cube
LV Ejection Fraction Cube
IVS Diastolic Thickness MM
IVS Systolic Thickness MM

B6

IVS Percent Thickening MM
LVPW Diastolic Thickness MM
LVPW Systolic Thickness MM
LVPW Percent Thickening MM
IVS to PW Ratio MM
LV Mass MM
LV Mass Normalized MM
MV E Point Septal Separation

B6

Left Ventricle:

Severe dilation with marked global myocardial dysfunction. Normalized B6 normalized.

Left Atrium:

Severe dilation with B6

Right Ventricle:

Right Atrium:

Mitral Valve:

Aortic Valve:

Tricuspid Valve:

Pulmonic Valve:

Aorta:

Pericardium:

B6

Diagnosis

Endocardiosis (chronic degenerative valve disease) - Degenerative changes in one or more heart valves have caused leaking across these valves. This is the source of the heart murmur. As this disease progresses, the heart enlarges. Eventually this can lead to symptoms of cough and shortness of breath (airway compression and/or congestive heart failure). This is usually a slowly progressive disease.

Dilated cardiomyopathy - This is a disease characterized by weakening of the heart muscle and dilation of the heart chambers. As the disease progresses, it can lead to congestive heart failure (fluid in the lungs causing shortness of breath and cough). Abnormal heart rhythms are common and can result in sudden death. Most commonly this is an inherited disease, though it can occur secondary to a deficiency in an amino acid called taurine.

Recommendations

Please continue the following medications as previously directed:

B6

As we discussed, **B6** unfortunately have very similar structural heart disease. Since they are related, this raises concern for a genetic component. You have expressed that there is no history of heart disease in their lineage. It is possible that the disease has remained silent in other related dogs or is inherited in a way that it is only expressed in certain individuals. The other common denominator that **B6** have is the kangaroo diet. Even though we have not specifically associated this protein source with taurine/carnitine deficiency, it may be warranted to consider a diet with a different protein source since it is a novel protein and both dogs have very similar disease manifestations. Lamb should be avoided as it has been associated with taurine deficiency in dogs.

We did not check **B6** blood taurine level today- since **B6** was normal it is highly unlikely that **B6** will be deficient as they are related and eat the same food.

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

With advanced heart disease, our biggest dietary concerns are adequate calorie content and low sodium content. We aim for less than 80mg sodium per 100 kilocalories (kcal) in patients that have developed congestive heart failure. We do not advise protein restriction unless there is concurrent kidney disease (i.e. kidney diets are not advised unless there is concurrent kidney disease). Please refer to our diet handouts with a list of currently adequate diets and treats, though this list is not exclusive. If you wish to feed a diet that is not on these lists, you will need to call the manufacturer of the diet to obtain a sodium content.

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

***As long as **B6** does well at home we would like to re-evaluate her in 4-6 weeks. At this time we will recheck her kidney values/electrolytes and blood pressure as well as repeat chest x-rays.

B6

B6

(Electronically Signed)

Final Date:

Like us on Facebook!
B6

Notes to our clients

- Please bring all medications to your pet's scheduled appointments.
- We require a 48 hour notice for all refills. When you call to request a refill, please leave the pharmacy phone number or clearly indicate if you plan on picking up the medication at our facility. PRESCRIPTION REFILLS ARE NOT AVAILABLE AFTER B6 Evenings, Fridays, holidays and weekends.
- Check out B6 and enter your local zip code to search for the best prices on your medications at your local pharmacies.
- If an emergency arises with your pet, B6 is a 24 hour facility.

JLR placed in cooler body care??

B6

B6

Date: **B6** Time: 22:45

Client:
Address:

B6

Patient:
Breed:
Age:

B6
Retriever, Labrador
B6

History:

B6 returned to **B6** for increased respiratory rate. The owner reports after the visit yesterday and the lasix bolus, **B6** did well until evening. Throughout the evening and night her respiratory rate increased to over 40/min. This afternoon she began to cough. The owner reports she coughed up pink tinged fluid. She also had an episode where she was excited and collapsed. She has been taking all of her medications as previously directed. She had her midday dose of **B6**. She is currently on **B6**.

B6 She has been dry heaving on the way here this morning. **B6**

Physical Exam:

Vitals:

- Vital Sign
- Weight
- Attitude
- Temp
- HR
- RQ
- Muc
- Memb
- CRT

B6

<2 sec

Mucous Membranes: Pale pink, moist
 Heart and lungs: 4/6 murmur, Fine crackles right dorsal lung fields/no dyspnea, regular rhythm, strong and synchronous femoral pulses
 Abdominal Exam: Soft and not painful to palpation,
 Musculoskeletal and Integument: Ambulatory with no lameness
 Eyes, Ears, Nose, and Throat: No ocular or nasal discharge
 Peripheral lymph nodes: No peripheral lymphadenopathy
 Urogenital Exam: Unremarkable
 Neuro Exam: Intact CN, normal mentation, no ataxia seen
 Rectal Examination: Formed stool with no blood

B6 / **B6** respiratory rate continued to increase throughout the night despite being on **B6**. Called owner and discussed poor prognosis. Owner elect humane euthanasia. **B6** also spoke to owner for euthanasia consent per phone consultation. **B6**

B6
Diagnostics:

Radiographs-

The cardiac silhouette is again noted to be generally enlarged. There is an unstructured interstitial pulmonary pattern within the right

B6

B6 22:45

middle and right caudal lung lobes. There is mild enlargement of the cranial lobar pulmonary veins. There are no abnormalities of the pleural space.

Conclusion

B6

B6

Conclusion

1. Persistent generalized cardiomegaly with persistent left-sided congestive heart failure characterized by cardiogenic pulmonary edema and pulmonary venous congestion.

B6 DVM, Diplomate ACVR

Diagnosis:

Endocardiosis

Dilated cardiomyopathy

Treatment:

B6

Due to poor response to treatment and declining condition owners elected humane euthanasia

Releasing DVM:

Client Signature

B6

Client Name (Print)

B6

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Glover, Mark; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 1/23/2018 6:35:32 PM
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

Jen,
 This sounds great!

Thank you for all of the information.

From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 1:25 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

Recommend collecting open product from **B6** case (only one available) and testing for **B5** with the other cases. Also based on message board-recommend **B5** from all the DCM cases. **B5** we can look at the case from last summer and measure cardiac muscle **B5**. For **B6** case (EON-345822) if dog dies-will ask to save heart tissue for potential testing and histopath. Vet-LIRN can purchase Zignature Essentials for testing based on California naturals testing results.
 MRx summaries attached.
 The Message Board is worth reading-start on the last page. Good article (DeLuca et al) with Tau biosynthesis diagram (below) attached.

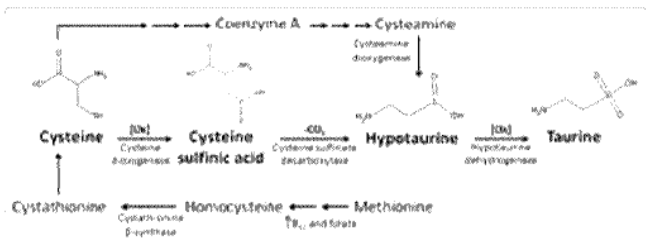


Fig. 1 Biosynthesis route of taurine from amino acids, cysteine and methionine. The synthesis does not primarily occur in liver, although other tissues can contribute to its synthesis based on presence of key enzymes. However, the major synthesis is generally liver and taurine needs to uptake via, getting taurine against gradients. In terms of the specific B6²⁺ dependent transport system, taurine is transported in fishery, plants, synthetic taurine and taurine-like peptides, in human urine with food. Can considered an important source of the amino acid for its specific importance of its role in health that as well as other general demand foods (e. milk).

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



From: Rotstein, David
Sent: Tuesday, January 23, 2018 7:02 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>;

Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

Thanks---that's what I figured!

From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 7:01 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

I wasn't-However, I bet it's related to our contact from NCSU. She had a cardiologist friend in **B6** with a few cases. We can get MRx, to start!

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



From: Rotstein, David
Sent: Monday, January 22, 2018 10:06 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

Not sure if you were expecting these at Vet-LIRN

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L
CC: Reimschuessel, Renate; Nemser, Sarah; Ceric, Olgica
Sent: 1/23/2018 6:45:11 PM
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

I don't think we are quite there yet

B5

B5

The message board certainly shows a pattern.

d.

From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 1:25 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

Recommend collecting open product from **B6** case (only one available) and testing for metals with the other cases. Also based on message board-recommend **B5** from all the DCM cases. If we find **B5** we can look at the case from last summer and measure cardiac muscle **B5**. For **B6** case (EON-345822) if dog dies-will ask to save heart tissue for potential testing and histopath. Vet-LIRN can purchase Zignature Essentials for testing based on California naturals testing results.

MRx summaries attached.

The Message Board is worth reading-start on the last page. Good article (DeLuca et al) with Tau biosynthesis diagram (below) attached.

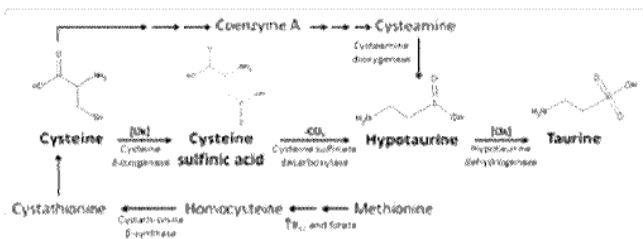


Fig 1 Biosynthetic route of taurine from amino acids (cysteine and methionine). The synthesis starts primarily in the liver, although other tissues can contribute to its synthesis based on presence of key enzymes. However, the final synthesis is primarily in the liver and tissues needs to uptake to deliver taurine against gradients. In many of the species, taurine synthesis depends on transporters. Taurine synthesis is a metabolic pathway that is highly conserved and is essential for many species, especially for health of fish. In fish, taurine is well as other amino acid-derived food (4, 1988).

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



From: Rotstein, David
Sent: Tuesday, January 23, 2018 7:02 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

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From: Jones, Jennifer L
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Jennifer Jones, DVM
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From: Rotstein, David
Sent: Monday, January 22, 2018 10:06 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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Not sure if you were expecting these at Vet-LIRN

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David
CC: Reimschuessel, Renate; Nemser, Sarah; Ceric, Olgica
Sent: 1/23/2018 6:46:59 PM
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

Yes, and we can test for those nutrients and compare to AAFCO's minimums.

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



From: Rotstein, David
Sent: Tuesday, January 23, 2018 1:45 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

I don't think we are quite there yet.

B5

B5

The message board certainly shows a pattern.

d.

From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 1:25 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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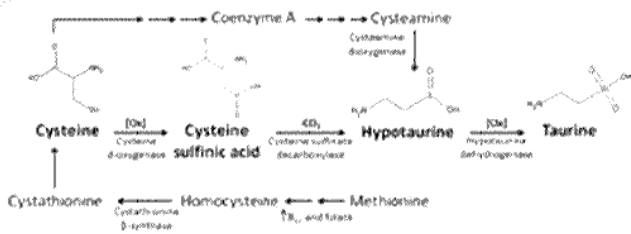


Fig. 1 Biochemical route of taurine from animals in all systems and species. The synthesis route primarily occurs in liver, although other tissues can contribute to its synthesis based on patterns of hepatic enzyme expression. The tissue synthesis is generally slow and occurs mostly in aquatic or diving mammals species by means of the specific "tau" iso. Dependence to aquatic systems, taurine synthesis is slow and occurs mostly in aquatic mammals and primarily depends on aquatic animals with fish. Taurine is synthesized in significant amounts in the animal world for all aquatic mammals. It is not in fish, but more so, in other aquatic mammals such as seals.

Jennifer Jones, DVM
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 Tel: 240-402-5421



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Sent: Tuesday, January 23, 2018 7:02 AM
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To: [B6]
Sent: 1/24/2018 11:54:22 AM
Subject: RE: FDA Case Investigation for [B6] dogs (800.218)

Thank you for the additional information, [B6]. When you submit the new FDA report(s), please email me the ICSR number (like a confirmation number). It will help me find the report in our system.

I will send you a box to re-use and send the leftover food to our lab. We send the food to a lab for testing. Please use the prepaid return label for shipping on a Monday-Wednesday (included in the box). You will call UPS to pick-up the package.

The testing will take a few weeks, but we'll send a copy of the results to you. Please share them with [B6].
The box should ship arrive by close of business Friday.

Please email or call with any questions.

Thank you,
Jen

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

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

From: [B6]
Sent: Tuesday, January 23, 2018 6:20 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: FDA Case Investigation for [B6] dogs (800.218)

Dr. Jones,

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Thanks for your assistance with this. I look forward to hearing back from you.

[B6]

B6

On 2018-01-23 11:53, Jones, Jennifer L wrote:

> Good afternoon: **B6**

>
> Thank you for submitting your consumer complaint to FDA. I'm sorry to
> hear about the dogs' illnesses.

>
> As part of our investigation, we'd like to request:

>
> * TEST REMAINING OPEN PRODUCT FROM **B6**

>
> * Testing for Co, Ca, P, Mg, Cu, Fe, Mg, Se, Zn, Taurine,
> Methionine, and Cysteine.
> * Please send me the size of the bag/approximate weight.
> * We will coordinate the testing through your office.

>
> In the unfortunate event that any of the dogs from these reports die
> or are euthanized, we may be able to offer cardiac histopathology
> (fixed formalin) and metals/aminoacids (fresh frozen) testing. Please
> contact me if this occurs and the owners are interested.

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> describe how Vet-LIRN operates and how veterinarians help with our
> case investigations.

>
> PLEASE RESPOND TO THIS EMAIL SO THAT WE CAN INITIATE OUR
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> Thank you kindly,

>
> Dr. Jones

>
> JENNIFER L. A. JONES, DVM

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> Veterinary Medical Officer
> U.S. Food & Drug Administration
> Center for Veterinary Medicine
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> Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
> 8401 Muirkirk Road, G704
> Laurel, Maryland 20708
> new tel: 240-402-5421

>
> fax: 301-210-4685
> e-mail: _jennifer.jones@fda.hhs.gov _ _

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

> [1]

>
> [2]

>
>
>
>

> Links:

> -----

> [1] <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

> [2] <http://www.fda.gov/>

From: Dr. [B6]
To: Jones, Jennifer L
Sent: 1/25/2018 5:52:12 PM
Subject: Re: FDA Case Investigation for [B6] dogs (800.218)

Hi Jen,
I just submitted the fifth report today. The ICSR number is 2040808. Unfortunately, I last saw the patient in July and though I have called both phone numbers we have on file, the owners have not returned my calls as yet. In our history, we have that he was fed a limited ingredient diet with kangaroo as the meat source but not a specific brand. I will be emailing them as well to see if I can get more specific information.

B6

On 2018-01-24 04:54, Jones, Jennifer L wrote:

> Thank you for the additional information, [B6] When you submit the
> new FDA report(s), please email me the ICSR number (like a
> confirmation number). It will help me find the report in our system.
>
> I will send you a box to re-use and send the leftover food to our lab.
> We send the food to a lab for testing. Please use the prepaid return
> label for shipping on a Monday-Wednesday (included in the box). You
> will call UPS to pick-up the package.
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> The testing will take a few weeks, but we'll send a copy of the
> results to you. Please share them with Ms. [B6]
> The box should ship arrive by close of business Friday.
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> Please email or call with any questions.
> Thank you,
> Jen
>
> Jennifer Jones, DVM
> Veterinary Medical Officer
> Tel: 240-402-5421

> -----Original Message-----

> From: Dr. [B6]
> Sent: Tuesday, January 23, 2018 6:20 PM
> To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
> Subject: Re: FDA Case Investigation for [B6]
> dogs (800.218)

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Dr.' [B6]
Sent: 2/23/2018 6:35:09 PM
Subject: RE: FDA Case Investigation for [B6] dogs (800.218)
Attachments: 800.218-Results-sent to [B6] 2.23.2018.xlsx

Good afternoon Dr. [B6]

I attached the food testing results for [B6]. The product contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. [B5]

Have you looked at an Iron Blood panel in any of the dogs? I didn't have the full CBC results from your cases, but did you see any hemogram parameter changes (MCHC etc)?

We'd like to request a total iron panel on [B6]. We would reimburse your clinic directly for the testing. Please send me an estimate for the charges, and I can make a purchase request. I must make a request prior to any testing.

After you complete the testing, please send me a copy of the results and an invoice. We can then call back with our VISA information.

Please respond if you're interested in the testing.

Thank you and take care,
Jen

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

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

From: Jones, Jennifer L
Sent: Wednesday, January 24, 2018 6:54 AM
To: 'Dr.' [B6]
Subject: RE: FDA Case Investigation for [B6] dogs (800.218)

Thank you for the additional information, [B6]. When you submit the new FDA report(s), please email me the ICSR number (like a confirmation number). It will help me find the report in our system.

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Sent: Tuesday, January 23, 2018 6:20 PM
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> Links:
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> [2] <http://www.fda.gov/>

DOCUMENT PRODUCED IN NATIVE

From: [redacted] B6
To: Jones, Jennifer L
Sent: 2/27/2018 12:54:18 PM
Subject: Re: FDA Case Investigation for [redacted] B6 dogs (800.218)

Not a problem at all. [redacted] B5

B5

Thank you for your help!

[redacted] B6

B6

On 2018-02-27 05:39, Jones, Jennifer L wrote:

- > Thank you [redacted] B6
- > Yes, we'd like to request the full Iron panel for [redacted] B6. Can you please
- > provide an estimate for that test? I need to make a purchase request.
- >
- > Jennifer Jones, DVM
- > Veterinary Medical Officer
- > Tel: 240-402-5421

> -----Original Message-----

- > From: [redacted] B6
- > Sent: Tuesday, February 27, 2018 7:37 AM
- > To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
- > Subject: Re: FDA Case Investigation for [redacted] B6
- > dogs (800.218)

- >
- > Dr. Jones,
- > I spoke with [redacted] B6 regarding this case as [redacted] B6 is out of
- > the [redacted] B6. We had not done a CBC as one was completed
- > through the referring vet, prior to her initial referral, and was
- > completely normal dated 1/5/18 through [redacted] B6. [redacted] B6 is actually
- > scheduled for a recheck tomorrow and if you would still like the [redacted] B5
- > panel, even though her CBC parameters were all within normal limits, we
- > could facilitate this at her visit. Please let us know.
- > Thank you.

[redacted] B6

[redacted] B6

B6

> On 2018-02-23 11:35, Jones, Jennifer L wrote:

>> Good afternoon **B6**

>> I attached the food testing results for **B6**. The product
>> contained inadequate iron content, below the AAFCO claim. In people,
>> low iron has been associated with idiopathic DCM (Marinescu and
>> McCullough 2011). According to the article, anemia was found in 12 to
>> 55% of patients in heart failure, and the anemia's severity correlated
>> to the degree of heart failure. **B5**

B5

>> We'd like to request a total iron panel on **B6**. We would
>> reimburse your clinic directly for the testing.

>> Please send me an estimate for the charges, and I can make a purchase
>> request. I must make a request prior to any testing.

>> After you complete the testing, please send me a copy of the results and
>> an invoice. We can then call back with our VISA information.

>>

>> Please respond if you're interested in the testing.

>> Thank you and take care,

>> Jen

>>

>> Jennifer Jones, DVM

>> Veterinary Medical Officer

>> Tel: 240-402-5421

>>

>>

>> -----Original Message-----

>> From: Jones, Jennifer L

>> Sent: Wednesday, January 24, 2018 6:54 AM

>> To: **B6**

>> Subject: RE: FDA Case Investigation for **B6**

>> dogs (800.218)

>>

>> Thank you for the additional information, **B6**. When you submit the
>> new FDA report(s), please email me the ICSR number (like a
>> confirmation number). It will help me find the report in our system.

>>

>> I will send you a box to re-use and send the leftover food to our lab.
>> We send the food to a lab for testing. Please use the prepaid return
>> label for shipping on a Monday-Wednesday (included in the box). You
>> will call UPS to pick-up the package.

>>

>> The testing will take a few weeks, but we'll send a copy of the
>> results to you. Please share them with **B6**.

>> The box should ship arrive by close of business Friday.

>>

>> Please email or call with any questions.

>> Thank you,

>> Jen

>>

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

>>
>>

>> -----Original Message-----

>> From: [REDACTED] B6
>> Sent: Tuesday, January 23, 2018 6:20 PM
>> To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
>> Subject: Re: FDA Case Investigation for [REDACTED] B6
>> dogs (800.218)

>>
>>

>> Dr. Jones,

>>

>> Thank you for reaching out. I have contacted [REDACTED] B6 owner to get a
>> sample of her food for analysis. Please let me know what to do from
>> there.

>>

>> For your information, we have pulled all our cases of dilated
>> cardiomyopathy that we diagnosed in 2017 and identified a fifth animal
>> on kangaroo and lentil diet (out of 23 total) - I will submit an FDA
>> case report for this-, and another one on a lentil-containing Vegan
>> diet. There are some cases in which the diet is not specified that we
>> still need to contact, but at least 11 of the cases are on grain-free
>> diets, including all of the cases in "atypical" breeds. As you may
>> have

>> seen from my listserve query to other cardiologists, not only have
>> Cardiologists been seeing cases in dogs fed kangaroo and lentil, but
>> there were a number of cases in dogs of "atypical" breeds on
>> lentil-based Vegan diets, and a series of Golden retrievers with
>> taurine

>> deficiency on grain-free diets. Grain-free diets are a fad right now
>> and lots of clients are feeding them, so the incidence of grain-free
>> diets may simply be coincidence. Interestingly however, [REDACTED] B6
>> who I saw recently and re-echoed after several months on another diet
>> with no documented improvement in echo findings is still being fed a
>> grain-free diet. I have asked her owner to switch her diet once again
>> to something not "grain-free" and we will see how things go over the
>> next several months.

>>

>> Thanks for your assistance with this. I look forward to hearing back
>> from you.

>>

>> [REDACTED] B6

>>

>>

>> [REDACTED] B6

>>

>> On 2018-01-23 11:53, Jones, Jennifer L wrote:

>>> Good afternoon [REDACTED] B6

>>>

>>> Thank you for submitting your consumer complaint to FDA. I'm sorry to
>>> hear about the dogs' illnesses.

>>>

>>> As part of our investigation, we'd like to request:

>>>

>>> * TEST REMAINING OPEN PRODUCT FROM B6

>>>

>>> * Testing for Co, Ca, P, Mg, Cu, Fe, Mg, Se, Zn, Taurine,
>>> Methionine, and Cysteine.

>>> * Please send me the size of the bag/approximate weight.

>>> * We will coordinate the testing through your office.

>>>

>>> In the unfortunate event that any of the dogs from these reports die
>>> or are euthanized, we may be able to offer cardiac histopathology
>>> (fixed formalin) and metals/aminoacids (fresh frozen) testing. Please
>>> contact me if this occurs and the owners are interested.

>>>

>>> I attached a copy of our Vet-LIRN network procedures. The procedures
>>> describe how Vet-LIRN operates and how veterinarians help with our
>>> case investigations.

>>>

>>> PLEASE RESPOND TO THIS EMAIL SO THAT WE CAN INITIATE OUR
>>> INVESTIGATION.

>>>

>>> Thank you kindly,

>>>

>>> Dr. Jones

>>>

>>> JENNIFER L. A. JONES, DVM

>>>

>>> Veterinary Medical Officer

>>> U.S. Food & Drug Administration

>>> Center for Veterinary Medicine

>>> Office of Research

>>> Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

>>> 8401 Muirkirk Road, G704

>>> Laurel, Maryland 20708

>>> new tel: 240-402-5421

>>>

>>> fax: 301-210-4685

>>> e-mail: _jennifer.jones@fda.hhs.gov__

>>>

>>> Web:

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

>>> [1]

>>>

>>> [2]

>>>

>>>

>>>

>>> Links:

>>> -----

>>> [1] <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

>>> [2] <http://www.fda.gov/>

From: [B6]
To: Jones, Jennifer L
Sent: 3/12/2018 5:41:26 PM
Subject: Documents from [B6] for [B6], Client: [B6]
[B6]
Attachments: [B6].pdf; [B6]-2018-03-09-0958.pdf

B6

B6

Client ID:
Client Name:
Spouse/Other:
Address:

B6

Telephone:

Patient ID:
Name:
Breed:
Sex:
Color:
Age:
DOB:

B6

Retriever, Labrador Mix
Spayed Female
Brindle

B6

Referring Veterinarian:
Practice:
Phone:
FAX:

B6

Dr. Jennifer Jones
FDA

Dear Dr. Jones,

Please find attached the normal results of the iron panel on **B6**. Please let me know if you have any other recommendations in **B6**.

I would love to discuss our findings on dilated cardiomyopathy and dietary relationships in our clinic over the past year. In particular, 75% of our DCM cases in 2017 for which we have adequate dietary histories were on grain free diets. We have started to do a survey of other cardiac patients during the same time period to see if we can get an idea of what percentage of our referral population were feeding these type of diets so we can see if this is truly significant. As we have been looking harder at these cases, we have found some other interesting things. For instance, two patients that were found to be taurine deficient were being fed Zignature diets. One was on the kangaroo variety and the other the pork variety. There continues to be a lot of discussion about diets and dilated cardiomyopathy on our list serve, but I can see it degenerating into I diagnosed DCM and the dog is on this diet so therefore this is a problem, which may or may not be true evidence to support a causative role of the diet.

I am not sure what information the FDA would want on all this at this point. We are certainly concerned that there may be a wider concern than simply the kangaroo and lentil diets that we first identified as a potential problem. Feel free to give me a call if you wish to discuss this further, or if you can suggest a direction for us to go with this inquiry. My clinic number is **B6** and I am in the clinics Monday through Thursday, or my cell phone is **B6**.

Sincerely,

B6

DYML



B6

PET OWNER: **B6**
SPECIES: Canine
BREED: Labrador Retriever
GENDER: Female
AGE: 6 Years
PATIENT ID: **B6**

B6

ACCOUNT #: 23896
ATTENDING VET: **B6**

LAB ID: 2600071832
ORDER ID: 109554033
COLLECTION DATE: **2/26/18**
DATE OF RECEIPT: **2/27/18**
DATE OF RESULT: **3/9/18**

IDEXX Services: **Iron Panel 1+*, Renal Panel**

IDEXX SDMA

Creatinine

BUN

B6

Jan '18 Feb '18 Jan '18 Feb '18 Jan '18 Feb '18

Chemistry



B6 (Order Received)
9:58 AM (Last Updated)

B6

TEST	RESULT	REFERENCE VALUE
B6 SDMA	B6	0 - 14 µg/dL
Creatinine		0.5 - 1.5 mg/dL
BUN		9 - 31 mg/dL
BUN:Creatinine Ratio		
Phosphorus		2.5 - 6.1 mg/dL
Calcium		8.4 - 11.8 mg/dL
Sodium		142 - 152 mmol/L
Potassium		4.0 - 5.4 mmol/L
Na:K Ratio		28 - 37
Chloride		108 - 119 mmol/L
TCO2 (Bicarbonate)		13 - 27 mmol/L
Anion Gap		11 - 26 mmol/L
Total Protein		5.5 - 7.5 g/dL
Albumin		2.7 - 3.9 g/dL
Globulin		2.4 - 4.0 g/dL
Alb:Glob Ratio		0.7 - 1.5

B6



B6

PET OWNER:

B6

DATE OF RESULT:

B6

LAB ID: Z600071832

Chemistry (continued)

TEST	RESULT	REFERENCE VALUE
Cholesterol	B6	131 - 345 mg/dL
Hemolysis Index		
Lipemia Index		

- a BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates kidney function is likely good. Evaluate a complete urinalysis and confirm there is no other evidence of kidney disease.
- b Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
- c Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

Therapeutics/Toxicology

B6 (Order Received)
:58 AM (Last Updated)

TEST	RESULT	REFERENCE VALUE
Serum Iron	B6	73 - 245 ug/dL
Ferritin		
TIBC		

- a Referral test performed at Kansas State University.

From: [redacted] **B6**
To: Jones, Jennifer L
Sent: 4/11/2018 3:24:34 PM
Subject: Fwd: Re: FDA Case Investigation for [redacted] **B6**
Attachments: cardio0013.pdf

We received a message stating this did not go through and wanted to make sure you actually get it so hopefully this works!?

[redacted] **B6**

Dr. Jones,

I have attached a copy of our idexx bill and highlighted the charge for the Iron panel. Please let me know if the attachment does not come through on your end for some reason.

Thanks,

[redacted] **B6**

[redacted] **B6**

On 2018-04-09 11:15, Jones, Jennifer L wrote:

- > Good afternoon [redacted] **B6**
- > Did you get the Idexx bill for the March testing that included the
- > iron panel for this case? If so, please send me a copy of the
- > statement highlighting the charge. Thank you,
- > Dr. Jones
- >
- > Jennifer Jones, DVM
- > Veterinary Medical Officer
- > Tel: 240-402-5421
- >
- >
- > -----Original Message-----
- > From: Jones, Jennifer L
- > Sent: Tuesday, March 20, 2018 2:46 PM
- > To: [redacted] **B6**
- > Subject: RE: FDA Case Investigation for [redacted] **B6**
- > dogs (800.218)
- >
- > Thank you for clarifying [redacted] **B6**
- > When I wrote the purchase request, I used your clinic as the group to
- > pay. Therefore, we'll need to reimburse your clinic directly. When you
- > get your March bill, please send me a copy of the statement
- > highlighting the charge, and we can call you directly to pay.
- >
- > Jennifer Jones, DVM
- > Veterinary Medical Officer
- > Tel: 240-402-5421
- >
- >
- > -----Original Message-----

> From: [REDACTED] **B6**
> Sent: Monday, March 19, 2018 12:10 PM
> To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
> Subject: Re: FDA Case Investigation for [REDACTED] **B6**
> dogs (800.218)

> Sorry for the delay in this response. I was doing some research on how
> we could go about getting this paid [REDACTED] **B6** receives a monthly
> bill from the laboratory and because the results were posted the 9th of
> March it was not listed on [REDACTED] **B6** February bill. I called and
> spoke with [REDACTED] **B6** in the billing department at Idexx and she let me know
> that they do accept third party payments. I was informed that our cost
> was \$177.90 for the iron panel. You will need our account number
> [REDACTED] **B6** (Cardiology)) and date of testing (order
> received 2/27/18 and results were posted 3/9/18) for [REDACTED] **B6**
> Please don't hesitate to call if there are any questions or issues.

> Thank you,
> [REDACTED] **B6**

> [REDACTED] **B6**

> On 2018-03-13 05:51, Jones, Jennifer L wrote:
>> Good morning,
>> Thank you for sending the final Iron panel results. Please email or
>> fax (301-210-4685) a copy of the invoice for the iron panel. We can
>> then call with our VISA information.
>> Thank you,
>> Dr. Jones
>>
>> Jennifer Jones, DVM
>> Veterinary Medical Officer
>> Tel: 240-402-5421

>> -----Original Message-----
>> From: [REDACTED] **B6**
>> Sent: Tuesday, February 27, 2018 10:56 AM
>> To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
>> Subject: Re: FDA Case Investigation for [REDACTED] **B6**
>> dogs (800.218)

>> The Iron Panel 1 costs us \$177.90, we get a small discount from the
>> list
>> price. (3-10 working days, 2 mL serum, spun and separated into plastic
>> tube and frozen (no hemolysis), List Price: \$193.69)

>> [REDACTED] **B6**

>> [B6]

>> [B6]

>> On 2018-02-27 05:39, Jones, Jennifer L wrote:

>>> Thank you, [B6]

>>> Yes, we'd like to request the full Iron panel for [B6] Can you please

>>> provide an estimate for that test? I need to make a purchase request.

>>> Jennifer Jones, DVM

>>> Veterinary Medical Officer

>>> Tel: 240-402-5421

>>> -----Original Message-----

>>> From: [B6]

>>> Sent: Tuesday, February 27, 2018 7:31 AM

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

>>> Subject: Re: FDA Case Investigation for [B6]

>>> dogs (800.218)

>>> Dr. Jones,

>>> I spoke with [B6] regarding this case as [B6] is out of

>>> the country this week. We had not done a CBC as one was completed

>>> through the referring vet, prior to her initial referral, and was

>>> completely normal dated 1/5/18 through Idexx. [B6] is actually

>>> scheduled for a recheck tomorrow and if you would still like the iron

>>> panel, even though her CBC parameters were all within normal limits,

>>> we

>>> could facilitate this at her visit. Please let us know.

>>> Thank you.

>>> [B6]

>>> [B6]

>>> On 2018-02-23 11:35, Jones, Jennifer L wrote:

>>>> Good afternoon [B6]

>>>> I attached the food testing results for [B6]. The product contained inadequate iron content, below the AAFCO claim. In people,

>>>> low iron has been associated with idiopathic DCM (Marinescu and

>>>> McCullough 2011). According to the article, anemia was found in 12

>>>> to

>>>> 55% of patients in heart failure, and the anemia's severity

>>>> correlated

>>>> to the degree of heart failure.

B5

B5

>>>> We'd like to request a total iron panel on [B6] We would
>>>> reimburse your clinic directly for the testing.

>>>> Please send me an estimate for the charges, and I can make a
>>>> purchase

>>>> request. I must make a request prior to any testing.

>>>> After you complete the testing, please send me a copy of the results

>>>> and

>>>> an invoice. We can then call back with our VISA information.

>>>>

>>>> Please respond if you're interested in the testing.

>>>> Thank you and take care,

>>>> Jen

>>>>

>>>> Jennifer Jones, DVM

>>>> Veterinary Medical Officer

>>>> Tel: 240-402-5421

>>>>

>>>>

>>>> -----Original Message-----

>>>> From: Jones, Jennifer L

>>>> Sent: Wednesday, January 24, 2018 6:54 AM

>>>> To: [B6]

>>>> Subject: RE: FDA Case Investigation for [B6]

>>>> dogs (800.218)

>>>>

>>>> Thank you for the additional information, [B6] When you submit the
>>>> new FDA report(s), please email me the ICSR number (like a
>>>> confirmation number). It will help me find the report in our system.

>>>>

>>>> I will send you a box to re-use and send the leftover food to our
>>>> lab.

>>>> We send the food to a lab for testing. Please use the prepaid return
>>>> label for shipping on a Monday-Wednesday (included in the box). You
>>>> will call UPS to pick-up the package.

>>>>

>>>> The testing will take a few weeks, but we'll send a copy of the
>>>> results to you. Please share them with [B6]

>>>> The box should ship arrive by close of business Friday.

>>>>

>>>> Please email or call with any questions.

>>>> Thank you,

>>>> Jen

>>>>

>>>> Jennifer Jones, DVM

>>>> Veterinary Medical Officer

>>>> Tel: 240-402-5421

>>>>

>>>>

>>>> -----Original Message-----

>>>> From [redacted] B6
>>>> Sent: Tuesday, January 23, 2018 6:20 PM
>>>> To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
>>>> Subject: Re: FDA Case Investigation fo [redacted] B6
>>>> dogs (800.218)

>>>> Dr. Jones,

>>>> Thank you for reaching out. I have contacted [redacted] B6 owner to get a
>>>> sample of her food for analysis. Please let me know what to do from
>>>> there.

>>>> For your information, we have pulled all our cases of dilated
>>>> cardiomyopathy that we diagnosed in 2017 and identified a fifth
>>>> animal
>>>> on kangaroo and lentil diet (out of 23 total) - I will submit an FDA
>>>> case report for this-, and another one on a lentil-containing Vegan
>>>> diet. There are some cases in which the diet is not specified that
>>>> we
>>>> still need to contact, but at least 11 of the cases are on
>>>> grain-free
>>>> diets, including all of the cases in "atypical" breeds. As you may
>>>> have
>>>> seen from my listserve query to other cardiologists, not only have
>>>> Cardiologists been seeing cases in dogs fed kangaroo and lentil, but
>>>> there were a number of cases in dogs of "atypical" breeds on
>>>> lentil-based Vegan diets, and a series of Golden retrievers with
>>>> taurine
>>>> deficiency on grain-free diets. Grain-free diets are a fad right
>>>> now
>>>> and lots of clients are feeding them, so the incidence of grain-free
>>>> diets may simply be coincidence. Interestingly however, [redacted] B6
>>>> [redacted] B6
>>>> who I saw recently and re-echoed after several months on another
>>>> diet
>>>> with no documented improvement in echo findings is still being fed a
>>>> grain-free diet. I have asked her owner to switch her diet once
>>>> again
>>>> to something not "grain-free" and we will see how things go over the
>>>> next several months.

>>>> Thanks for your assistance with this. I look forward to hearing
>>>> back
>>>> from you.

>>>> [redacted] B6

>>>> [redacted] B6

>>>> On 2018-01-23 11:53, Jones, Jennifer L wrote:

>>>>> Good afternoon [redacted] B6

>>>>> Thank you for submitting your consumer complaint to FDA. I'm sorry

>>>> to
>>>> hear about the dogs' illnesses.
>>>>
>>>> As part of our investigation, we'd like to request:
>>>>
>>>> * TEST REMAINING OPEN PRODUCT FROM B6
>>>>
>>>> * Testing for Co, Ca, P, Mg, Cu, Fe, Mg, Se, Zn, Taurine,
>>>> Methionine, and Cysteine.
>>>> * Please send me the size of the bag/approximate weight.
>>>> * We will coordinate the testing through your office.
>>>>
>>>> In the unfortunate event that any of the dogs from these reports
>>>> die
>>>> or are euthanized, we may be able to offer cardiac histopathology
>>>> (fixed formalin) and metals/aminoacids (fresh frozen) testing.
>>>> Please
>>>> contact me if this occurs and the owners are interested.
>>>>
>>>> I attached a copy of our Vet-LIRN network procedures. The
>>>> procedures
>>>> describe how Vet-LIRN operates and how veterinarians help with our
>>>> case investigations.
>>>>
>>>> PLEASE RESPOND TO THIS EMAIL SO THAT WE CAN INITIATE OUR
>>>> INVESTIGATION.
>>>>
>>>> Thank you kindly,
>>>>
>>>> Dr. Jones
>>>>
>>>> JENNIFER L. A. JONES, DVM
>>>>
>>>> Veterinary Medical Officer
>>>> U.S. Food & Drug Administration
>>>> Center for Veterinary Medicine
>>>> Office of Research
>>>> Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
>>>> 8401 Muirkirk Road, G704
>>>> Laurel, Maryland 20708
>>>> new tel: 240-402-5421
>>>>
>>>> fax: 301-210-4685
>>>> e-mail: _jennifer.jones@fda.hhs.gov__
>>>>
>>>> Web:
>>>> <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>
>>>> [1]
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>>>> [2]
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>>>> Links:
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>>>> [1]
>>>> <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>
>>>> [2] <http://www.fda.gov/>

From: Palmer, Lee Anne
To: Rotstein, David; Jones, Jennifer L; Carey, Lauren; Queen, Jackie L
Subject: RE: limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls); [REDACTED] B6 EON-345965
Date: Thursday, January 25, 2018 1:23:37 PM

Whoops, that's 2 from [REDACTED] B6 rather than [REDACTED] B6 Same household. thx!

From: Rotstein, David
Sent: Thursday, January 25, 2018 1:00 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: RE: limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls); [REDACTED] B6 EON-345965

Fantastic!

Hope it goes well!

From: Palmer, Lee Anne
Sent: Thursday, January 25, 2018 12:57 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: RE: limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls); [REDACTED] B6 EON-345965

Hi - trying out the epi summary in EON to give it a dry run (Dave, I've temporarily assigned it to myself). FYI - this makes 6 cases now, 5 from [REDACTED] B6 1 from [REDACTED] B6 involving 2 dogs, 1 death) all eating LID type diet with Kangaroo and Red Lentil, onset dates between 1/20/2017 and 12/30/2017). I'll double check that info as I read through the reports and summarize it in the incident. Just had to try out the new functionality, needed some fun today.

From: Rotstein, David
Sent: Thursday, January 25, 2018 12:27 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: Fwd: limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls); [REDACTED] B6 EON-345965

Another one from: [REDACTED] B6

From: PFR Event <ppreventcreation@fda.hhs.gov>
Date: January 25, 2018 at 12:25:12 PM EST
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>, [REDACTED] B6
Subject: limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls); [REDACTED] B6 EON-345965

A PFR Report has been received and PFR Event [EON-345965] has been created in the EON System.

A "PDF" report by name "2040808-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 "2040808-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-345965

ICSR #: 2040808

EON Title: PFR Event created for limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls); 2040808

AE Date	04/24/2017	Number Fed/Exposed	5
Best By Date		Number Reacted	5
Animal Species	Dog	Outcome to Date	Unknown
Breed	Shih Tzu		
Age	8 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2040808

Product Group: Pet Food

Product Name: limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls)

Description: At his scheduled visit to my clinic, thoracic radiographs showed generalized cardiomegaly which had been progressive compared to prior chest radiographs from his regular veterinarian but there was no evidence of cardiogenic edema. Echocardiogram was performed which showed dilated cardiomyopathy. Fundic exam was abnormal with a suspected partial retinal detachment OS. Diet history revealed that B6 was eating a kangaroo based diet. At this time the patient was continued on the B6 was discontinued, and B6 and taurine (500mg BID) were started. Taurine was discontinued after a normal taurine level was received. Cough persisted despite these changes and a course of B6 was prescribed. B6. The cough improved significantly but did not completely resolve so the B6 was continued an additional 14 days. The dog has since been lost to follow-up. I have attempted to contact the owner and am waiting for a response. I did contact the referring veterinarian and to their knowledge the dog is still alive.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 5

Number of Animals Reacted With Product: 5

Product Name	Lot Number or ID	Best By Date
limited ingredient diet with kangaroo as protein source - manufacturer not specified in written history (we have attempted to contact the owner but they do not return phone calls)		

Sender information

B6
USA

Owner information

B6

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

<https://eon.fda.gov/eon/browse/EON-345965>

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

<https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=362153>

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Palmer, Lee Anne; Rotstein, David; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'
Sent: 4/4/2018 1:32:19 PM
Subject: RE: 800.261-Zignature Kangaroo Formula: [B6] - EON-350158
Attachments: EON-350158; [B6] case summary-4.4.2018.doc

MRx summary below. We are purchasing store-bought product for Tau, Met, Cys testing. A previous case without food had a Cocker Spaniel-same Zignature Essentials Food. low Tau on labwork. If the Food results are

[B5]

MRx summary:

Presenting complaint [B6] to rDVM: developed a cough on [B6] cough for 3-4 days, not lethargic, normal eating/drinking, no vomiting or diarrhea, worse when lying down, dog didn't cough while in clinic except for a tracheal cough when pulling on the leasha treated with [B6] a stopped all 3 drugs Monday b/c cough worsened a to ER on [B6] after coughing up pink tinged foam: no lethargy, continues to eat and drink; UTD on vaccines and HWP, no drugs a treat with [B6]
Tau, L-carnitine and **vet recommended a diet change** alabwork done 11/14 a to rDVM 11/16: doing well a recheck 2/26/18: intermittent cough, related to excitement, change diet to RC Early Cardiac a on recheck improved a suspect Tau responsive DCM-mild, suspect cough secondary to bronchial or primary respiratory disease a recheck 3/13: resting RR 16 rpm, minimal coughing only when excited, since switching to cardiac food BMs are dense and tenesmus, owner is weaning dog off [B6]

PE [B6] @ rDVM: [B6] shallow breathing

PE [B6] @ specialist: [B6] HR 100 bpm, mild [B6] Gr II/VI, left apical protosystolic murmur, questionable mild inc bronchovesicular sounds bilaterally: [B6]

[B6]

PE 11/16 @ rDVM: mild underbite, H/L wnl

Labs:

[B6]

Rads [B6] generalized cardiomegaly, left atrial enlargement, slight left auricular bulge, increased sternal contact & rounded heart, dorsal tracheal deviation, prominent pulmonary vasculature with questionably mild inc interstitial opacity in caudal-dorsal lungs, suggesting early CHF/PE

[B6] **Echo:** severe LV hypertrophy, mild-mod MV regurgitation, mod-sev LA dilation, mild TV regurg, mild RV & RA dilation, mod-sev lower systolic function values

-2/26: mild LV dilation, mild MV regurg, normal LA, mild TV regurg, normal RV & RA, low normal systolic functional indices of LV

[B6] **ECG:** normal sinus rhythm

Prior MHx:

[B6]

[B6] consistently,

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



From: Jones, Jennifer L
Sent: Tuesday, March 27, 2018 3:40 PM
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-350158

Yes-let's take a look! I think we should check taurine, cysteine, methionine, and beta-alanine. [B5]
[B5]
<https://academic.oup.com/alcalc/article/36/1/29/138000>

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



From: Palmer, Lee Anne
Sent: Tuesday, March 27, 2018 3:25 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: FW: Zignature Kangaroo Formula: [B6] EON-350158

In case of interest – taurine level low?

From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Tuesday, March 27, 2018 3:20 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
Subject: Zignature Kangaroo Formula: [B6] - EON-350158

A PFR Report has been received and PFR Event [EON-350158] has been created in the EON System.

A "PDF" report by name "2044632-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 "2044632-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350158
ICSR #: 2044632
EON Title: PFR Event created for Zignature Kangaroo Formula; 2044632

AE Date	[B6]	Number Fed/Exposed	1
---------	------	--------------------	---

Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	13 Years		
District Involved	PFR B6		

Product information

Individual Case Safety Report Number: 2044632

Product Group: Pet Food

Product Name: Zignature Kangaroo Formula

Description: At the time of diagnosis **B6** was a 13 year old female spayed Labrador retriever who had been maintained on a Zignature Kangaroo formula. She presented with a history of a progressive cough which, prior to presentation, became productive and she coughed up a small volume of pink foam (possible pulmonary edema). On examination she had a 2/6 left apical systolic heart murmur and on echo diagnosed with advanced dilated cardiomyopathy with severe left ventricular dilation, moderate to severe left ventricular systolic dysfunction, and moderate to severe left atrial dilation. Thoracic radiographs were suspicious for early congestive heart failure. A whole blood taurine level was submitted and was low at **B6** She was treatment with **B6** **B6** and her diet was changed to Royal Canin Early Cardiac. At her recheck in 2/26/18, **B6** heart had improved significantly with now mild dilated cardiomyopathy with normalized left atrial dimensions, mild left ventricular dilation and low normal left ventricular systolic function. The **B6** was able to be discontinued at this time.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature Kangaroo Formula		

Sender information

B6

USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-350158>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=366527>

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Nemser, Sarah
Sent: 4/4/2018 6:06:23 PM
Subject: RE: 800.261-Zignature Kangaroo Formula: **B6** EON-350158

Sometimes, I'm the only one on the emails.

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



From: Nemser, Sarah
Sent: Wednesday, April 04, 2018 9:42 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FW: 800.261-Zignature Kangaroo Formula: **B6** - EON-350158

I am not getting original emails about cases. Am I not on the emails?

S

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: **240-402-0892**

fax: **301-210-4685**
sarah.nemser@fda.hhs.gov

From: Jones, Jennifer L
Sent: Wednesday, April 04, 2018 9:32 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.261-Zignature Kangaroo Formula: **B6** - EON-350158

MRx summary below. We are purchasing store-bought product for Tau, Met, Cys testing. A previous case without food had a Cocker Spaniel-same Zignature Essentials Food, low Tau on labwork. If the Food results are

B5

MRx summary:

Presenting complaint **B6** to rDVM: developed a cough or **B6** cough for 3-4 days, not lethargic, normal eating/drinking, no vomiting or diarrhea, worse when lying down, dog didn't cough while in clinic except for a tracheal cough when pulling on the leash; treated with **B6** stopped all 3 drugs Monday b/c cough worsened; to ER on **B6** after coughing up pink tinged foam; no lethargy, continues to eat and drink; UTD on vaccines and HWP, no drugs; treat with **B6** Tau, L-carnitine and **vet recommended a diet change**; labwork done 11/14; to rDVM 11/16: doing well; a recheck 2/26/18: intermittent cough, related to excitement, change diet to RC Early Cardiac; a on recheck

improved à suspect Tau responsive DCM-mild, suspect cough secondary to bronchial or primary respiratory disease à recheck 3/13: resting RR 16 rpm, minimal coughing only when excited, since switching to cardiac food
BMs are dense and tenesmus. owner is weaning dog off. **B6**

PE B6 @ rDVM: **B6** shallow breathing

PE B6 @ specialist: **B6** HR 100 bpm, mild **B6** Gr II/VI left apical protosystolic murmur, questionable mild inc bronchovesicular sounds bilaterally, **B6**

B6
PE 11/16 @ rDVM: mild underbite, H/L wnl

Labs:

B6

Rads B6 generalized cardiomegaly, left atrial enlargement, slight left auricular bulge, increased sternal contact & rounded heart, dorsal tracheal deviation, prominent pulmonary vasculature with questionably mild inc interstitial opacity in caudal-dorsal lungs, suggesting early CHF/PE

B6 Echo: severe LV hypertrophy, mild-mod MV regurgitation, mod-sev LA dilation, mild TV regurg, mild RV & RA dilation, mod-sev lower systolic function values
-2/26: mild LV dilation, mild MV regurg, normal LA, mild TV regurg, normal RV & RA, low normal systolic functional indices of LV

B6 ECG: normal sinus rhythm

B6

consistently,

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



From: Jones, Jennifer L
Sent: Tuesday, March 27, 2018 3:40 PM
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-350158

Yes-let's take a look! I think we should check taurine, cysteine, methionine, and beta-alanine **B5**

B5

<https://academic.oup.com/alcalc/article/36/1/29/138000>

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



From: Palmer, Lee Anne
Sent: Tuesday, March 27, 2018 3:25 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: FW: Zignature Kangaroo Formula: [B6] - EON-350158

In case of interest – taurine level low?

From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Tuesday, March 27, 2018 3:20 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [B4]
Subject: Zignature Kangaroo Formula [B6] EON-350158

A PFR Report has been received and PFR Event [EON-350158] has been created in the EON System.

A "PDF" report by name "2044632-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 "2044632-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350158
ICSR #: 2044632
EON Title: PFR Event created for Zignature Kangaroo Formula; 2044632

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	13 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2044632

Product Group: Pet Food

Product Name: Zignature Kangaroo Formula

Description: At the time of diagnosis (10/31/17) [B6] was a 13 year old female spayed Labrador retriever who had been maintained on a Zignature Kangaroo formula. She presented with a history of a progressive cough which, prior to presentation, became productive and she coughed up a small volume of pink foam (possible

pulmonary edema). On examination she had a 2/6 left apical systolic heart murmur and on echo diagnosed with advanced dilated cardiomyopathy with severe left ventricular dilation, moderate to severe left ventricular systolic dysfunction, and moderate to severe left atrial dilation. Thoracic radiographs were suspicious for early congestive heart failure. A whole blood taurine level was submitted and was low at [B6]. She was treatment with [B6] [B6] taurine and l-carnitine and her diet was changed to Royal Canin Early Cardiac. At her recheck in 2/26/18, [B6] heart had improved significantly with now mild dilated cardiomyopathy with normalized left atrial dimensions, mild left ventricular dilation and low normal left ventricular systolic function. The [B6] was able to be discontinued at this time.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature Kangaroo Formula		

Sender information

[B6]

USA

Owner information

[B6]

USA

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

<https://eon.fda.gov/eon//browse/EON-350158>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=366527>

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
CC: Peloquin, Sarah
Sent: 9/16/2018 3:41:46 PM
Subject: FW: Safety Report ID 243137 Submission Confirmation
Attachments: discharge 9-14-18.pdf; ecg.pdf; echo 9-12-18.pdf; fda submission.pdf; med records 9-12-18.pdf; profile 9-13-18.pdf; profile 9-14-18.pdf; rdvm lab 9-11-18.pdf; rdvm med records 9-12-18.pdf; rdvm rads.pdf; rdvm treatment 9-12-18.pdf; soaps.pdf; taurine.pdf

Hi Jen
This is the additional records that go along with this submission [REDACTED] B6
This one is interesting because he is the brother of [REDACTED] B6 who also developed DCM and CHF in July and was submitted to FDA by owner.

Sorry to send all this by email. If there's a better way to submit when there are too many to be uploaded (or a different person to send to), please let me know. I'm copying Sarah this time but not sure who the best person to send to is.

Thanks
Lisa

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

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

From: noreply.safetyreporting@hhs.gov <noreply.safetyreporting@hhs.gov>
Sent: Sunday, September 16, 2018 11:39 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: Safety Report ID 243137 Submission Confirmation

Your initial Pet Food Safety Report , Submitted by: Lisa Freeman, ID 243137, was successfully submitted on 9/16/2018 11:38:42 AM EST to the FDA, and it was issued an Individual Case Safety Report Number (ICSR) of 2054966.

Thank you for using the Safety Reporting Portal.

Please do not reply to this message. Replies to this message are routed to an unmonitored mailbox. If you have questions please refer to the Portal's Contact Us page for further instructions.

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
CC: Peloquin, Sarah
Sent: 9/16/2018 3:44:32 PM
Subject: RE: Safety Report ID 243137 Submission Confirmation - diet history
Attachments: B6 diet history.pdf

Sorry - forgot the diet history

Lisa

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

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

From: Freeman, Lisa
Sent: Sunday, September 16, 2018 11:42 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: FW: Safety Report ID 243137 Submission Confirmation

Hi Jen
This is the additional records that go along with this submission B6 This one is interesting because he is the brother of B6 who also developed DCM and CHF in July and was submitted to FDA by owner.

Sorry to send all this by email. If there's a better way to submit when there are too many to be uploaded (or a different person to send to), please let me know. I'm copying Sarah this time but not sure who the best person to send to is.

Thanks

Lisa

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

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

From: noreply.safetyreporting@hhs.gov <noreply.safetyreporting@hhs.gov>
Sent: Sunday, September 16, 2018 11:39 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: Safety Report ID 243137 Submission Confirmation

Your initial Pet Food Safety Report , Submitted by: Lisa Freeman, ID 243137, was successfully submitted on 9/16/2018 11:38:42 AM EST to the FDA, and it was issued an Individual Case Safety Report Number (ICSR) of 2054966.

Thank you for using the Safety Reporting Portal.

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
CC: Peloquin, Sarah
Sent: 9/19/2018 2:36:06 PM
Subject: RE: Safety Report ID 243137 Submission Confirmation

Got it! Thanks, Lisa.

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

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

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Sunday, September 16, 2018 11:42 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: FW: Safety Report ID 243137 Submission Confirmation

Hi Jen
This is the additional records that go along with this submission (B6)
This one is interesting because he is the brother of (B6) who also developed DCM and CHF in July and was submitted to FDA by owner.

Sorry to send all this by email. If there's a better way to submit when there are too many to be uploaded (or a different person to send to), please let me know. I'm copying Sarah this time but not sure who the best person to send to is.

Thanks

Lisa

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

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

From: noreply.safetyreporting@hhs.gov <noreply.safetyreporting@hhs.gov>
Sent: Sunday, September 16, 2018 11:39 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: Safety Report ID 243137 Submission Confirmation

Your initial Pet Food Safety Report , Submitted by: Lisa Freeman, ID 243137, was successfully submitted on 9/16/2018 11:38:42 AM EST to the FDA, and it was issued an Individual Case Safety Report Number (ICSR) of 2054966.

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Please do not reply to this message. Replies to this message are routed to an unmonitored mailbox. If you have questions please refer to the Portal's Contact Us page for further instructions.

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 10/25/2018 11:49:00 AM
Subject: [B6] case-FW: Purina One Lamb and Rice: Lisa Freeman - EON-369324
Attachments: 2057944-report.pdf; Purina One Lamb and Rice: Lisa Freeman - EON-369323

Here is one of the ones that you were waiting for.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Thursday, October 25, 2018 7:45 AM
To: [B6] Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [B6]
Subject: Purina One Lamb and Rice: Lisa Freeman - EON-369324

A PFR Report has been received and Related PFR Event [EON-369324] has been created in the EON System.

A "PDF" report by name "2057944-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-369324
ICSR #: 2057944
EON Title: Related PFR Event created for Purina One Lamb and Rice; 2057944

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Pit Bull		

Age	7 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2057944

Product Group: Pet Food

Product Name: Purina One Lamb and Rice

Description: DCM and CHF with ventricular tachycardia Taurine within normal limits Unclear if diet associated but reporting since lamb and rice diet Clarification: Owner confirmed that dog was eating Purina One Lamb and Rice when diagnosed but changed after diagnosis (and before recheck) to Purina One Beef or Chicken only. We will recheck in Jan to see if any improvement

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Purina One Lamb and Rice		

This report is linked to:

Initial EON Event Key: EON-369323

Initial ICSR: 2057943

Sender information

Lisa Freeman
 200 Westboro Rd
 North Grafton, MA 01536
 USA

Owner information

B6 USA

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

<https://eon.fda.gov/eon//browse/EON-369324>

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=386246&parentIssueTypeId=12>

=====

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Carey, Lauren; Palmer, Lee Anne
CC: Peloquin, Sarah
Sent: 12/11/2018 8:14:44 PM
Subject: RE: 800.267-cc-166-EON-363323 [B6] case-FW: Purina One Lamb and Rice
Attachments: compiled medical record.pdf

Lamb & Rice diet-not GF
Interview pending

rDVM MRx are illegible

[B6] 6 yr MC Pit Bull

2/12: x-rad: cardiomeg, Labs-wnl

2/13 echo: murmur detected; tj [B6]

[B6] concern w/ kidneys, ECG 200+ bpm, PU/PD since furo, HW neg, eats Purina One lamb & rice +/- hamburger or cold cuts;

[B6] to ER: tachyarrhyth; choking sound at home ~1 mo ago, ~2/10 was coughing, owned past 2 years w/ no known prior hx:

[B6]

[B6] cardio: confirmed DCM, freq v-tach during exam

4Dx: Lyme pos

[B6]

8/31: [B6]

9/5: sev LV dil, mod LA inc. mild inc RB. dec sys fxn, arrhythmia, mild MR

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



From: Rotstein, David
Sent: Thursday, October 25, 2018 7:49 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: [B6] case-FW: Purina One Lamb and Rice; Lisa Freeman - EON-369324

Here is one of the ones that you were waiting for.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Thursday, October 25, 2018 7:45 AM
To: [REDACTED] B6 Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [REDACTED] B6
Subject: Purina One Lamb and Rice: Lisa Freeman - EON-369324

A PFR Report has been received and Related PFR Event [EON-369324] has been created in the EON System.

A "PDF" report by name "2057944-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-369324
ICSR #: 2057944
EON Title: Related PFR Event created for Purina One Lamb and Rice; 2057944

AE Date	[REDACTED] B6	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Pit Bull		
Age	7 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2057944

Product Group: Pet Food

Product Name: Purina One Lamb and Rice

Description: DCM and CHF with ventricular tachycardia Taurine within normal limits Unclear if diet associated but reporting since lamb and rice diet Clarification: Owner confirmed that dog was eating Purina One Lamb and Rice when diagnosed but changed after diagnosis (and before recheck) to Purina One Beef or Chicken only. We will recheck in Jan to see if any improvement

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Purina One Lamb and Rice		

This report is linked to:
Initial EON Event Key: EON-369323
Initial ICSR: 2057943

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

To view this Related PFR Event, please click the link below:
<https://eon.fda.gov/eon//browse/EON-369324>

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=386246&parentIssueTypeId=12>

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 9/7/2018 9:22:49 PM
Subject: And another Tufts!!! cleaning house on Friday :) FW: Honest Kitchen Whole Grain Turkey: Lisa Freeman - EON-364577
Attachments: 2054750-report.pdf; 2054750-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: PFR Event <pfpreventcreation@fda.hhs.gov>
Sent: Friday, September 07, 2018 5:21 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; **B6**
Subject: Honest Kitchen Whole Grain Turkey: Lisa Freeman - EON-364577

A PFR Report has been received and PFR Event [EON-364577] has been created in the EON System.

A "PDF" report by name "2054750-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 "2054750-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-364577
ICSR #: 2054750
EON Title: PFR Event created for Honest Kitchen Whole Grain Turkey Beef or CHicken, Ziwi Peak (recently started); 2054750

AE Date	09/05/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1

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

Product information

Individual Case Safety Report Number: 2054750

Product Group: Pet Food

Product Name: Honest Kitchen Whole Grain Turkey, Beef, or CHicken, Zivi Peak (recently started)

Description: Not true DCM but reduced contractility **B6** taurine (whole blood)

Submission Type: Initial

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

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

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zivi Peak (recently started)		
Honest Kitchen Whole Grain Turkey, Beef, or CHicken		

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:

<https://eon.fda.gov/eon//browse/EON-364577>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issuelid=381311>

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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Rotstein, David; Carey, Lauren; Palmer, Lee Anne
CC: Peloquin, Sarah
Sent: 12/12/2018 3:53:00 PM
Subject: RE: 800.267-cc-170-EON-364577-367347; **B6** Honest Kitchen whole grain turkey

NFA

B6 11 yr FS Golden Retriever

B6

9/27/2018 to Tufts: check for DCM, been on GF diet (normal Tau lvl); diet Honest Kitchen GF w/ Primal (once x month), home cooked here and there; now on Canine Natural, bag of RC GR and Ziwi Peak; gets OFA oil,

B6

PE-nsf
Echo-mild dec LV contrxn, RH mild dil, Tr PR
ECG-nsr, HR 90bpm; proBNP: done but no result listed
Tx: diet change to main stream brand diet, recheck 6-12 mo

B6 11 yr MC Golden Retriever

B6

8/21/2018: Davis WB Tau **B6** wner shipped self from home after blood draw

9/5/2018 to Tufts: **B6** POS but asymptomatic, tx in past; in last yr gets out of pool sooner than usual, exercise intolerance, may breath faster than other dog (34 rpm); diet-ZiwiPeak GF, home cooked, switched to Honest Kitchen about 3 yr ago, Bravo canned rotates food, gets grains filled treats and sardines, coughs after swimming; gets OFAs

B6

Tx: diet change, Tau 1g BID

Repeat WB Tau Davis **B6**

9/5 **B6**

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



From: Rotstein, David

Sent: Monday, October 01, 2018 5:25 PM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: please see prior PFR 364577-FW: Honest Kitchen whole grain turkey: Lisa Freeman - EON-367347

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: PFR Event <ppreventcreation@fda.hhs.gov>
Sent: Monday, October 01, 2018 5:05 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [REDACTED] **B6**
Subject: Honest Kitchen whole grain turkey: Lisa Freeman - EON-367347

A PFR Report has been received and PFR Event [EON-367347] has been created in the EON System.

A "PDF" report by name "2055560-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 "2055560-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367347
ICSR #: 2055560
EON Title: PFR Event created for Honest Kitchen whole grain turkey beef or chicken + Ziwi Peak (just started again) - see diet history for [REDACTED] **B6** and [REDACTED] **B6** attached; 2055560

AE Date	09/27/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	[REDACTED] B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055560

Product Group: Pet Food

Product Name: Honest Kitchen whole grain turkey, beef, or chicken + Ziwi Peak (just started again) - see diet

history for [B6] and [B6] attached

Description: Housemate diagnosed with reduced contractile function on echo [B6]

Asymptomatic NT-proBNP tested at RDVM. Will send results

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Honest Kitchen whole grain turkey, beef, or chicken + Ziwi Peak (just started again) - see diet history for [B6] and [B6] attached		

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:

<https://eon.fda.gov/eon//browse/EON-367347>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=384261>

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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) 839-8739
<http://vetmed.tufts.edu/>

Emergency & Critical Care Liaison: (508) 887-4745

Patient

Name:

B6

Signalment:

B6 Years Old White/Brown Male
(Neutered) Beagle Cross

Owner

Name:

Address:

B6

Patient ID:

B6

Primary Clinician:

B6

DVF (Emergency and Critical Care Resident)

Consulting Clinician:

Attending Clinician:

B6

Discharge Instructions

Admit Date: 7/22/2016 1:44:13 PM

Check Out Date: 7/23/2016

Case summary

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. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management, although B6 did not show any signs of arrhythmia.

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.

DCM can be the consequence of taurine deficiency. Given the age and the breed of B6, we can't rule out this possibility. A dosage of taurine has been sent and we are expecting the results in 10 to 15 days. Meanwhile B6 will be treated for this deficiency, the treatment is harmless.

Diagnosis:

1. Dilated cardiomyopathy (DCM)
2. Taurine deficiency :Results pending

Diagnostic test results and findings:

Chest radiograph (x ray) findings: Moderate generalized cardiomegaly, left atrial enlargement, diffuse interstitial to alveolar pattern.

Echocardiogram findings: All chambers of the heart are enlarged and there is a leak at the mitral valve

ECG findings: The ECG showed no arrhythmia with a heart rate between 120 and 130 bpm.

Labwork findings: The kidney values are within normal limits. Urea = B6 mg/dl (12-18), Creatinine = B6 µg/dl (0.2-2.1)

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- An increase in breathing rate or effort will usually mean that you should give an extra dose of B6. If difficulty breathing is not improved by within 30-60 minutes after giving extra B6 then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/>).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

Diet suggestions:

Dogs with heart failure 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/>)

Your dog's usual diet may also have more sodium than recommended - we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50-50, etc.). Hopefully you can find a diet on the list that your dog likes to eat.

Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

The HeartSmart web site also has some information on supplements such as fish oil, taurine, and other supplements that you might have questions about.

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:

Recheck appointment scheduled with cardiology on Tuesday August 2nd at 11AM. Please call 508 887 4696 if need to reschedule.

At this visit we will check your dog's breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram is recommended in 3-4 months.

Please visit our HeartSmart website for more information

<http://vet.tufts.edu/heartsmart/>

Thank you for bringing us Jackson, he is a very cute dog. If you have any questions or concern, please e-mail me (maeva.coulet_paris@tufts.edu) or feel free to contact our emergency service 24/7 : 508-839-5395.

Case: B6

Owner: B6

Discharge Instructions

Date/Time	Patient	Description	Type	Results	Unit/Meas	Res	High	Low	Notes	Technician	Location	Specimen	Accession	Case	Reg	Num
7/22/2	B6	FI02	NOVA		%	21%	(r	0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		NOVA SA	NOVA			Venou		0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		A	NOVA		mmHg			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		HCO3	IRMA		mmol/			24.0	18.0		Techn	Fost	1983	Nova	9980	
7/22/2		BEb	NOVA		mmol/			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		BEecf	NOVA		mmol/			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		CA/MG	NOVA		mol/m			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		GAP	NOVA		mmol/			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		nMG	NOVA		mmol/			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		nCA	NOVA		mmol/			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		TCO2 (P	NOVA		mmol/			0.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		CREAT (NOVA		mg/dL			2.10	0.20		Techn	Fost	1983	Nova	9980	
7/22/2	B6	BUN (PO	NOVA	B6	mg/dL			28.0	12.0		Techn	Fost	1983	Nova	9980	
7/22/2		LACTATE	NOVA		mmol/			2.00	0.00		Techn	Fost	1983	Nova	9980	
7/22/2		GLUCOS	NOVA		mg/dL			120.	80.0		Techn	Fost	1983	Nova	9980	
7/22/2		MG (POC	NOVA		mmol/			0.40	0.10		Techn	Fost	1983	Nova	9980	
7/22/2		CA (ioniz	NOVA		mmol/			1.38	1.17		Techn	Fost	1983	Nova	9980	
7/22/2		CL(POC)	NOVA		mmol/			120.	109.		Techn	Fost	1983	Nova	9980	
7/22/2		K (POC)	NOVA		mmol/			4.80	3.60		Techn	Fost	1983	Nova	9980	
7/22/2		NA (POC	NOVA		mmol/			154.	140.		Techn	Fost	1983	Nova	9980	
7/22/2		HB (POC	NOVA		g/dL			16.0	12.6		Techn	Fost	1983	Nova	9980	
7/22/2		HCT (PO	NOVA		%			48.0	38.0		Techn	Fost	1983	Nova	9980	
7/22/2		SO2%	NOVA		%			100.	94.0		Techn	Fost	1983	Nova	9980	
7/22/2		PO2	nova		mmHg			100.	80.0		Techn	Fost	1983	Nova	9980	
7/22/2		PCO2	IRMA		mmHg			44.0	36.0		Techn	Fost	1983	Nova	9980	
7/22/2		PH	IRMA					7.46	7.33		Techn	Fost	1983	Nova	9980	

Accession ID:	Patient	Description	Type	Results	Unit/Meas	Res	High	Low	Notes	Technician	Location	Specimen	Accession	Case	Reg	Num
7/22/2	B6	PCV **	PCV/T	B6	%			0.00	0.00		Techn	Fost	1984	Non		
7/22/2		TS (FHS	PCV/T	B6	g/dl			0.00	0.00		Techn	Fost	1984	Non		

Accession ID:	Patient	Description	Type	Results	Unit/Meas	Res	High	Low	Notes	Technician	Location	Specimen	Accession	Case	Reg	Num
7/23/2		FI02	NOVA		%	21%	(r	0.00	0.00		Techn	Fost	1985	Nova	9989	
7/23/2		NOVA SA	NOVA			Venou		0.00	0.00		Techn	Fost	1985	Nova	9989	
7/23/2		A	NOVA		mmHg			0.00	0.00		Techn	Fost	1985	Nova	9989	
7/23/2	B6	HCO3	IRMA	B6	mmol/			24.0	18.0		Techn	Fost	1985	Nova	9989	
7/23/2		BEb	NOVA		mmol/			0.00	0.00		Techn	Fost	1985	Nova	9989	
7/23/2		BEecf	NOVA		mmol/			0.00	0.00		Techn	Fost	1985	Nova	9989	
7/23/2		CA/MG	NOVA		mol/m			0.00	0.00		Techn	Fost	1985	Nova	9989	

Date/Time	Patient	Description	Type	Results/Meas	Res	High	Low	Notes	Technician	Site	Year	Case	Tag	Num
7/23/2		GAP	NOVA		mmol/	0.00	0.00							
7/23/2		nMG	NOVA		mmol/	0.00	0.00							
7/23/2		nCA	NOVA		mmol/	0.00	0.00							
7/23/2		TCO2 (P	NOVA		mmol/	0.00	0.00							
7/23/2		CREAT (NOVA		mg/dL	2.10	0.20							
7/23/2		BUN (PO	NOVA		mg/dL	28.0	12.0							
7/23/2		LACTATE	NOVA		mmol/	2.00	0.00							
7/23/2		GLUCOS	NOVA		mg/dL	uncalib	120.	80.0						
7/23/2		MG (POC	NOVA		mmol/	0.40	0.10							
7/23/2	B6	CA (ioniz	NOVA	B6	mmol/	1.38	1.17		B6					
7/23/2		CL(POC)	NOVA		mmol/	120.	109.							
7/23/2		K (POC)	NOVA		mmol/	4.80	3.60							
7/23/2		NA (POC	NOVA		mmol/	154.	140.							
7/23/2		HB (POC	NOVA		g/dL	16.0	12.6							
7/23/2		HCT (PO	NOVA		%	48.0	38.0							
7/23/2		SO2%	NOVA		%	100.	94.0							
7/23/2		PO2	nova		mmHg	100.	80.0							
7/23/2		PCO2	IRMA		mmHg	44.0	36.0							
7/23/2		PH	IRMA			7.46	7.33							

Accession ID: **B6**

7/23/2	B6	PCV **	PCV/T	B6	%	0.00	0.00		B6	Techn	Fost	1985	Non	
7/23/2		TS (FHS	PCV/T		g/dl	0.00	0.00			Techn	Fost	1985	Non	

Accession ID: 198604

7/23/2		OSMOLA	Chemi		mmol/	315.	291.							
7/23/2		CHOLES	Chemi		mg/dL	355.	82.0							
7/23/2		AST	Chemi		U/L	95 Res	54.0	9.00						
7/23/2		ALT	Chemi		U/L		86.0	14.0						
7/23/2		ALK PHO	Chemi		U/L		127.	12.0						
7/23/2		I BILIRU	Chemi		mg/dL	0.00	0.20	0.00						
7/23/2	B6	D. BILIRU	Chemi	B6	mg/dL	0.00	0.10	0.00						
7/23/2		T BILIRU	Chemi		mg/dL		0.30	0.10		B6				
7/23/2		NA/K	Chemi				40.0	29.0						
7/23/2		POTASSI	Chemi		mEq/L	3.4 Re	5.40	3.70						
7/23/2		CHLORI	Chemi		mEq/L	91 Res	116.	106.						
7/23/2		SODIUM	Chemi		mEq/L	148 Re	150.	140.						
7/23/2		POIKILO	CBC			Occasi	0.00	0.00						
7/23/2		COMMEN	CBC			10-25	0.00	0.00						
7/23/2		A/G RAT	Chemi				1.60	0.70						

Date/Time	Patient	Description	Type	Results	Meas/er	Res	High	Low	Notes	sterin	chn	ospit	essor	file	N	Case	Tag	Numt
7/23/2		GLOBALI	Chemi		g/dL		4.20	2.30			Techn	Fost	1986	Che	9990			
7/23/2		RDW (A	CBC				15.2	11.9			Techn	Fost	1986	CBC	9990			
7/23/2		H-J BOD	CBC			Occasi	0.00	0.00			Techn	Fost	1986	Micr	9990			
7/23/2		WBC MO	CBC			No Mo	0.00	0.00			Techn	Fost	1986	Micr	9990			
7/23/2		MCHC(A	CBC		g/dL		34.3	31.9			Techn	Fost	1986	CBC	9990			
7/23/2		ALBUMI	Chemi		g/dL		4.00	2.80			Techn	Fost	1986	Che	9990			
7/23/2		MONOS	CBC		K/uL		1.50	0.10			Techn	Fost	1986	Micr	9990			
7/23/2		MCH(AD	CBC		pg		25.9	21.3			Techn	Fost	1986	CBC	9990			
7/23/2		T. PROT	Chemi		g/dL		7.80	5.50			Techn	Fost	1986	Che	9990			
7/23/2		CALCIU	Chemi		mg/dL		11.3	9.40			Techn	Fost	1986	Che	9990			
7/23/2		MCV(AD	CBC		fL		77.5	64.5			Techn	Fost	1986	CBC	9990			
7/23/2	B6	LYMPHS	CBC	B6	K/uL		4.80	1.00			B6	Techn	Fost	1986	Micr	9990		
7/23/2		HCT(AD	CBC		%		55.0	39.0			Techn	Fost	1986	CBC	9990			
7/23/2		PHOSPH	Chemi		mg/dL		7.20	2.60			Techn	Fost	1986	Che	9990			
7/23/2		SEGS (A	CBC		K/uL		11.5	2.80			Techn	Fost	1986	Micr	9990			
7/23/2		CREATIN	Chemi		mg/dL		2.00	0.60			Techn	Fost	1986	Che	9990			
7/23/2		HGB(AD	CBC		g/dL		20.5	13.3			Techn	Fost	1986	CBC	9990			
7/23/2		MONOS	CBC		%		15.0	1.00			Techn	Fost	1986	Micr	9990			
7/23/2		LYMPHS	CBC		%		47.0	7.00			Techn	Fost	1986	Micr	9990			
7/23/2		UREA	Chemi		mg/dL		30.0	8.00			Techn	Fost	1986	Che	9990			
7/23/2		RBC(ADV	CBC		M/uL		8.50	5.80			Techn	Fost	1986	CBC	9990			
7/23/2		GLUCOS	Chemi		mg/dL		135.	87.0			Techn	Fost	1986	Che	9990			
7/23/2		WBC (AD	CBC		K/uL		15.1	4.40			Techn	Fost	1986	CBC	9990			
7/23/2		SEGS%	CBC		%		86.0	43.0			Techn	Fost	1986	Micr	9990			

Accession ID: **B6**

7/23/2	B6	TAURINE	Chemi	B6	nmol/	>200	350.	200.			B6	Techn	Fost	1986	Tauri	9992		
7/23/2		TAURINE	Chemi		nmol/	>40 n	120.	60.0				Techn	Fost	1986	Tauri	9992		

Accession ID: **B6**

8/2/20		OSMOLA	Chemi		mmol/		315.	291.				Fost	2015	Che	1014			
8/2/20		CHOLE	Chemi		mg/dL		355.	82.0				Fost	2015	Che	1014			
8/2/20		AST	Chemi		U/L		54.0	9.00				Fost	2015	Che	1014			
8/2/20		ALT	Chemi		U/L		86.0	14.0				Fost	2015	Che	1014			
8/2/20	B6	ALK PHO	Chemi	B6	U/L		127.	12.0			B6	Fost	2015	Che	1014			
8/2/20		T BILIRU	Chemi		mg/dL		0.20	0.00				Fost	2015	Che	1014			
8/2/20		D.BILIRU	Chemi		mg/dL	0.00	0.10	0.00				Fost	2015	Che	1014			
8/2/20		T BILIRU	Chemi		mg/dL		0.30	0.10				Fost	2015	Che	1014			
8/2/20		NA/K	Chemi				40.0	29.0				Fost	2015	Che	1014			
8/2/20		POTASSI	Chemi		mEq/L		5.40	3.70				Fost	2015	Che	1014			

Date/Time	Patient	Description	Type	Results	Unit/Meas	Res	High	Low	Notes	sterin	echnic	ospit	essio	file N	Case I	Tag Num	
8/2/20		CHLORI	Chemi		mEq/L		116.	106.						Fost	2015	Che	1014
8/2/20		SODIUM	Chemi		mEq/L		150.	140.						Fost	2015	Che	1014
8/2/20		A/G RAT	Chemi				1.60	0.70						Fost	2015	Che	1014
8/2/20		GLOBULI	Chemi		g/dL		4.20	2.30						Fost	2015	Che	1014
8/2/20		ALBUMI	Chemi		g/dL		4.00	2.80						Fost	2015	Che	1014
8/2/20	B6	T. PROT	Chemi	B6	g/dL		7.80	5.50						Fost	2015	Che	1014
8/2/20		CALCIU	Chemi		mg/dL		11.3	9.40						Fost	2015	Che	1014
8/2/20		PHOSPH	Chemi		mg/dL		7.20	2.60						Fost	2015	Che	1014
8/2/20		CREATIN	Chemi		mg/dL		2.00	0.60						Fost	2015	Che	1014
8/2/20		UREA	Chemi		mg/dL		30.0	8.00						Fost	2015	Che	1014
8/2/20		GLUCOS	Chemi		mg/dL		135.	67.0						Fost	2015	Che	1014

Accession ID: B6

12/8/2		COMMEN	Chemi			Slight	0.00	0.00						Fost	2385	Che	1199
12/8/2		OSMOLA	Chemi		mmol/		315.	291.						Fost	2385	Che	1199
12/8/2		CHOLES	Chemi		mg/dL		355.	82.0						Fost	2385	Che	1199
12/8/2		AST	Chemi		U/L		54.0	9.00						Fost	2385	Che	1199
12/8/2		ALT	Chemi		U/L		86.0	14.0						Fost	2385	Che	1199
12/8/2		ALK PHO	Chemi		U/L		127.	12.0						Fost	2385	Che	1199
12/8/2		I BILIRU	Chemi		mg/dL	0.00	0.20	0.00						Fost	2385	Che	1199
12/8/2		D. BILIRU	Chemi		mg/dL	0.00	0.10	0.00						Fost	2385	Che	1199
12/8/2		T BILIRU	Chemi		mg/dL	<0.1	0.30	0.10						Fost	2385	Che	1199
12/8/2		NA/K	Chemi				40.0	29.0						Fost	2385	Che	1199
12/8/2		POTASSI	Chemi		mEq/L		5.40	3.70						Fost	2385	Che	1199
12/8/2		CHLORI	Chemi		mEq/L		116.	106.						Fost	2385	Che	1199
12/8/2	B6	SODIUM	Chemi	B6	mEq/L		150.	140.						Fost	2385	Che	1199
12/8/2		A/G RAT	Chemi				1.60	0.70						Fost	2385	Che	1199
12/8/2		GLOBULI	Chemi		g/dL		4.20	2.30						Fost	2385	Che	1199
12/8/2		ALBUMI	Chemi		g/dL		4.00	2.80						Fost	2385	Che	1199
12/8/2		T. PROT	Chemi		g/dL		7.80	5.50						Fost	2385	Che	1199
12/8/2		CALCIU	Chemi		mg/dL		11.3	9.40						Fost	2385	Che	1199
12/8/2		E CANIS/	Snap			Negati	0.00	0.00						Fost	2385	4DX	1199
12/8/2		PHOSPH	Chemi		mg/dL		7.20	2.60						Fost	2385	Che	1199
12/8/2		CREATIN	Chemi		mg/dL		2.00	0.60						Fost	2385	Che	1199
12/8/2		A. PHAG	Snap			Positiv	0.00	0.00						Fost	2385	4DX	1199
12/8/2		UREA	Chemi		mg/dL		30.0	8.00						Fost	2385	Che	1199
12/8/2		LYME C6	Snap			Negati	0.00	0.00						Fost	2385	4DX	1199
12/8/2		HW ANT	Snap			Negati	0.00	0.00						Fost	2385	4DX	1199
12/8/2		GLUCOS	Chemi		mg/dL		135.	67.0						Fost	2385	Che	1199

Date/Time	Patient Description	Type	Results	Meas/ner	Res	High	Low	Notes	sterin	chnical	ospit	essicrfile	NCase	Tag	Numt
Accession ID: B6															
6/22/2	OSMOLA	Chemi		mmol/		315.	291.						Fost	2936	Che 1485
6/22/2	CHOLES	Chemi		mg/dL		355.	82.0						Fost	2936	Che 1485
6/22/2	AST	Chemi		U/L		54.0	9.00						Fost	2936	Che 1485
6/22/2	ALT	Chemi		U/L		86.0	14.0						Fost	2936	Che 1485
6/22/2	ALK PHO	Chemi		U/L		127.	12.0						Fost	2936	Che 1485
6/22/2	I BILIRU	Chemi		mg/dL	0.00	0.20	0.00						Fost	2936	Che 1485
6/22/2	D.BILIRU	Chemi		mg/dL	0.00	0.10	0.00						Fost	2936	Che 1485
6/22/2	T BILIRU	Chemi		mg/dL	<0.1	0.30	0.10						Fost	2936	Che 1485
6/22/2	NA/K	Chemi				40.0	29.0						Fost	2936	Che 1485
6/22/2	POTASSI	Chemi		mEq/L		5.40	3.70						Fost	2936	Che 1485
6/22/2	CHLORI	Chemi		mEq/L		116.	106.						Fost	2936	Che 1485
6/22/2	SODIUM	Chemi		mEq/L		150.	140.						Fost	2936	Che 1485
6/22/2	A/G RAT	Chemi				1.60	0.70						Fost	2936	Che 1485
6/22/2	GLOBULI	Chemi		g/dL		4.20	2.30						Fost	2936	Che 1485
6/22/2	ALBUMI	Chemi		g/dL		4.00	2.80						Fost	2936	Che 1485
6/22/2	T. PROT	Chemi		g/dL		7.80	5.50						Fost	2936	Che 1485
6/22/2	CALCIU	Chemi		mg/dL		11.3	9.40						Fost	2936	Che 1485
6/22/2	PHOSPH	Chemi		mg/dL		7.20	2.60						Fost	2936	Che 1485
6/22/2	CREATIN	Chemi		mg/dL		2.00	0.60						Fost	2936	Che 1485
6/22/2	UREA	Chemi		mg/dL		30.0	8.00						Fost	2936	Che 1485
6/22/2	GLUCOS	Chemi		mg/dL		135.	67.0						Fost	2936	Che 1485

Accession ID: B6															
12/8/2	COMMEN	Chemi			Slight	0.00	0.00						Fost	3450	Che 1751
12/8/2	OSMOLA	Chemi		mmol/		315.	291.						Fost	3450	Che 1751
12/8/2	CHOLES	Chemi		mg/dL		355.	82.0						Fost	3450	Che 1751
12/8/2	AST	Chemi		U/L		54.0	9.00						Fost	3450	Che 1751
12/8/2	ALT	Chemi		U/L		86.0	14.0						Fost	3450	Che 1751
12/8/2	ALK PHO	Chemi		U/L		127.	12.0						Fost	3450	Che 1751
12/8/2	I BILIRU	Chemi		mg/dL	0.00	0.20	0.00						Fost	3450	Che 1751
12/8/2	D.BILIRU	Chemi		mg/dL	0.00	0.10	0.00						Fost	3450	Che 1751
12/8/2	T BILIRU	Chemi		mg/dL	<0.1	0.30	0.10						Fost	3450	Che 1751
12/8/2	NA/K	Chemi				40.0	29.0						Fost	3450	Che 1751
12/8/2	POTASSI	Chemi		mEq/L		5.40	3.70						Fost	3450	Che 1751
12/8/2	CHLORI	Chemi		mEq/L		116.	106.						Fost	3450	Che 1751
12/8/2	SODIUM	Chemi		mEq/L		150.	140.						Fost	3450	Che 1751
12/8/2	A/G RAT	Chemi				1.60	0.70						Fost	3450	Che 1751
12/8/2	GLOBULI	Chemi		g/dL		4.20	2.30						Fost	3450	Che 1751
12/8/2	ALBUMI	Chemi		g/dL		4.00	2.80						Fost	3450	Che 1751

Lab Work
for **B6**

Date/Time	Patient	Description	Type	Results	Unit/Meas	Res	High	Low	Notes	sterin	ar	technic	olospit	essio	file N	Case Tag	Numb
12/8/2	B6	T. PROT	Chemi	B6	g/dL		7.80	5.50		B6	Fost	3450	Che	1751			
12/8/2		CALCIU	Chemi		mg/dl		11.3	9.40			Fost	3450	Che	1751			
12/8/2		PHOSPH	Chemi		mg/dL		7.20	2.60			Fost	3450	Che	1751			
12/8/2		CREATIN	Chemi		mg/dL		2.00	0.60			Fost	3450	Che	1751			
12/8/2		UREA	Chemi		mg/dL		30.0	8.00			Fost	3450	Che	1751			
12/8/2		GLUCOS	Chemi		mg/dL		135.	67.0			Fost	3450	Che	1751			

Clinical History for B6
Client B6
Breed Beagle mix
Sex Male
Colour White/Black
Age B6
Desexed Y
Alive Y

B6

17-May 2018 at 09:11 am
#1384011 B6

Notes
B6

Qty	Product / Service	Provider	Staff	Date
100.00	B6	B6		17-May 2018 9:11 AM
1.00				17-May 2018 9:12 AM

20-Apr 2018 at 02:59 pm
#1381295 B6

Notes
Appointment reason: ch B6

B6

Qty	Product / Service	Provider	Staff	Date
1.00	B6	B6		20-Apr 2018 2:59 PM
1.00	B6	B6		20-Apr 2018 2:59 PM
1.00	B6	B6		20-Apr 2018 3:04 PM
1.00	B6	B6		20-Apr 2018 3:04 PM

26-Mar 2018 at 11:26 am

#1378785 **B6**

Qty	Product / Service	Provider	Staff	Date
200.00	B6	B6		26-Mar 2018 11:26 AM

19-Mar 2018 at 02:16 pm

#1378184 **B6**

Notes

B6

13-Feb 2018 at 02:38 pm

#1375066 **B6**

Notes

Appointment reason: n/t

Qty	Product / Service	Provider	Staff	Date
1.00	B6	B6		13-Feb 2018 2:38 PM

01-Feb 2018 at 03:27 pm

#1374039 **B6**

Qty	Product / Service	Provider	Staff	Date
100.00	B6	B6		01-Feb 2018 3:27 PM

08-Jan 2018 at 09:30 am

#1371813 **B6**

Qty	Product / Service	Provider	Staff	Date
100.00	B6	B6		08-Jan 2018 9:30 AM

03-Nov 2017 at 04:04 pm

#1366448 **B6**

Notes

Appointment reason: n/t

Qty	Product / Service	Provider	Staff	Date
1.00	B6	B6		03-Nov 2017

Services

4:04 PM

01-Nov 2017 at 10:19 am
#1366057 B6

Qty	Product / Service	Provider	Staff	Date
100.00	B6	B6		01-Nov 2017 10:19 AM

26-Sep 2017 at 11:43 am
#1362388 B6

Qty	Product / Service	Provider	Staff	Date
1.00	B6	B6		26-Sep 2017 11:43 AM

25-Jul 2017 at 09:03 am
#1356103 B6

Qty	Product / Service	Provider	Staff	Date
2.00	B6	B6		25-Jul 2017 9:03 AM

12-Jul 2017 at 11:28 am
#1354672 B6

Notes
Appointment reason: recheck
Inom 7/11

Qty	Product / Service	Provider	Staff	Date
1.00	B6	B6		12-Jul 2017 11:28 AM

03-Jul 2017 at 11:08 am
#1353789 B6

Notes
Appointment reason: recheck B6
catch up on vax B6
Vomited last night several times. No other concerns B6

B6

B6

Qty	Product / Service	Provider	Staff	Date
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:15 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:15 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:22 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:22 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:22 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:22 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:22 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:43 AM
1.00	[B6]	[B6]	[B6]	03-Jul 2017 11:43 AM

27-Jun 2017 at 08:57 am
#1353159 [B6]

Qty	Product / Service	Provider	Staff	Date
1.00	[B6]	[B6]	[B6]	27-Jun 2017 8:57 AM

26-Jun 2017 at 09:40 am
#1353036 [B6]

Notes

[B6]

Foster Hospital for Small Animals

Liaison Fax: (508) 839-7951

(508) 887-4363

Liaison Phone: (508) 887-4988

Liaison E-mail: liaisons@tufts.edu

Medical Records Phone: (508) 887-4636

Referral Form

Please return form to liaisons via e-mail or fax.

Service to which referred: Emergency Appointment Date: _____ Time: _____

Owner Information

Name: _____ Daytime (work) phone: _____

Home phone: _____ Mobile phone: _____

Email: _____

Address: _____ City: _____ State: _____ Zip Code: _____

Patient Information

Registered Name/ID: _____

Species: Canine Breed: Beagle / Foxhound Sex: AC Age: 3 1/2 yrs

Your Information

Please check preferred method of contact: Phone Fax Email

Dr. Caine Clinic/Hospital: **B6**

Phone: **B6** Fax: **B6**

Clinic Email: **B6** Doctor Email: _____

Please complete address section if this is a first referral.

Address: _____ City: _____ State: _____ Zip Code: _____

Primary reason for referral:

Cardiomegaly, lethargy, anorexia

Significant History (Brief synopsis is best including concurrent conditions, anesthetic concerns, vaccination history, etc):

Cough 6 weeks, treated 30 day with doxycycline - cough, coughing, lethargic. Full color

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

SCANNED **B6**

~~Will email radiographs~~ Acbs were emailed

Referral Form continued

FOSTER HOSPITAL FOR SMALL ANIMALS

Physical exam findings:

T=100.5 Resists palpation of full colon.
Tachycardic ~~at rest~~

Test results (pertinent to this medical/surgical issue):

Lab work attached: yes no

Biopsy: yes no

Includes digital imaging (DICOM (*.DCM) format for orthopedic cases strongly recommended): yes no

Please send digital imaging records to liaisons@tufts.edu

Previous treatments and response:

30 days Doxycycline, no change

Preliminary Diagnosis:

Cardiomyopathy? +/- pericardic
Pericardial effusion?

Current treatment or special instructions:

None

Questions you want answered from consultation:

Snapshot Dx (**B6** 9:24 AM)

B6
4:09 PM

B6

Printed: July 11, 2015 9:24 AM

Page 1 of 1



Client: **B6**
Patient Name: **B6**
Species: Canine
Breed: Mixed

Gender: Male/Castrated
Weight:
Age: 2 Years
Doctor:

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
SNAPshot Dx	B6	9:24 AM)			B6

B6

Client: **B6**
Patient Name: **B6**
Species: Canine
Breed: Mixed

Gender: Male/Castrated
Weight:
Age: 3 Years
Doctor:

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
Catalyst Dx	B6	10:15 AM)			
GLU	B6	74 - 143			
BUN		7 - 27			
CREA		0.5 - 1.8			
BUN/CREA					
PHOS		2.5 - 6.8			
CA		7.9 - 12.0			
TP		5.2 - 8.2			
ALB		2.3 - 4.0			
GLOB		2.5 - 4.5			
ALB/GLOB					
ALT		10 - 125			
ALKP		23 - 212			
GGT		0 - 11			
TBIL		0.0 - 0.9			
CHOL		110 - 320			
Na	144 - 160				
K	3.5 - 5.8				
Na/K					
Cl	109 - 122				
Osm Calc					

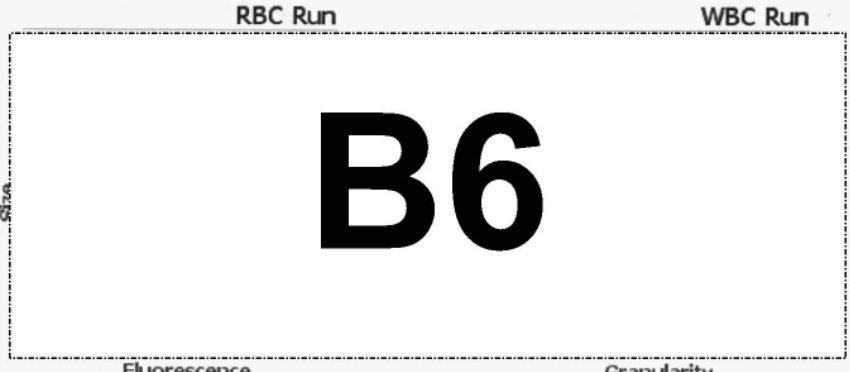
B6

Client: **B6**
 Patient Name: **B6**
 Species: Canine
 Breed: Mixed

Gender: Male/Castrated
 Weight:
 Age: 3 Years
 Doctor:

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
ProCyt Dx	B6	10:05 AM)			
RBC	B6	5.65 - 8.87	B6		
HCT		37.3 - 61.7			
HGB		13.1 - 20.5			
MCV		61.6 - 73.5			
MCH		21.2 - 25.9			
MCHC		32.0 - 37.9			
RDW		13.6 - 21.7			
%RETIC					
RETIC		10.0 - 110.0			
WBC		5.05 - 16.76			
%NEU					
%LYM					
%MONO					
%EOS					
%BASO					
NEU		2.95 - 11.64			
LYM		1.05 - 5.10			
MONO		0.16 - 1.12			
EOS		0.06 - 1.23			
BASO		0.00 - 0.10			
PLT	148 - 484				
MPV	8.7 - 13.2				
PDW	9.1 - 19.4				
PCT	0.14 - 0.46				



■ RBC ■ RETICS ■ PLT ■ RBC Frags ■ WBC ■ NEU ■ LYM ■ MONO ■ EOS ■ BASO ■ URBC



VACCINATION CERTIFICATE

Account #:

Owner:

Address:

Phone:

B6

H
E

Animal: **B6**

Species: **Canine**

Breed: **Beagle mix**

Color: **Wht/Blk/Brwn**

Gender: **Male Neutered**

Birthdate: **B6**

Age: **B6**

Weight: **55.00**

Chip #:

Date	Vaccine	Manufacturer	Serial #	Type	Tag #	Due on	
06/09/2016	B6					06/08/2017	
06/09/2016						06/08/2017	
06/06/2016				B6			07/07/2018
05/09/2016							05/08/2017
05/09/2016							05/08/2017
07/24/2014							07/20/2017

B6

B6

07/22/2016

Client: **B6**
Patient Name: **B6**
Species: Canine
Breed: Mixed

Gender: Male/Castrated
Weight:
Age: 3 Years
Doctor:

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
Catalyst Dx	B6	10:15 AM)			
GLU	B6	74 - 143			
BUN		7 - 27			
CREA		0.5 - 1.8			
BUN/CREA					
PHOS		2.5 - 6.8			
CA		7.9 - 12.0			
TP		5.2 - 8.2			
ALB		2.3 - 4.0			
GLOB		2.5 - 4.5			
ALB/GLOB					
ALT		10 - 125			
ALKP		23 - 212			
GGT		0 - 11			
TBIL		0.0 - 0.9			
CHOL		110 - 320			
Na		144 - 160			
K		3.5 - 5.8			
Na/K					
Cl	109 - 122				
Osm Calc					

B6

Client: **B6**
 Patient Name: **B6**
 Species: Canine
 Breed: Mixed

Gender: Male/Castrated
 Weight:
 Age: 3 Years
 Doctor:

B6

Test Results Reference Interval LOW NORMAL HIGH

Test	Results	Reference Interval	LOW	NORMAL	HIGH
ProCyte Dx	B6	10:05 AM)			B6 10:14 AM
RBC	B6	5.65 - 8.87	B6		
HCT		37.3 - 61.7			
HGB		13.1 - 20.5			
MCV		61.6 - 73.5			
MCH		21.2 - 25.9			
MCHC		32.0 - 37.9			
RDW		13.6 - 21.7			
%RETIC					
RETIC		10.0 - 110.0			
WBC		5.05 - 16.76			
%NEU					
%LYM					
%MONO					
%EOS					
%BASO					
NEU		2.95 - 11.64			
LYM		1.05 - 5.10			
MONO		0.16 - 1.12			
EOS	0.06 - 1.23				
BASO	0.00 - 0.10				
PLT	148 - 484				
MPV	8.7 - 13.2				
PDW	9.1 - 19.4				
PCT	0.14 - 0.46				



■ RBC ■ RETICS ■ PLT ■ RBC Frags ■ WBC ■ NEU ■ LYM ■ MONO ■ EOS ■ BASO ■ URBC



B6

plus my
Blood

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>

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

Breed: Beagle Cross Patient ID: **B6**
Sex: Male (Neutered) Home Phone:
Weight kg: 20.00
Date of Birth: **B6** Ref Facility
Color: White/Brown Ref Phone

Vet/Tech Contact: **B6**

Company Name: Tufts Cummings School of Veterinary Medicine

Address: 200 Westboro Road

North Grafton, MA 01536

B6
B6 Canine
12:50 PM
TAURINE PANEL
Lithium Heparin

Email: clinpath@tufts.edu

Tel: 508-887-4669

Fax: 508-839-7936

Billing Contact: **B6**

TAX ID: _____

Email: **B6**

Tel: **B6**

Patient Name: **B6**

Species: Dog

Owner's Name: **B6**

Sample Type: Plasma Whole Blood Urine Food Other: _____

Test Items: Taurine Complete Amino Acid Other: _____

Taurine Results (nmol/ml)

Plasma: **B6** Whole Blood: **B6** Urine: _____ Food: _____

Reference Ranges (nmol/ml)

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

B6
B6 12:50 PM
Canine
TAURINE PANEL
Lithium Heparin

B6

Clinical Nutrition Service

Foster Hospital for Small Animals
200 Westboro Road
North Grafton, MA 01536
Phone: (508) 887-4696 Attn: Nutrition Liaison
Fax: 508-887-4363
<http://vetnutrition.tufts.edu/>
vetnutrition@tufts.edu



Nutrition Consultation

Date: 7/7/17 (Phone consultation)

Pet Name:

Signalment: 1 ½ year old castrated male Boxer

Weight: 69 pounds (31 kg), body condition score 4/9 (ideal), muscle condition score: Normal

Diagnosis/Problems: Dilated cardiomyopathy with low taurine level; possible food sensitivities, bee and environmental allergies

Medications:

RDVM:

Recommendations below are based on information obtained from owner and referring veterinarians.

Diet History:

- Current diet: Petcurean Go! Limited Ingredient dry, Petcurean Now Fresh, Stella & Chewy's raw patties, Lean Treats, Wellness Core treats; bread or banana for medication administration. Just started transitioning to Purina Pro Plan Focus Adult Sensitive Skin and Stomach salmon and rice dry based on Dr. recommendations
- Petcurean Now Fresh large breed puppy dry; initially on Iams Smart Puppy Small and Toy Breed dry (8-12 weeks of age), Go Salmon (not finishing food)
- Supplements: Taurine 1000 mg 3 times daily, L-carnitine 2000 mg 2 times daily (NOW or Whole Foods)

Nutritional Goals

- Complete and balanced diet
- Adequate calorie intake to maintain ideal body weight (approximately 70 pounds)
- Reduced sodium
- Moderate protein
- Taurine and L-carnitine supplementation
- Omega-3 fatty acid supplementation

Recommendations:

- I'm happy that we were able to talk about diet to ensure he's getting optimal nutrition. Nutrition is an integral part of the treatment for a dog with heart disease. This is especially important for because we're suspicious of taurine and/or carnitine deficiencies playing a role in his disease. Hopefully, the taurine and carnitine supplementation and a diet we can be more confident in will be helpful for his heart!
- As we discussed, there's a lot of misinformation about pet foods so I'll only be recommending diets that meet all the criteria for being of the highest quality: <http://vetnutrition.tufts.edu/2016/12/questions-you-should-be-asking-about-your-pets-food/>
- My estimate of daily calorie needs is approximately 1700 calories per day (based on the average of 2 cups twice daily that he was getting from the Go Fresh Now dry food). This is an initial estimate to keep him at a weight 70 pounds. However, since every dog is an individual, I'd like to have you weigh him in 2 weeks to be sure he's maintaining his weight. If he's losing weight, you should increase the amount of food and continue to weigh him and if he's gaining weight, you should reduce the amount of food and continue to weigh him. Let me know if you need help with adjusting the amounts.
- The current diet you're feeding (Purina Pro Plan Sensitive Skin and Stomach) is of excellent quality, high in omega-3 fatty acids, and not too high in sodium. Since not in heart failure, the dietary sodium doesn't

need to be quite as low so I'm comfortable having him continue to eat the Pro Plan (especially since he seems to enjoy it!). However, I'm providing a few other options that are also high in omega-3 fatty acids. Please note the variable calorie density of these foods and adjust the number of cups accordingly to provide our starting point for calories of 1700 calories/day:

Dry Food	Calories/cup	Sodium (mg/100 calories)
Pro Plan Focus sensitive skin & stomach salmon & rice (dry)	447	128
Purina JM (dry)*	408	100
Purina DRM Naturals (dry)*	418	80
Royal Canin Boxer (dry)	335	73
Royal Canin Mobility Support JS (dry)*	324	70

Diets with an asterisk are ones that must be purchased from Dr. **B6** or, if not available, from an online pet food store (eg, Chewy.com, Petfooddirect.com) with a prescription or approval from her. The other 2 diets are available over-the-counter

- Make all changes gradually over 5-7 days to avoid gastrointestinal upset.
- We didn't discuss this on our call but I strongly urge you to discontinue the raw patties immediately. There is no evidence of any health benefit of raw meat diets and there are many, many documented risks. In addition, raw meat diets put you, your family, and your dogs at risk for bacterial infections because of high rates of bacterial contamination of raw meat diets.

Supplements:

- Unfortunately, there is little regulation of supplements for people or animals (safety, effectiveness, and quality control do not have to be proven for them to be sold), and some of these products may be harmful rather than helpful. Therefore, I am very selective when it comes to recommending specific supplements that have undergone independent quality control testing. Looking for the USP logo or using Consumerlab.com is very helpful for finding products with independent testing of quality.
- Taurine and L-carnitine: Since results of independent testing of taurine and carnitine are not available on Consumerlab, we tested a number of products in 2009. Although I don't know that the results are still true 8 years later, the products that did well in our testing were:
 - Taurine: Solgar, Twinlab, Swanson, NOW, Country Life, and GNC.
 - L-carnitine: Solgar, Country Life, Jarrow. Although we did not test the liquid L-carnitine from Solgar, I think that would be a reasonable one to try if it's easier to get him to take it as a liquid.
 - The doses that you're giving **B6** are appropriate.
 - We have some additional information on these supplements on our HeartSmart website: <http://vet.tufts.edu/heartsmart/diet/important-nutrients-for-pets-with-heart-disease/>
- Omega-3 fatty acids: Fish oil, which is high in the omega-3 fatty acids, EPA and DHA, can have modest benefits in reducing inflammation, maintaining muscle mass, reducing abnormal heart rhythms, and improving appetite. The diets above all contain sufficient omega-3 fatty acids but if we do need to use a supplement in the future, we have brands with independent testing on our HeartSmart website: http://vet.tufts.edu/wp-content/uploads/omega-3_supplementation.pdf

Treats:

- Some good treat options
 - Hill's Ideal Balance Breakfast Medleys with Country Chicken & Egg Dog Treat
 - Hill's Ideal Balance Oven-Baked Naturals with Chicken & Apples Dog Treat
 - Science Diet Grain Free treat with Chicken & Apples Dog Treat
 - Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots Dog Treat
 - Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat
 - Royal Canin Veterinary Diets Original Dog Treats
 - Frosted Mini Wheats (original)
 - Fresh vegetables/fruit – eg, carrots, green beans, apple, orange, bananas, berries (except ones listed below)
- Avoid macadamia nuts, avocado, garlic, onions, grapes, raisins, and other foods known to be toxic to dogs.

Medication Administration

- Dog tablet sized Greenies Pill Pockets are relatively low in sodium (just be sure to avoid Duck and Pea flavor which is high in sodium) but try to limit the total to 4-5/day
- You can also insert medications into one of the following foods:
 - Low-sodium canned pet food (I can give you some specific canned foods if you want to try this option)
 - Mini marshmallows
 - Fruit such as banana, orange, melon, or berries (avoid grapes)
 - Peanut butter (labeled as “no salt added”)
 - Pro Plan Additions Puree (Chicken and berries or chicken and pumpkin). This also works well for some dogs to give them pills

Follow Up:

- Monitor body weight to ensure he stays at an ideal weight of about 70 pounds (it may take some adjustment of the new food).
- Please let me know how things go at [B6] recheck cardiology evaluation at the end of August. Hopefully, there will be an improvement in his heart function!

Please contact me if you have any questions about [B6] nutritional plan.

Sincerely,

Lisa M. Freeman, DVM, PhD, DACVN
Professor, Clinical Nutrition
508-887-4696 (telephone)
vetnutrition@tufts.edu (email)
www.petfoodology.org (FAQs and other resources)

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 8/21/2018 2:55:45 PM
Subject: RE: updates

Hi Jen
Actually, [B6] [B6] submitted [B6] If you don't have that one, let me know and I can submit
Owner would be very happy to talk to you
Thanks
Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, August 21, 2018 10:46 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: updates

Thank you, Lisa.
We're going to send you the box this week with 7 whirl-pak bags. Each bag will be labelled for the dog and our internal identifier number (EON-XXXXXX). Please fill the bags with the respective food. I've calculated the return weight based on filling 7 bags full.

Also, I have the medical records for [B6] but did you submit a pet food report for him? I'm wondering if I didn't see it on our end.

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



From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Monday, August 20, 2018 6:18 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: updates

Hi Jen
I forgot to note on the report I submitted today that I have a food sample and UPC code for the Acana food that the 2 Dobies were eating.

Also, for [B6] whose heart has improved significantly, I just got a sample from the owner who found some food remaining at her summer house – it is not fresh but I'm saving for you in case you want
Thanks
Lisa

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

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Jones, Jennifer L
Sent: 1/16/2019 3:23:24 PM
Subject: cc-193-EON-367839; **B6**

B6 3 yr FS Great Dane
Hx-nsf

7/17/2018-vaccines,

PE: Gr II/VI murmur; **B6**

B6

10/4 recheck: no behavior changes; eats Acana, Fromm, dry food

PE-Gr II/VI L apical musical, Gr III/VI right low freq rumbling, intermitt gallop

Chem: no results listed

proBNP: **B6** (900)

Echo: thin LV wall w/ dec sys fxn, LV mod to mark dil, LA mod to mark dil, MV slt thick, PA smaller than aorta, RH subj enl, 1-2+ MR

ECG-sinus tachy

Tau @ Davis: WB **B6** Plasma **B6**

Tx-RC Early Cardiac diet, **B6** Tau 1 g BID

Jennifer L. A. Jones, DVM

Veterinary Medical Officer

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704

Laurel, Maryland 20708

new tel: 240-402-5421

fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 1/16/2019 10:55:53 PM
Subject: **B6** bnp and echo - 1/15/19 (updates to previously reported case)
Attachments: echo 1-15-19.pdf; IDEXX Results **B6** 01152019.pdf

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

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

From: Tufts Veterinary Cardiology Service
Sent: Wednesday, January 16, 2019 11:50 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: FW: IDEXX Results (Final): (Cl): **B6** (Pt): **B6** (Rq)RUSH (Ord)01/15/2019

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

From: VetConnect@idexx.com <VetConnect@idexx.com>
Sent: Wednesday, January 16, 2019 10:21 AM
To: Tufts Veterinary Cardiology Service <cardiovet@tufts.edu>
Subject: IDEXX Results (Final): (Cl): **B6** (Pt): **B6** (Rq)RUSH (Ord)01/15/2019

IDEXX VetConnect
1-888-433-9987
TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395
Account # 88933
Owner: **B6**
Patient: **B6**
Species: CANINE
Breed: GREAT_DANE
Age: 3Y
Gender: FEMALE
Requisition #: 423595
Accession #: **B6**
Order rec'd: 1/15/2019
Ordered by: RUSH
CARDIOPET proBNP - CANINE
Test Result Reference Range
CARDIOPET proBNP - CANINE (1) **B6** 0 - 900 pmol/L HIGH
Comments:

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.

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed: GREAT_DANE
Gender: FEMALE SPAYED
Age: 3Y

Date: 01/15/2019
Requisition #: 423595
Accession #: B6
Ordered by: RUSH

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

Account #88933

CARDIOPET proBNP - CANINE

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

Comments:

1. Cardiopet proBNP >1800pmol/L

B6

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

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/10/2019 8:12:52 PM
Subject: Acana Heritage formula dog food (mostly freshwater fish: Lisa Freeman - EON-390089
Attachments: 2068034-report.pdf; 2068034-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390089] has been created in the EON System.

A "PDF" report by name "2068034-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 "2068034-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390089

ICSR #: 2068034

EON Title: Related PFR Event created for Acana Heritage formula dog food (mostly freshwater fish free run poultry and meats (beef pork and lamb) formulas. Also Meadowlands; 2068034

AE Date	10/04/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068034

Product Group: Pet Food

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

Description: Murrur identified by RDVM 7/17/18. Asymptomatic. DCM diagnosed 10/4/18. Has been eating Acana diet. Owner is happy to talk to FDA and to provide more info. Taurine levels pending. Details on diet and

treats below: I can tell you, for starters, that **B6** was put on a Fromm diet from July of 2015 thru about March of 2016. Since that period, she has been eating only Acana Heritage formula dog food. This contains "0% grain, potato, gluten, meat by-products, and plant protein concentrates" as listed on their label. She has had a variety of flavors from this brand. Primarily, it has been "freshwater fish", "free run poultry", and "meats formula" (beef, pork, and lamb). **B6** has also had multiple bags of Acana "meadowland" which is advertised as poultry, fish, and eggs. I have also discovered that all of her treats have been produced by Acana. One is labeled as macarel and greens, another is poultry and monkfish, and the last is lamb, liver, and tripe. I should be able to get some records from our local pet store as they have a rewards program we are part of and all of our purchases from the last three years are on our account.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands		

This report is linked to:

Initial EON Event Key: EON-367839

Initial ICSR: 2055788

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

<https://eon.fda.gov/eon//browse/EON-390089>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=10100&issueId=407361&parentIssueTypeId=12>

=====
This email and attached document are being provided to you in your capacity as a Commissioned Official with

the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

Report Details - EON-390089

ICSR:	2068034
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 16:05:54 EDT
Initial Report Date:	10/08/2018
Parent ICSR:	2055788
Follow-up Report to FDA Request:	Yes

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

Product Information:	Product Name:	Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: Owner can provide more details.
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	[B6]
	Type Of Species:	Dog
	Type Of Breed:	Great Dane
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	42.2 Kilogram
	Age:	3.6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
Owner Information:	Owner Yes	

	Information provided:						
	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:
Name:	B6						
Phone:							
Email:							
	Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States			
B6							
United States							
Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine					
	Contact:	<table border="1"> <tr> <td>Name:</td> <td>Lisa Freeman</td> </tr> <tr> <td>Phone:</td> <td>(508) 887-4523</td> </tr> <tr> <td>Email:</td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	Name:	Lisa Freeman	Phone:	(508) 887-4523	Email:
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:	<table border="1"> <tr> <td>Phone:</td> <td>5088874523</td> </tr> <tr> <td>Email:</td> <td>lisa.freeman@tufts.edu</td> </tr> </table>	Phone:	5088874523	Email:	lisa.freeman@tufts.edu	
	Phone:	5088874523					
	Email:	lisa.freeman@tufts.edu					
Permission To Contact Sender:	Yes						
Preferred Method Of Contact:	Email						
Additional Documents:	Attachment:	Recheck ECG.pdf					
	Description:	ECG					
	Type:	Medical Records					
	Attachment:	Follow-up med records pt 2.pdf					
	Description:	Med Records					
	Type:	Medical Records					
	Attachment:	Follow-up med records pt 1.pdf					
	Description:	Med Records					
	Type:	Medical Records					

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

IDEXX BNP - 1/15/2019

IDEXX Reference Laboratories

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

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

Date: 01/15/2019
Requisition #: 1225705
Accession #: **B6**
Ordered by: RUSH

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

CARDIOPET proBNP- CANINE

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

Comments:

1. Cardiotet proBNP >1800pmol/L

B6

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

Client:
Patient:

B6

Chem 1/15/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB:	B6	Sex: SF	Provider: Dr. John Rush
Patient ID:		Age: 3	Order Location: V320559: Investigation into
Phone number:		Species: Canine	Sample ID: 1901150061
Collection Date: 1/15/2019 11:07 AM		Breed: Great Dane	
Approval date: 1/15/2019 12:23 PM			

Research Chemistry Profile - Small Animal (Cobas)

		Ref. Range/Females
CSTCYR		
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

B6

Sample ID: 1901150061/1
REPRINT: Orig. printing on 1/15/2019 (Final)

Reviewed by: _____

Client: Patient: **B6**

Diet Hx 4/18/19

B6

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 4/18/19

1. How would you assess your pet's appetite? (mark the box that best represents your pet's appetite)
Example: **Poor** _____ **Excellent**

Poor _____ **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
 Eats about the same amount as usual Eats less than usual Eats more than usual
 Seems to prefer different foods than usual Other _____

3. Over the last few weeks, has your pet (check one)
 Lost weight Gained weight Stayed about the same weight Don't know

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 cup	2x/day	Jan 2016-present
85% lean hamburger	microwaved	3 oz	1x/week	June-Aug 2016
Pupperoni original beef flavor	treat	1/2	1x/day	Sept 2016-present
Rawhide	treat	6 inch twist	1x/week	Dec 2018-present
Royal Canin Early Cardiac	dry	3 cups	2x/day	Oct 2018-present
Balobespresso all natural PB unsalted	treat	3tblsp	2x/week	2015-present

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

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

	Brand/Concentration	Amount per day
Taurine <input type="checkbox"/> Yes <input 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

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): peanut butter or cheese

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

NT-proBNP 4/18/2019

IDEXX Reference Laboratories

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

Client: **B6**
Patient: **B6**
Species: CANINE
Breed: GREAT_DANE
Gender: FEMALE SPAYED
Age: 5Y

Date: 04/18/2019
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	B6	0 - 900 pmol/L			B6

Comments:

1. Cardiopet proBNP >1800pmol/L

B6

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

Client: **B6**
Patient:

Troponin 5/31/2019



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

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:
423595

GI Lab Accession:

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6 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

Discharge Instructions

Patient

Name: B6
Species: Canine
Black Female (Spayed) Great Dane
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Admit Date: B6 9:42:49 AM

Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with mitral regurgitation

Clinical Findings:

Thank you for bringing B6 to Tufts today. On presentation B6 was bright, alert, and nervous. She has normal lung sounds and was panting. Her heart rate was increased (likely stress/ excitement) and we were still able to hear the same II/VI heart murmur on the left side of chest, and an extra heart sound (gallop). On echocardiogram B6 the left ventricle is still dilated with thinned walls and there is decreased ability of the heart to contract. The left atrium is moderately to markedly enlarged and there is also some mitral and tricuspid regurgitation. We performed her echocardiogram standing and without sedation (in comparison to last visit where she was sedated and lying down) so while her measurements were slightly worse today, there may be some mild variability due to her positioning and lack of sedation.

Since she has remained stable, or possibly slightly worse, since her last visit, we recommend starting another medication (B6) at this time to help slow the progression to heart failure and help minimize changes within the heart.

Today we performed a blood test to assess B6 kidneys prior to starting the new medication. We also are running an NT-proBNP test to continue to monitor stretch within the heart muscle. She had this test performed at her last visit and so by checking it again after seeing that her DCM may have worsened, it would be beneficial to see if this test reflects what we are seeing on echocardiogram, or if her BNP values are improving despite the changes that we are seeing.

Monitoring at Home:

We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest.

In general, most dogs have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal. If you notice fast or labored breathing then a chest x-ray should be performed.

We want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination. If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Diet Suggestions:

As long as B6 is still enjoying the Royal Canin Early Cardiac diet, please continue to feed her this at home.

Exercise Recommendations:

B6 can continue with her normal activity level, we recommend that she not exercise to the point of exhaustion.

Recommended Medications:

B6

Recheck Visits: 10-14 days after getting to twice a day on the lisinopril, we would recommend a blood test for kidney values and electrolytes - this can be done here as a technician appointment (send an email to the email address below to set up), or it can be done at your primary care veterinarian. As long as B6 is doing well at home, we would like to see her back in 3 months. At this visit we will want to check breathing effort and heart function, as well as another echocardiogram and blood test.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508) 887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

<http://vet.tufts.edu/heartsmart/>

Prescription Refill Disclaimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case: B6

Owner: B6

Discharge Instructions

B6

Patient ID: **B6**

B6

Canine

Years Old Female (Spayed) Great Dane
Black

Cardiology Appointment Report
ENROLLED IN DCM STUDY

Date: **B6**

Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC (primary)

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: **B6** V19

Presenting Complaint: Recheck DCM

Concurrent Diseases: None

General Medical History:

B6 is here today for a recheck of her DCM which was diagnosed **B6** on echo after being referred to Tufts Cardiology for a murmur. Since then owner reports she is doing well at home but maybe has some increased exercise intolerance. No coughing, collapse, or increased respiratory rate/ effort.

Diet and Supplements:

Early Cardiac RC Diet - 3c 2x/d

Cardiovascular History:

Prior CHF diagnosis? No

Prior heart murmur? Yes

Prior ATE? No

Prior arrhythmia? No

Monitoring respiratory rate and effort at home? Yes - Around 20bpm when resting.

Cough? No

Shortness of breath or difficulty breathing? No

Syncope or collapse? No

Sudden onset lameness? No

Exercise intolerance? Yes - Only wants to play for a few minutes, stops sooner than before.

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

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

Cardiovascular Physical Exam:

Murmur Grade:

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

Murmur location/description: Can be heard on left and right side; has a musical component

Jugular vein:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Bottom 1/3 of the neck | <input type="checkbox"/> 1/2 way up the neck |
| <input type="checkbox"/> Middle 1/3 of the neck | <input type="checkbox"/> Top 2/3 of the neck |

Arterial pulses:

- | | |
|--|---|
| <input type="checkbox"/> Weak | <input type="checkbox"/> Bounding |
| <input checked="" type="checkbox"/> Fair | <input type="checkbox"/> Pulse deficits |
| <input type="checkbox"/> Good | <input type="checkbox"/> Pulsus paradoxus |
| <input type="checkbox"/> Strong | <input type="checkbox"/> Other: |

Arrhythmia: Suspect sinus tachycardia on exam and during echo - ECG not done today

- | | |
|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Bradycardia |
| <input type="checkbox"/> Sinus arrhythmia | <input checked="" type="checkbox"/> Tachycardia |
| <input type="checkbox"/> Premature beats | |

Gallop:

- | | |
|---|--|
| <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Pronounced |
| <input type="checkbox"/> No | <input type="checkbox"/> Other: |
| <input type="checkbox"/> Intermittent | |

Pulmonary assessments: Panting/excited but less excited than without gabapentin

- | | |
|---|---|
| <input checked="" type="checkbox"/> Eupneic | <input type="checkbox"/> Pulmonary crackles |
| <input type="checkbox"/> Mild dyspnea | <input type="checkbox"/> Wheezes |
| <input type="checkbox"/> Marked dyspnea | <input type="checkbox"/> Upper airway stridor |
| <input type="checkbox"/> Normal BV sounds | |

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:

DCM with secondary mitral regurgitation

Diagnostic plan:

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

Echocardiogram Findings:

B6

Assessment and recommendations:

DCM with soem mitral regurgitation and exercise limitation. No major change from before - the findings today could indicate mild progression of disease or may be a combination of sedated echo and on table for first exam and standing unsedated echo today. Recommend continue **B6** and add in lisinopril.

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM Classification: Exercise limitation suggests low output

- A
- B1
- B2
- C
- D

B6

B6 Female (Spayed)
Canine: Great Dane Black
Patient ID: **B6**

Outside Prescription Log

- 1. Date: 03/19/2019
Clinician: John Rush
Prescription: **B6**
Pharmacy sent to: **B6**
Completed by: **B6**
Origin of request: Owner (medication on back order and doubling up on the 5mg is to expensive for the client)

- 2. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

- 3. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

- 4. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

- 5. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

- 6. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

7. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

8. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

9. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

10. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

Discharge Instructions

Patient

Name: B6
Species: Canine
Black Female (Spayed) Great Dane
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 v20

Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with mitral regurgitation

Clinical Findings:

Thank you for bringing B6 to Tufts today. On presentation B6 was bright, alert, and a bit excited. Her lungs sound normal, but her heart rate was increased (likely due to excitement). On physical exam, we were still able to hear the same II/VI heart murmur on the left side of chest. Since her last visit, you report that she is she has remained stable, and still has a good appetite and a great deal of energy at home!

On echocardiogram (ultrasound of the heart), we found that B6 left ventricle is still dilated and has thinned walls, with measurements similar to her previous exam. Her heart has a decreased ability to contract, as well. Our findings indicate that B6 DCM (dilated cardiomyopathy) is stable compared to last time. She still has significant heart disease, but we are pleased to see that there is no worsening. We performed an EKG to look at the electrical activity of her heart. We found that while her heart beats at a rapid rate (tachycardia), there is no evidence of an abnormal rhythm (arrhythmia).

We performed bloodwork to assess B6 NT-proBNP (to monitor stretch within the heart muscle) and troponin (to monitor damage to the heart). We will call you with these results. If you have not heard from us within 1-2 weeks, please give us a call.

For B6 next visit, you can consider giving 900 mg (three 300 mg capsules) B6 in the night before and the morning of her re-check appointment. This will help curb her excitement and allow her to feel a bit more comfortable during her examination.

Monitoring at Home:

We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. In general, most dogs have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal. If you notice fast or labored breathing, please contact your veterinarian as soon as possible.

Please notify us if B6 experiences weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly, as these findings indicate that you should have her seen by a veterinarian as soon as possible. If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Diet Suggestions:

As long as B6 is still enjoying the Royal Canin Early Cardiac diet, please continue to feed her this at home.

Exercise Recommendations:

B6 can continue with her normal activity level, but we recommend that she not exercise to the point of exhaustion.

Recommended Medications:

B6

Recheck Visits: We would like to see B6 back in 3 months for a recheck for the DOM study. When we call you with B6 blood work results we will schedule this appointment for the end of July. You can also email us at cardiovet@tufts.edu for non-emergent questions or concerns.

Thank you for entrusting us with B6 care. She is such a sweet girl.

Please visit our HeartSmart website for more information

<http://vet.tufts.edu/heartsmart/>

Prescription Refill Disclaimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case: B6

Owner: B6

Discharge Instructions

B6

Patient ID: B6

B6

Canine

Years Old Female (Spayed) Great Dane
Black

Cardiology Appointment Report
DCM STUDY RECHECK

Date: 4/18/2019

Attending Cardiologist:

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 v20

Presenting Complaint: Recheck DCM w/ mitral regurgitation (II/VI murmur)

Concurrent Diseases: None

General Medical History: B6 is presenting today for a DCM recheck (diagnosed B6) on echo after referral to our service. She received B6 capsules of 300mg?) prior to today's visit.

Diet and Supplements:

Early Cardiac RC diet - 3 cups 2x/d

Hides pills in meatball or piece of cheese

Peanut butter - no sodium, all natural

Cardiovascular History:

Prior CHF diagnosis? no

Prior heart murmur? yes

Prior ATE? no

Prior arrhythmia? no

Monitoring respiratory rate and effort at home?

Cough? No - maybe in winter time when it was super cold & she ran around?

Shortness of breath or difficulty breathing? No

Syncope or collapse? no

Sudden onset lameness? no

Exercise intolerance? Not particularly - still hyper, runs in backyard, etc. Not increased since diagnosis

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

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

Cardiovascular Physical Exam:

Murmur Grade:

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

Murmur location/description: systolic left apical, high pitched

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 checked="" type="checkbox"/> Good | <input type="checkbox"/> Pulsus paradoxus |
| <input type="checkbox"/> Strong | <input type="checkbox"/> Other: |

Arrhythmia:

- | | |
|---|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Bradycardia |
| <input type="checkbox"/> Sinus arrhythmia | <input checked="" type="checkbox"/> Tachycardia |
| <input type="checkbox"/> Premature beats | |

Gallop:

- | | |
|--|-------------------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> Pronounced |
| <input type="checkbox"/> No | <input type="checkbox"/> Other: |
| <input checked="" type="checkbox"/> Intermittent | |

Pulmonary assessments:

- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:

- Normal - tight & tucked up
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:

- DCM with mitral valve regurgitation

Diagnostic plan:

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

Echocardiogram Findings:

General/2-D findings:

B6

Mitral inflow:

- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

ECG findings:

B6

Assessment and recommendations:

Echocardiogram reveals similar structural changes compared to previous exam. Recommend continuing current medications. If BNP is markedly increased from previous exam then we may consider having the owners have B6 on hand at home. Continue RC early cardiac. Recheck echocardiogram in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease such as increased RR/RE, cough, exercise intolerance, or syncope.

Final Diagnosis:

- Occult DCM with MR (r/o genetic vs. diet related)

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- IIIa

- Ib
- II

IIb

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
- EPSS

B6

- cm
- cm
- cm
- cm
- cm
- cm
- ml
- ml
- %
- %
- ml
- 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
- LVPWd
- EDV(Teich)
- IVSs

B6

- cm
- cm
-
- cm
- cm
- cm
- ml
- cm

LVIDs
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)
LVld A4C
LVEDV MOD A4C
LVls A4C
LVESV MOD A4C
LVEF MOD A4C
SV MOD A4C

B6

cm
cm
ml
%
%
ml
cm
ml
cm
ml
%
ml

Doppler
MR Vmax
MR maxPG
AV Vmax
AV maxPG
PV Vmax
PV maxPG

B6

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

Client: **B6**
Patient:

ECG from cardio

B6

4/18/2019 4:40:13 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from cardio

B6

4/18/2019 4:40:13 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

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: 6/11/2019 2:19:34 AM
Subject: Freeman DCM updates
Attachments: Acana Heritage formula dog food (mostly freshwater fish: Lisa Freeman - EON-367839; Acana Heritage formula dog food (mostly freshwater fish: Lisa Freeman - EON-390089; Acana: Lisa Freeman - EON-380708; Acana: Lisa Freeman - EON-390104; Bil Jac Picky No More--Small Breed-Persnickety Recipe w/ chicken liver: [REDACTED] B6 - EON-388960; Bil Jac Picky No More--Small Breed-Persnickety Recipe w/ chicken liver: [REDACTED] B6 - EON-390090; Fromm Game Bird Recipe Dog - Four-Star - Dry -Grain-Free formula: [REDACTED] B6 - EON-388971; Fromm Game Bird Recipe Dog - Four-Star - Dry -Grain-Free formula: [REDACTED] B6 - EON-390092

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Jones, Jennifer L
Sent: 4/3/2018 7:08:22 PM
Subject: FW: Grain Free Easy to Digest Salmon: [B6] EON-350359
Attachments: 2044946-report.pdf; 2044946-attachments.zip

Did you get/were you expecting these reports?

From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Monday, April 02, 2018 3:28 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [B6]
Subject: Grain Free Easy to Digest Salmon: [B6] EON-350359

A PFR Report has been received and PFR Event [EON-350359] has been created in the EON System.

A "PDF" report by name "2044946-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 "2044946-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350359

ICSR #: 2044946

EON Title: PFR Event created for Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe; 2044946

AE Date	02/26/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Spaniel - Cocker American		
Age	13 Years		
District Involved	PFR [B6]		

Product information

Individual Case Safety Report Number: 2044946

Product Group: Pet Food

Product Name: Grain Free Easy to Digest Salmon, Sweet Potato, & Pumpkin Recipe

Description: A heart murmur was auscultated on a routine exam and patient was diagnosed on 2/26/18 with moderate dilated cardiomyopathy - ruleout idiopathic vs. taurine/amino acid responsive - with moderately decreased left ventricular contractility. Patient is on a grain free diet - Nature's Recipe Salmon and Sweet Potato.

It is suspected that some grain free diets provide insufficient levels of taurine, contributing to the development of dilated cardiomyopathy. At presentation, [B6] had no cough; normal appetite and attitude; no exercise intolerance. Medication management and taurine supplementation was recommended. She will be rechecked in June 2018.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Grain Free Easy to Digest Salmon, Sweet Potato, & Pumpkin Recipe		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-350359>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=366747>

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

Report Details - EON-350359

ICSR: 2044946
 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: 2018-04-02 15:19:51 EDT

Reported Problem:

Problem Description: A heart murmur was auscultated on a routine exam and patient was diagnosed on 2/26/18 with moderate dilated cardiomyopathy - ruleout idiopathic vs. taurine /amino acid responsive - with moderately decreased left ventricular contractility. Patient is on a grain free diet - Nature's Recipe Salmon and Sweet Potato. It is suspected that some grain free diets provide insufficient levels of taurine, contributing to the development of dilated cardiomyopathy. At presentation, **B6** had no cough; normal appetite and attitude; no exercise intolerance. Medication management and taurine supplementation was recommended. She will be rechecked in June 2018.

Date Problem Started: 02/26/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: **B6**

Outcome to Date: Unknown

Product Information:

Product Name: Grain Free Easy to Digest Salmon, Sweet Potato, & Pumpkin Recipe

Product Type: Pet Food

Lot Number:

Package Type: BAG

Product Use Information:

Description: Daily as main diet

Perceived Relatedness to Adverse Event: Probably related

Manufacturer /Distributor Information:

Name: The J.M. Smucker Co.

Type(s): Manufacturer

Address: 1 Strawberry Lane
Orville
Ohio
44667
United States

Contact:

Phone: (888) 550-9555

Web Address: www.naturesrecipe.com

Possess One or More Labels from This Product: Yes

Purchase Location Information:

Animal Information:

Name:

Type Of Species: Dog

Type Of Breed: Spaniel - Cocker American

Gender: Female

Reproductive Status: Neutered

Weight: 11.7 Kilogram

Age: 13 Years

Assessment of Prior: Good

	Health:			
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided: No		
	Healthcare Professional Information:	Practice Name:	CVCA Cardiac Care for Pets	
		Contact:	Name: B6	
			Phone:	
			Email:	
		Address:	B6	
			United States	
Practice Name:		CVCA Cardiac Care for Pets		
Contact:		Name: B6		
		Phone:		
		Email:		
Address:	B6			
	United States			
Type of Veterinarian:	Referred veterinarian			
Date First Seen:	02/26/2018			
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:	Attachment:	Echo Report 2-26-2018.pdf		
	Description:	Echo Report 2/26/18		
	Type:	Echocardiogram		
	Attachment:	Echo Data 2-26-18.pdf		
	Description:	Echo Data 2/26/18		
	Type:	Echocardiogram		

Patient Demographics

B6		Study Date: 02/26/2018	
Patient ID: B6	Accession #:	Alt ID:	
DOB:	Age:	Gender:	Ht: Wt: 25lb 13oz BSA:
Institution: CVCA B6	Referring Physician:	Physician of Record:	Performed By: B6
Comments:			

Adult Echo: Measurements and Calculations

2D

LVIDd (2D)	B6	FS (2D-Cubed)	B6	IVS/LVPW (2D)	B6
LVPWd (2D)		EF (2D-Cubed)		SV (A4C)	
IVSs (2D)		A4Cd		EF (A4C)	
		LV Vol			
		LV Length			
		LV Area			
LVIDs (2D)		A4Cs		IVSd (2D)	
		LV Vol			
		LV Length			
		LV Area			
LVPWs (2D)		LVLd (A4C)		RVIDd/LVIDd	
EDV (2D-Teich)		LVLs (A4C)		RVIDd (2D)	
ESV (2D-Teich)		LVAd (A4C)		LA Area	
SV (2D-Teich)		LVAAs (A4C)		LA Dimen (2D)	
FS (2D-Teich)		EDV (A4C)		LA/Ao (2D)	
EF (2D-Teich)	ESV (A4C)	AoR Diam (2D)			
EDV (2D-Cubed)	LV Mass (Cubed)	HR - AV			
ESV (2D-Cubed)	IVS % (2D)				
SV (2D-Cubed)	LVPW % (2D)				

MMode

IVSd (MM)	B6	ESV (MM-Teich)	B6	FS (MM-Cubed)	B6
LVIDd (MM)		SV (MM-Teich)		IVS % (MM)	
LVPWd (MM)		FS (MM-Teich)		LVPW % (MM)	
IVSs (MM)		EF (MM-Teich)		RVIDd (MM)	
LVIDs (MM)		EDV (MM-Cubed)		LA Dimen (MM)	
LVPWs (MM)		ESV (MM-Cubed)		AoR Diam (MM)	
IVS/LVPW (MM)		SV (MM-Cubed)		LA/Ao (MM)	
EDV (MM-Teich)		EF (MM-Cubed)		MV EPSS	

Doppler

LVOT Vmax Max PG Vmax	B6	MV Peak A Vel Vel PG	B6	Med A` Vel	B6
AV Vmax Max PG Vmax		MV E/A		Lat A` Vel	
AV VTI Mean PG VTI Vmean		Med E` Vel		E`/A` Medial	
AV VR		Lat E` Vel		E`/A` Lateral	
MR Vmax Max PG Vmax		E/Med E`		TR Vmax Max PG Vmax	
MV Peak E Vel Vel PG		E/Lat E`		PV Vmax Max PG Vmax	

Other Measurements

Dimensions: Diameters

LVID/Ao (2D)

EF & Volume: Simpson's

Sphericity Id

EDVI

ESVI

B6

B6

B6

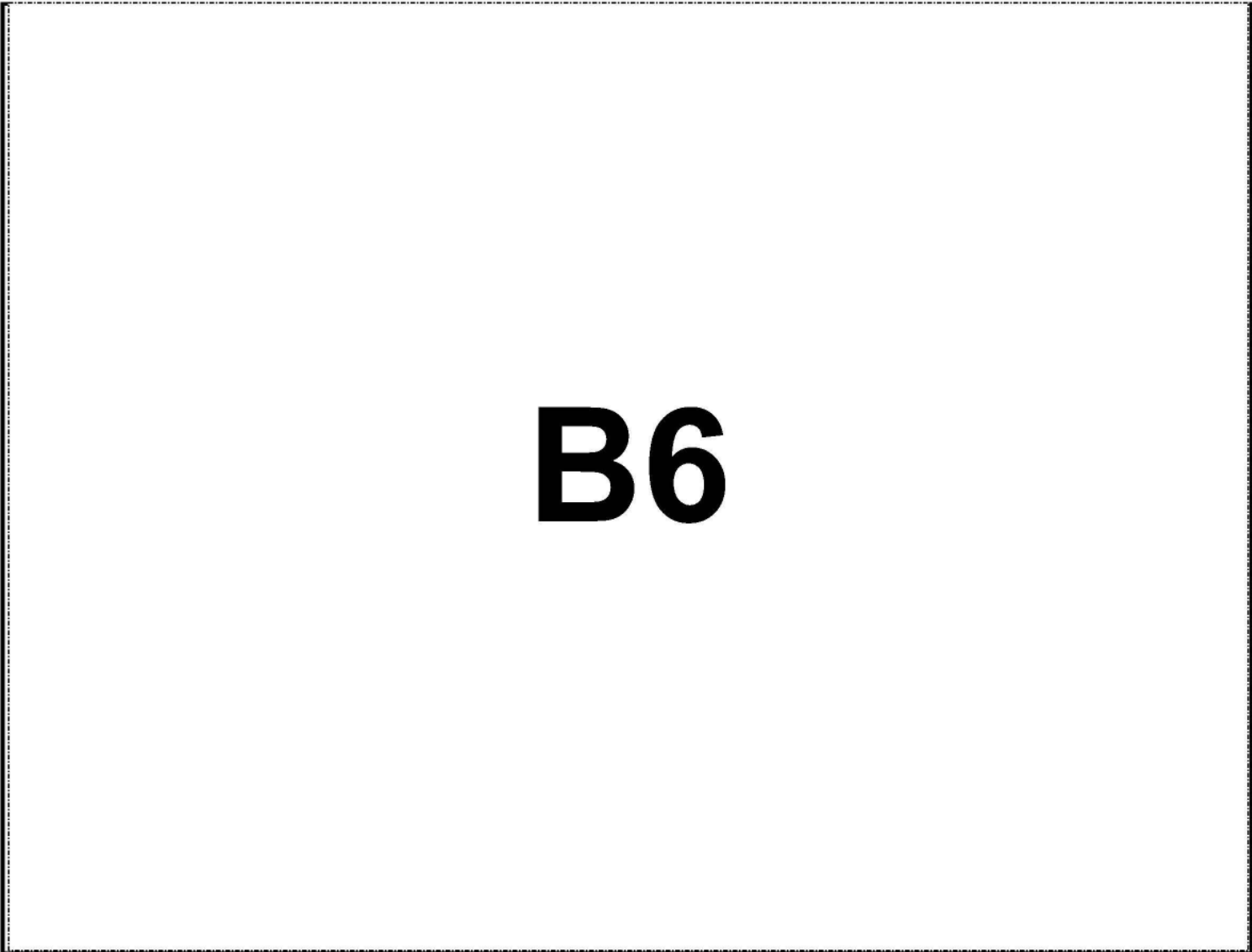
02/26/2018

Created: 03:43PM 02/26/2018

2/3

B6

Images



Signature

Signature:

Name(Print):

Date:

B6

B6

02/26/2018

Created: 03:43PM 02/26/2018

3/3

B6

www.cvcavets.com



Client: **B6**
Co-owner:
Patient name: **B6**
Species: Canine
Breed: Cocker Spaniel
Sex:
Age: 13 years and 2 months old
Weight: 11.7kg. / 25.79 lbs

Primary Care Veterinarian: **B6**
Primary Care Hospital: **B6** Veterinary Hospital
Phone: **B6** ext:
Fax: **B6**
Email: **B6** email only: **B6**

Cardiac Evaluation Report

Exam Date: 02/26/2018

Diagnosis

- Moderate dilated cardiomyopathy - ruleout idiopathic vs. taurine/amino acid responsive
- Moderate mitral valve regurgitation as source of heart murmur
- Mild tricuspid valve regurgitation
- Borderline secondary left atrial chamber dilation
- Moderate eccentric left ventricular chamber dilation with moderately decreased contractility
- No evidence of congestive heart failure

Medications

- Begin: **B6** tablets - Give 1/2 tablet twice daily for 4 days then increase to 1 tablet twice daily thereafter.
- Begin Taurine 500 mg twice daily.
- You may purchase the taurine at any health food or nutrition store www.puritanspride.com

In 5 days, if **B6 is eating and feeling well:**

- Begin: **B6** tablets - Give 1/4 tablet once daily for 4 days then increase to 1/4 tablet twice daily thereafter.

• Continue with **B6** other meds as prescribed by: **B6**

• Please call if you notice a decrease in appetite, vomiting, lethargy, weakness or any other signs of illness while beginning/adjusting the medications.

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

Please Note

Information for: **B6**

CVCA: **B6** 04/02/2018

- Please see our website www.cvcavets.com for more information about [B6] dilated cardiomyopathy.

Nutrition Recommendations:

- Continue current diet and try to avoid salty foods/ treats. For more information about sodium content of various foods, please visit:
 - Dog: http://vet.tufts.edu/wp-content/uploads/reduced_sodium_diet_for_dogs.pdf
 - Treats: http://vet.tufts.edu/wp-content/uploads/treats_for_dogs_with_heart_disease.pdf

Activity Recommendations:

- Continue routine exercise/activity/play as tolerated to maintain a slow resting heart rate.
- Please try avoid burst type activity, as this increases the arrhythmia risk and avoid exercise in the hot/humid weather.
- Please try to warm [B6] up for 5-10 minutes with walking prior to moderate activity and take more rests during more vigorous activity.

At Home Monitoring:

- [B6] is at mild increased risk for signs due to her heart disease. Please monitor for signs of cough, respiratory difficulty, exercise intolerance, weakness, fainting, lethargy, etc. If you note any of these symptoms, please notify CVCA or [B6] as these symptoms may indicate worsening of [B6] heart disease.

Dental Health:

- Dental health is important to prevent tartar and for overall health - Please discuss home dental care practices with Dr. [B6] - Ideally brushing [B6] teeth to aid in the prevention of tartar.

Future Anesthesia/Fluid Recommendations

- Avoid elective anesthesia, IV/SQ fluid therapy and corticosteroids (prednisone) due the severity of [B6] heart disease. Please call CVCA for recommendations, if [B6] requires these therapies. Avoid intravenous or subcutaneous fluid therapy in the future, if possible. If fluid therapy is indicated for [B6] in the future, please contact CVCA.
- Avoid elective anesthesia, as [B6] is at increased risk for complications due to the degree of cardiac disease. If anesthesia is necessary in the future, please contact CVCA for recommendations for monitoring and anesthetics.

Reevaluation

- Please recheck with [B6] Veterinary Hospital in 2 weeks for a follow up examination and blood chemistry profile with electrolytes and as recommended by [B6]. Please forward these results when available.
- Please recheck with [B6] Veterinary Hospital every 4-6 months for a follow up examination and blood chemistry profile with electrolytes and as recommended by [B6]. Please forward these results when available.
- Please recheck with CVCA in 4-5 months for a follow up consultation/examination, blood pressure, and echocardiogram. 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].

Visit Summary

Heart Rate: 92

BP: 140mmhg

Cuff size/location: LFL

History: New murmur on routine exam needs [B6]

[B6]

[B6]

on a grain free (salmon/ sweet potato) diet

Physical Exam Findings: QAR-H; nervous/ skittish but did okay; mm pink; difficult fundic exam OD due to cataract but NSL; no cough with tracheal palpation; H/L: 92 bpm; relatively regular rhythm; loud grade 2/6 systolic murmur PMI MV; eupneic RR 32 brpm; mild increase BV tones; abd palp tense/ WNL; femoral pulses fair

Echocardiographic Findings

Borderline increase in LA size; mild MV thickening /myxomatous type change with mild dynamic prolapse AML; upper side of mild to moderate dynamic centrally directed mitral regurgitation jet; normal MR velocity; moderate LV dilation / globoid eLVH with moderately decreased measurements of contractility/ systolic function with M mode as well as 2 D

EF; EPSS 1.2 cm; normal E/A TMI; normal E/e'; mild TR with RVSP estimate 41 + 5 mm HG; right heart size unremarkable; normal hepatic veins on brief evaluation; no pleural or pericardial effusion;

Comments

Dear **B6**

Thank you for sending **B6** to see us with **B6** today. **B6** has moderate dilated cardiomyopathy with moderate left ventricular dilation and systolic dysfunction but only borderline left atrial enlargement. Cocker spaniels can have a taurine responsive dilated cardiomyopathy and we discussed getting a baseline plasma taurine but **B6** opted for the see if she responds to taurine supplementation approach. With the history of **B6** this could also be secondary to myocardial injury/myocardial infarction but I think this is less likely. Due to the presence of volume overload, we have begun **B6** on therapy. The goal of therapy is to slow down the progression of the disease and to delay the onset of congestive heart failure. Over time, there will be progressive chamber dilation and systolic dysfunction as well as possible congestive heart failure. We will continue to closely monitor **B6** heart disease via serial echocardiography and institute further therapy when progression is noted. While on this course of therapy, it is important to monitor the renal function and electrolytes by periodic chemistry profiles. At this time, **B6** is not a candidate for **B6** administration, although we will likely add it in the future. We are hopeful that **B6** will continue to do well and remain compensated for her dilated cardiomyopathy. I am keeping my fingers crossed she is taurine responsive.

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 and complete our online referring veterinarian survey.

Sincerely,

B6 DVM, DACVIM (Cardiology)

B6

Created: 07/13/2018 02:57:02 PM

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

Species: Canine
Breed: Boston Terrier
DOB: **B6**
Sex: FS

Echocardiogram Report

This report describes evaluation of echocardiography.

The left ventricle is severely dilated with poor contractility. A large jet of mitral regurgitation is apparent. The left atrium is moderately dilated.

B6

A small jet of tricuspid regurgitation is apparent. The right atrium and ventricle are mildly dilated. The systolic pressure gradient across the tricuspid valve is mildly elevated (**B6**)

B6

The LVOT and RVOT flows are laminar with normal velocity. No pericardial lesions are noted.

SUMMARY:

1. Dilated cardiomyopathy with severe left-sided cardiomegaly and mild right sided cardiomegaly
2. Mitral and tricuspid regurgitation
3. Mild pulmonary hypertension

CONCLUSION: The pulmonary hypertension may be due to pulmonary congestion associated with DCM or non-cardiac pulmonary pathology. No radiographic evidence of cardiogenic edema is apparent on recent referral thoracic radiographs.

Sincerely,

B6

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Rotstein, David; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L
Sent: 2/25/2019 4:38:27 PM
Subject: RE: DCM 1 of 2 - Freeman Reports ONLY- 2/25/2019 0615
Attachments: 2059961-report.pdf; 2061171-report.pdf; 2059961-attachments.zip; 2061171-attachments.zip

EON-380714 shares a household with these reports: EON-376361 – EON-373457

From: Rotstein, David
Sent: Monday, February 25, 2019 6:20 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM 1 of 2 - Freeman Reports ONLY- 2/25/2019 0615

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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Report Details - EON-373457

ICSR:	2059961
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-12-10 20:13:49 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I took B6 to vet to check her Platelets and MCH which were low last August and B6 questioned me about the food I was feeding my dogs. When I said TOTW no grain she asked me to include BPN due to amount of cardiac issues that could be associated with No Grain food and bigger number in Golden. I agreed but never thought that B6 would come back elevated since she was OFA certified and cardiologist said her heart was an Athlete conditioning. She was always jumping fences and very active. I had notice her not very active lately but thought she was not adjusting to going outside with a muzzle to prevent her from eating junk all the time - the reason she got sick last year. Her BNP count is B6 and I am completely devastated from having a healthy female, previously heart tested to this diagnosis. I have contacted the cardiologist to have echocardiogram done and I am waiting for an appointment. I would like to check if there is any funding from FDA at this time to help cover some of the expenses since I will probably have to test all others and the amount of money is too much for me at this time. I would appreciate any help if possible and I will be glad to provide all her information to help investigations being done on this matter. DCM is a serious issue and many pet owners trying to do the best for their pets will be devastated if the food is the main cause. Thanks for your attention to B6 situation. B6
	Date Problem Started:	12/04/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	taste of the wild Sierra Mountain	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	11/23/2018	
	Number Purchased:	3	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	Yes	
	Storage Conditions:	food container	
	Product Use Information:	Description:	Food was given twice daily
		First Exposure Date:	11/30/2018
Last Exposure Date:		12/07/2018	
Time Interval between Product Use and Adverse Event:		6 Months	
Product Use Stopped After the Onset of the Adverse Event:		Yes	
Adverse Event	Unknown		

Abate After Product Stop:	
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related
Other Foods or Products Given to the Animal During This Time Period:	No

Manufacturer /Distributor Information:

Purchase Location Information:	Name:	chewy.com
	Address:	online Pennsylvania United States

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:	68 Pound		
Age:	3 Years		
Assessment of Prior Health:	Excellent		
Number of Animals Given the Product:	9		
Number of Animals Reacted:	1		
Owner Information:			
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
		Email:	B6
	Address:	B6 United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	12/04/2018	
	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: Phone

Reported to Other Parties: None

Additional Documents:

Attachment: B6 2018-12-05-1041.pdf (Unable to load attachment)

Description: Last Blood work with elevated result

Type: Laboratory Report

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: 2019-01-14 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 [B6] Taurine WNL [B6] 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:	<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>[B6]</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td>[B6]</td></tr></table></td></tr><tr><td>Address:</td><td><table border="1"><tr><td>[B6]</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>[B6]</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td>[B6]</td></tr></table>	Name:	[B6]	Phone:		Email:	[B6]	Address:	<table border="1"><tr><td>[B6]</td></tr><tr><td>United States</td></tr></table>	[B6]	United States
Owner Information provided:	Yes														
Contact:	<table border="1"><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td>[B6]</td></tr></table>	Name:	[B6]	Phone:		Email:	[B6]								
Name:	[B6]														
Phone:															
Email:	[B6]														
Address:	<table border="1"><tr><td>[B6]</td></tr><tr><td>United States</td></tr></table>	[B6]	United States												
[B6]															
United States															

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

Foster Hospital for Small Animals

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

All Medical Records

Client: [B6]
Address: [B6]

Patient: [B6]
Breed: Golden Retriever
DOB: [B6]

Species: Canine
Sex: Female

Home Phone: [B6]
Work Phone: [B6]
Cell Phone: [B6]

Referring Information

[B6]

None none North Grafton, MA 01536 () -

Client: [B6]
Patient: [B6]

Initial Complaint:

Scanned Record

Initial Complaint:

New [B6] - DCM study

SOAP Text Jan 2 2019 11:10AM [B6]

Initial Complaint:

Drop Off Lab Sample

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:	Golden Retriever
Sex:	Female
Age:	B6 Years Old

Lab Results Report

Accession ID:			
Test	Results	Reference Range	Units



Client: [B6]
Patient: [B6]

RDVM [B6] records

Clinical History for [B6]

Client [B6]
Breed Golden Retriever
Sex Female
Colour white
Age [B6]
Sexed N
Alive Y

[B6]

13-Dec 2018 at 09:16 am

#55091 [B6] DVM

Notes

Multiple emails with a re: options for cardiology consults in area and pet food labels (feeding trials vs formulation to meet asfco guidelines; all stage diets vs maintenance, taurine supplementation is not going to "fix" a grain free diet...)

Notified o that I have heard confirmation from Dr. Freeman at Tufts that [B6] qualifies for a new study there- O gave permission to send Tufts Nutrition office her contact info and they will reach out directly to her to set up a visit. Her other dogs may also qualify for study, based on [B6] results. Keep [B6] (and her other dogs) on original diet until [B6] is evaluated there, and they direct her to transition to new diet.

O states [B6] (and several of her other dogs) had normal echos when they were approx 1 1/2 yo, as she wanted to screen before considering breeding. O to bring all records with her in case Tufts would like to see baseline echo measurements; also collect all labels of food she has fed in past year or so, including dry/canned/treats and list of any people foods she feeds them even just as treats or snacks.

[B6]

07-Dec 2018 at 02:40 pm

#55041 [B6] DVM

Notes

See labwork results: CBC wnl, Chem wnl, HWT neg; proBNP elevated at [B6]

Rec echo to r/o DCM

PCTC- disc results; o would like to pursue echo- can do here with IM specialist (not specific to cardiology) but would have to delay until next semester- can refer for outpatient echo (ocean state, westboro vca) or tufts/other cardiologist. O would like to go to tufts if not too pricey- will enquire about consult/echo fee. will also enquire about contacts for golden retriever study mentioned in Dr. Freeman's jvma article from 12/1 edition.

[B6]

04-Dec 2018 at 09:28 am

#54942 [B6] DVM

Notes

[B6]

Examination Report Canine

Presenting For: recheck values from this summer

[B6]

History/Owners Concerns: Rechecking labwork as rec'd by [B6] this summer. Doing well. Only concern is that she eats things she shouldn't- chews on carpet, was eating soil with all the other dogs recently (rabbit droppings?), coprophagic. Wears a basket muzzle to prevent ingestion. last heat cycle Sept? (o not sure) Would like to breed in future. 7 dogs at home. No further travel [B6] back planned.

Current Meds & Supplements: one

Client: **B6**
Patient:

RDVM **B6** records

Flea & Tick Prevention: **B6** monthly year round
Heartworm Prevention: **B6** monthly year round

Physical Exam: Attitude: BAR

Hydration Status: normal if Abnormal: %

Mouth:
 Normal:
 Abnormal:
 Did Not Examine:

Cardiovascular:
 Normal/NMA MSP reg
 Abnormal:
 Did Not Examine:

Musculoskeletal:
 Normal:
 Abnormal:
 Did Not Examine:

Eyes:
 Normal:
 Abnormal:
 Did Not Examine:

Respiratory:
 Normal:
 Abnormal:
 Did Not Examine:

Integument:
 Normal:
 Abnormal:
 Did Not Examine:

Ears:
 Normal:
 Abnormal:
 Did Not Examine:

Abdomen:
 Normal:
 Abnormal:
 Did Not Examine:

Neurologic:
 Normal:
 Abnormal:
 Did Not Examine:

Nose/Throat:
 Normal:
 Abnormal:
 Did Not Examine:

Urogenital:
 Normal: intact, no dic, no mgt
 Abnormal:
 Did Not Examine:

Lymph Nodes:
 Normal:
 Abnormal:
 Did Not Examine:

Other: verified microchip

Exam Notes:

DDx: 3 yo FI Eng GRel- app healthy; grain free diet; hx labwork abnormalities improved in 8/18- but low K and pit values are being rechecked today

Recommendations/Plan: Rec grad change to different diet; gave o article on diet related cardiomyopathy in dogs; avoid grain-free and "boutique" or "exotic ingredient" diets until more is understood about this correlation. Will run proBNP to determine if further work up is necessary at this time (no HM, no clinical signs heart dz).

O requests cPL to find out if "enzymes" would help her digestive issues- no diarrhea at this time. Disc FPL, she does not have clinical signs consistent with this dz; but can run test if o is interested in result- ideally should be fasted

B6

Meds Dispensed: none

Tech: **B6**

Veterinarian: **B6** DVM

Qty	Product / Service	Provider	Staff	Date
1.00	Bio Hazard Waste Disposal Fee	B6		04-Dec-2018 10:12 AM
1.00	Canine Young w/ Cardipal proBNP (29249999) Standard CBC, Chem B6 HW AG			04-Dec-2018 10:12 AM
1.00	Physical Exam / Office Visit - Brief/Recheck			04-Dec-2018 10:13 AM

04-Dec-2018 at 08:51 am

#54940 **B6** DVM

Notes

Appointment reason: consult to discuss blood work performed in August and going forward

04-Sep-2018 at 01:14 pm

#52707 **B6**

Notes

Date and Time: 1:10 pm 9/4/18

Client Communication Notes: left message with owner with pricing for recheck test **B6** test code 3099 platelet count manual if indicated **B6** test code 7 electrolyte panel 2, plus tech appt charge, owner advised call back to schedule or if any questions.

Client: **B6**
Patient:

RDVM **B6** records

Initials: **B6**

04-Sep 2018 at 12:05 pm

#52697 **B6**

Notes
Date and Time: 12:02 pm 9/4/18

Client Communication Notes: spoke with owner regarding bw results, see below, owner had been away, per owner no concerns at home, owner interested in scheduling to recheck lyles and platelets as a precaution, to check pricing for owner and have reception call back to schedule tech appt

Initials: **B6**

20-Aug 2018 at 09:51 am

#52446

Notes
Date and Time: 8/20/18 9:53 am

Client Communication Notes: see enclosed bw results, 4DX negs4, bw overall much improved compared to previous, slight decrease K+ 3.8 and slight increase Na/K ratio 39, platelet clumps which may effect counts, platelets may be slight decreased on blood film, otherwise WNL, consider recheck platelets and lyles in 2-3 weeks as precaution, at least recheck prior to any surgeries or if any health concerns, left message for owner

Initials: **B6**

14-Aug 2018 at 11:07 am

#52374 **B6**

Notes

B6

Presenting For: PE, 4DX, update vaccines

B6

History/Owners Concerns: originally from **B6** owner got as a puppy, owner planning on breeding, no litters yet, last heat @ 1 year ago, per owner OFA cardiac, hips/elbows were good, history negative exploratory @ 1 year ago, no problems since

Current Meds & Supplements:

Client: **B6**
Patient:

RDVM: **B6** records

Flea & Tick Prevention: **B6**
Heartworm Prevention: month(s) **B6** product that owner gets from **B6** (owner travels there)

Physical Exam: Attitude: BAR

Hydration Status: Normal If Abnormal: %

Mouth: Cardiovascular: Musculoskeletal:
 Normal: Normal: Normal:
 Abnormal: Abnormal: Abnormal:
 Did Not Examine: Did Not Examine: Did Not Examine:

Eyes: Respiratory: Integument:
 Normal: Normal: Normal:
 Abnormal: Abnormal: Abnormal:
 Did Not Examine: Did Not Examine: Did Not Examine:

Ears: Abdomen: Neurologic:
 Normal: Normal: Normal:
 Abnormal: Abnormal: Abnormal:
 Did Not Examine: Did Not Examine: Did Not Examine:

Nose/Throat: Urogenital: Lymph Nodes:
 Normal: Normal: Normal:
 Abnormal: Abnormal: Abnormal:
 Did Not Examine: Did Not Examine: Did Not Examine:

Other:

Exam Notes:

slight tartar

DDx: intact, appears healthy

Recommendations/Plan: teeth brushing, OVH when done breeding, fecal - owner to drop off, from past history some bw abnormalities about 1 year ago, owner opt recheck bw as precaution, send out CBC, Chem, 4DX

Meds Dispensed:

Tech: **B6**

Veterinarian: **B6**

Qty	Product / Service	Provider	Staff	Date
1.00	Physical Exam / Office Visit - (Annual wirereminder)	B6	B6	14-Aug 2018 11:07 AM
1.00	B6	B6	B6	14-Aug 2018 11:07 AM
1.00		B6	B6	14-Aug 2018 11:07 AM
1.00	Canine Standard CBC, Chem 25, 4DX (25048999)	B6	B6	14-Aug 2018 11:07 AM

Client: **B6**
Patient:

RDVM **B6** records

Ordered ▾ Updated Status Order Source
04-Dec-2018 10:12 am 05-Dec-2018 10:42 am Final Canine Young w/ Cardiotet proBNP (29249999) Standard CBC, Chem **B6** HW AG

Source
B6

Final | Accession # **B6**

→ View in **B6**

HEMATOLOGY

RBC	5.39 - 8.70 M/uL
Hematocrit	36.3 - 56.5 %
Hemoglobin	13.4 - 20.7 g/dL
MCV	59 - 76 fL
MCH	21.9 - 26.1 pg
MCHC	32.6 - 39.2 g/dL
% Reticulocyte	%
Reticulocytes	10 - 110 K/uL
Reticulocyte Hemoglobin	22.3 - 29.6 pg
WBC	4.9 - 17.6 K/uL
% Neutrophils	%
% Lymphocytes	%
% Monocytes	%
% Eosinophils	%
% Basophils	%
Neutrophils	2,940 - 12,670 /uL
Lymphocytes	1,080 - 4,950 /uL
Monocytes	130 - 1,150 /uL
Eosinophils	70 - 1,490 /uL
Basophils	0 - 100 /uL
Platelets	143 - 448 K/uL

B6

B6

↳ AUTOMATED CBC

CHEMISTRY

Glucose	63 - 114 mg/dL
IDEXX SDMA	0 - 14 ug/dL
Creatinine	0.5 - 1.5 mg/dL
BUN	9 - 31 mg/dL
Potassium	4.0 - 5.4 mmol/L
Total Protein	5.5 - 7.5 g/dL
Albumin	2.7 - 3.9 g/dL
Globulin	2.4 - 4.0 g/dL
Albumin: Globulin Ratio	0.7 - 1.5
ALT	18 - 121 U/L
ALP	5 - 160 U/L
Hemolysis Index	
Lipemia Index	
Cardiotet proBNP - Canine	0 - 900 pmol/L

B6

B6

Client: **B6**
Patient:

RDVM **B6** records

CHEMISTRY

- 1 BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL WHICH INDICATES kidney function is likely good. Evaluate a complete urinalysis and confirm there is no other evidence of kidney disease.
- 2 Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
- 3 Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
- 4 Cardiotop proBNP (96) = 2588 pmol/L
Normal. NT-proBNP concentration is compatible with increased stretch and stress on the myocardium. Clinically significant heart disease is likely at this time. If clinical signs are present (i.e. respiratory signs, exercise intolerance), additional diagnostics are necessary to determine the cause. Additional diagnostics including thoracic radiographs, electrocardiogram and echocardiogram are recommended to diagnose and assess severity of cardiac disease.

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

SERIOLOGY

Heartworm Antigen by ELISA

- 1 NEGATIVE
- 2 The American Heartworm Society recommends that a confirmatory test be run on all positive antigen test results prior to therapy, especially when a positive test result is unexpected. For a positive result on a Heartworm Antigen by ELISA, we recommend submission of a new sample for a second Heartworm Antigen by ELISA (test code 711) as a confirmatory test.

colloque now! ▲

14-Aug 2018 15-Aug 2018
11:37 am 04:17 am

Final Canine Standard CBC, Chem **B6** 4DX (25049999)

IDEXX
Reference
Laboratories

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

RDVM **B6** records

Ordered	Updated	Status	Order	Source
04-Dec-2018 10:13 am	05-Dec-2018 10:41 am	Final	Cerive Young w/ Cardipap proBNP (2024999), Bloodwork CBC, Chem B6 HW AG	IDEXX Reference Laboratories
14-Aug-2018 11:27 am	15-Aug-2018 04:11 am	Final	Cerive Standard CBC, Chem B6 (2024999)	IDEXX Reference Laboratories

Final | Accession **B6**

↳ View in WebConnect Print

HEMATOLOGY

RBC	5.38 - 6.70 MIL
Hematocrit	36.3 - 50.5 %
Hemoglobin	13.4 - 20.7 g/dL
MCV	59 - 76 fL
MCH	21.9 - 26.1 pg
MCHC	32.6 - 36.2 g/dL
% Reticulocyte	%
Reticulocytes	10 - 119 K/L
Reticulocyte Hemoglobin	22.3 - 29.6 pg
WBC	4.9 - 17.6 K/L
% Neutrophils	%
% Lymphocytes	%
% Monocytes	%
% Eosinophils	%
% Basophils	%
Neutrophils	2,940 - 12,670 /L
Lymphocytes	1,060 - 4,950 /L
Monocytes	150 - 1,150 /L
Eosinophils	70 - 1,490 /L
Basophils	0 - 100 /L
Platelets	143 - 448 K/L

B6

B6

B6

B6

↳ AUTOMATED EM

↳ 0.6% PLATELET COUNT

CHEMISTRY

Glucose	63 - 154 mg/dL
IDEX x IDMA	0 - 14 ug/dL
Creatinine	0.5 - 1.5 mg/dL
BUN	0 - 31 mg/dL
BUN: Creatinine Ratio	
Phosphorus	2.5 - 6.1 mg/dL
Calcium	8.4 - 11.8 mg/dL
Bilirubin	142 - 192 mmol/L

B6

B6

Client: **B6**
Patient:

RDVM **B6** records

CHEMISTRY

Potassium	4.0 - 5.4 mmol/L
Na:K Ratio	28 - 37
Chloride	108 - 118 mmol/L
TCO2 (Bicarbonate)	13 - 27 mmol/L
Anion Gap	11 - 26 mmol/L
Total Protein	5.5 - 7.5 g/dL
Albumin	2.7 - 3.9 g/dL
Globulin	2.4 - 4.0 g/dL
Albumin: Globulin Ratio	0.7 - 1.5
ALT	18 - 121 U/L
AST	18 - 55 U/L
ALP	5 - 160 U/L
GST	0 - 13 U/L
Bilirubin - Total	0.0 - 0.3 mg/dL
Bilirubin - Unconjugated	0.0 - 0.2 mg/dL
Bilirubin - Conjugated	0.0 - 0.1 mg/dL
Cholesterol	131 - 345 mg/dL
Creatinine Kinase	10 - 200 U/L
Hemolysis Index	0 - 6
Lipemia Index	0 - 6

B6

B6

- 1. Both K⁺ and creatinine are within the reference intervals which indicates kidney function is likely good. Evaluate a complete urinalysis and confirm there is no other evidence of kidney disease.
- 2. Index of K⁺, 1+, 2+ exhibits no significant effect on chemistry values.
- 3. Index of K⁺, 1+, 2+ exhibits no significant effect on chemistry values.

SERIOLOGY

Histovirus Antigen
Ehrlichia canis / ewingi
Lyme (Borrelia burgdorferi)
Anaplasma phagocytophilum / platys

B6

Client: **B6**
Patient:

RDVM **B6** records

SEROLOGY

- The American Heartworm Society recommends that a confirmatory test be run on all positive antigen test results prior to therapy, especially when a positive test result is unexpected. For a positive heartworm result on a 4Dx Plus, we recommend test code J23, Heartworm Antigen by ELISA as a confirmatory test.

The Ehrlichia canis/Ehrlichia ewingii antibody portion of the test uses peptides from each organism that are sensitive and specific for detecting exposure to these pathogens. If positive, submission of a fresh whole blood sample with an air-dried smear for a comprehensive CBC, test code 888, is recommended to identify abnormalities consistent with infection, primarily thrombocytopenia and anemia. PCR testing is complementary to serology and may be useful for confirmation of infection and for detection of infection in patients early in infection prior to seroconversion, especially in patients with clinical signs. Consider test code 2834, Ehrlichia spp RealPCR Test, or test code 28381, Tick/Vector Comprehensive RealPCR Panel Add-on (preferred).

The Lyme (Borrelia burgdorferi) antibody portion of the test detects Lyme C6 antibodies. A positive Lyme C6 antibody response indicates infection in dogs, rather than exposure or vaccination. This test may detect antibodies before clinical signs of joint disease. The quantitative assay for Lyme C6 antibodies (Lyme Quant C6 Antibody by ELISA, test code 7246) is preferred for assessing response to treatment. A measurable decline in quantitative Lyme C6 antibody levels within 6 months correlates with effective treatment, whereas the 4Dx Plus test may remain positive. For more information on Lyme, please visit <https://www.idexx.com/usa/labinal/facts-about-lyme.html>

The Anaplasma phagocytophilum/Anaplasma platys antibody portion of the test uses a peptide that is sensitive and specific for detecting exposure to these organisms. If positive, submission of a fresh whole blood sample with an air-dried smear is recommended to identify abnormalities consistent with infection, primarily thrombocytopenia. PCR testing is complementary to serology and may be useful for confirmation of infection and for detection of infection in patients early in infection prior to seroconversion, especially in patients with clinical signs. Consider test code 2824, Anaplasma spp RealPCR Test, or test code 28781, Tick/Vector Comprehensive RealPCR Panel Add-on (preferred).

20240501.0001

Client: **B6**
Patient:

RDVM

B6

Client Information:

B6

Patient Information:

B6
Canine, golden retriever, Female, . Gold
Birthdate:
Neutered: N

Cardiovascular Examination Summary

for **B6**

Dear **B6**

B6 was evaluated at **B6** or **B6** by **B6** in the **B6** office. The results of that evaluation are found below:

Referred by: **B6** Hospital

Presenting Complaint: Congenital cardiac OFA certification

History: **B6** has no history of a murmur with no clinical signs of cardiac disease or heart failure

Cardiovascular Physical Examination: BCS 2/5, BAR, MM pink; moist, CRT 2.0 sec, no jugular pulsations, RR 36 BPM, lung sounds slightly increased but no crackles or wheezes noted, HR 60-80 BPM with a regularly regular rhythm, no murmur is noted, femoral pulse is regular, symmetrical, and equal.

Diagnostics Performed:

Laboratory Findings: Not recommended or performed at this evaluation.

Imaging:

Thoracic Radiographs: Not recommended or performed at this evaluation.

Echocardiogram: Not recommended or performed at this evaluation.

Other:

Electrocardiogram: Not recommended or performed as part of this evaluation

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

RDVM

In-Hospital Treatments: None

Diagnostics Pending: None

Cardiovascular Case Assessment: Normal cardiovascular physical exam

Medical Therapy/Treatment Recommendations: None

Diet Recommendations: No change in diet is recommended at this time.

Exercise Limitations: No specific limitations are recommended based on this evaluation. Please allow **B6** to continue to set the pace and rest as needed.

Follow-up: No follow-up evaluation is indicated

If you have any questions or concerns, please feel free to call.
Sincerely,

B6 DVM
Diplomate ACVIM – Cardiology

MEDICATIONS MAY HAVE PRICE CHANGES THAT ARE BEYOND OUR CONTROL. WE APOLOGIZE FOR ANY INCONVENIENCE.

MEDICATION REFILLS (only for medications from **B6** Cardiology with a refill option):
*Refill requests can be called into the Specialty Center during normal business hours: Mon-Fri 8am-5pm. We will not always be able to accommodate refill requests after hours or on weekends. You can pick the prescriptions up after hours only if you call before 6pm on Friday.

WEEKEND OR AFTER HOURS MEDICATION REFILLS WILL HAVE A \$20 FEE IF CALLED IN AFTER 5PM ON FRIDAY**
IF YOU CALL BEFORE 5PM ON FRIDAY, WE WILL HAVE IT READY FOR PICK UP ANYTIME, EVEN AFTER HOURS AND WEEKENDS
Thank you for your understanding!

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

IDEXX BNP - 1/2/2019

IDEXX Reference Laboratories

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

Client: **B6**
Patient: **B6**
Species: CANINE
Breed: GOLDEN_RETRIEVE
Gender: FEMALE SPAYED
Age: 0Y

Date: 01/02/2019
Requisition #: 434853
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	High/Low/Normal
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH B6

Comments:

1. Cardiopet proBNP 901 - 1500 pmol/L

B6

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

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

CBC/CHEM - 1/2/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: **B6** Sex: F Provider: **B6**
Patient ID: **B6** Age: 3 Order Location: **V320422 Barkley Fund Lipitor Study**
Phone number: Species: Canine Sample ID: 1901020129
Collection Date: 1/2/2019 11:22 AM Breed: Golden Retriever
Approval date: 1/2/2019 1:17 PM

CBC, Comprehensive, Sm Animal (Research)

Parameter	Value	Ref. Range/Females
SMACHUNSK	B6	
WBC (ADVIA)	B6	4.40-15.10 K/uL
RBC (Advia)	B6	5.80-8.50 M/uL
Hemoglobin (ADVIA)	B6	13.3-20.5 g/dL
Hematocrit (Advia)	B6	39-55 %
MCV (ADVIA)	B6	64.5-77.5 fL
MCH (ADVIA)	B6	21.3-25.9 pg
MCHC (ADVIA)	B6	31.9-34.3 g/dL
RDW (ADVIA)	B6	11.9-15.2
Platelet Count (Advia)	B6	173-486 K/uL
01/02/19 1:17 PM	10-25 platelets per 100x field (estimated count of 200,000-500,000/uL)	
Mean Platelet Volume (Advia)	B6	8.29-13.20 fl
01/02/19 11:41 AM	Platelet clumps (if present) and sample age (greater than 4 hours) can result in a falsely increased MPV.	
Platelet Cnt	B6	0.129-0.403 %
01/02/19 11:41 AM	Platelet Cnt is invalid when clumped platelets are present. Interpretation of PltCt is unclear in species other than canines.	
Reticulocyte Count (Advia)	B6	0.20-1.60 %
Absolute Reticulocyte Count (Advia)	B6	14.7-113.7 K/uL

Microscopic Exam of Blood Smear (Advia)

Parameter	Value	Ref. Range/Females
SMACHUNSK	B6	
Seg Neuts (%)	B6	43-86 %
Lymphocytes (%)	B6	7-47 %
Monocytes (%)	B6	1-15 %
Eosinophils (%)	B6	0-16 %
Nucleated RBC	B6	0-1 / 100 WBC
01/02/19 11:41 AM	White blood cell count has been corrected for the presence of nucleated red blood cells	
Seg Neutrophils (Abs) Advia	B6	2.80-11.50 K/uL
Lymphs (Abs) Advia	B6	1.00-4.80 K/uL
Mono (Abs) Advia	B6	0.10-1.50 K/uL
Eosinophils (Abs) Advia	B6	0.00-1.40 K/uL
WBC Morphology	No Morphologic Abnormalities	
Echinocytes	Occasional	

Research Chemistry Profile - Small Animal (Cobas)

Sample ID: 1901020129/1
This report continues... (Final)

Reviewed by: _____

Client: **B6**
Patient:

CBC/CHEM - 1/2/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6	Sex: F	Provider: B6
Patient ID: B6	Age: 3	Order Location: V32042275 BARNEY FUND Lipitor Study
Phone number:	Species: Canine	Sample ID: 1901020129
Collection Date: 1/2/2019 11:22 AM	Breed: Golden Retriever	
Approval date: 1/2/2019 1:17 PM		

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

		Ref. Range/Females
DNOYES		
Glucose	B6	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: 1901020129/2
REPRINT: Orig. printing on 1/2/2019 (Final)

Reviewed by: _____
Page 2

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

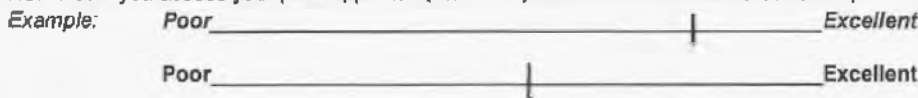
diet history 1/2/19

CARDIOLOGY DIET HISTORY FORM

Answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 1/2/19

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

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

Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
Pupperoni original beef flavor	treat	3	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
parts of the wild Sierra Hummin Dry	dry	1 1/2 cup	2x/day	June 2018
Hills Science Adult Salmon Veggie	canned	2 spoon	2x/day	Sept 2018
Theomob Small Animal Biscuits	treat	1 biscuit	10x/day	July 2018
Gravol Dental Toothbrush Treats	treat	1	1x/week	July 2018
American Tanned Salmon & Vegetable	dry	1 1/2 cup	2x/day	May 2017 - May 18
Old Mother Hubbard Classic Biscuits	treat	18	10x/day	Jul 17 - May 18
Victor Best Grain Free	dry	1 1/2	2x/day	Feb 2017
Whisper Growth Form	dry	1 1/2	2x/day	Jun 17 - Jul 17
Prana Non-GMO Free Kibble Multigrain	dry	1 1/2	2x/day	Jul 15 - Jun 17

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

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

	Brand/Concentration	Amount per day
Taurine	_____	_____
Carnitine	_____	_____
Antioxidants	_____	_____
Multivitamin	_____	_____
Fish oil	_____	5 spoon
Coenzyme Q10	_____	_____
Other (please list):	_____	_____
Example: Vitamin C	Nature's Bounty	500 mg tablets – 1 per day
_____	_____	_____
_____	_____	_____
_____	_____	_____

6. How do you administer pills to your pet?

- I do not give any medications
 I put them directly in my pet's mouth without food after they eat regular 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): dry food

Client:
Patient:

B6

diet history 1/2/19

Peara Wild Atlantic July 14 - June 2015

Blue Buffalo Wilderness,
Feb 14 - July 2014

Home Food

Bread

Cheese

Steak

Ham

Banana

Squash

Sweet Potato

Liver

Chicken Gizzards & Hearts

Tripe

Chicken Breast

Supplement

American Journey Wild Alaskan
Salmon Oil

Nov 2018 - present

B6

for large dogs

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

UCDavis Taurine Level

B6

PL
WB

B6

B6 Canine
1/27/2019 11:25 AM
TAURINE PANEL
Lithium Heparin

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616

Telephone: 530-752-5058, Fax: 530-752-4698

Email: ucd.aminoacid.lab@ucdavis.edu

www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: **B6**

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Grafton MA 01538

Email: Clinpath@tufts.edu cardivet@tufts.edu

Telephone: 508-887-4889 Fax: 508-830-7938

Billing Contact: **B6** Email: **B6**

Billing Contact Phone: **B6** Tax ID: _____

Patient Name: **B6** Species: Canine

Breed: Golden Owner's Name: **B6**

Current Diet: taste of the wild

Sample type: Plasma Whole Blood Urine Food Other _____

Test: Taurine Complete Amino Acids Other: _____

Taurine Results (lab use only)

Plasma: **B6** Whole Blood: **B6** Urine: _____ Food: _____

	Plasma (nMol/ml)		Whole Blood (nMol/ml)	
	Normal Range	No known risk for deficiency	Normal Range	No known risk for deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

* Please note with the recent increase in the number of dogs screened for taurine deficiency, we are seeing dogs with values within the reference ranges (or above the "no known risk for deficiency range") yet are still exhibiting signs of cardiac disease. Veterinarians are welcome to contact our laboratory for assistance in evaluating your patient's results.

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

Vitals Results

1/2/2019 10:17:06 AM	Weight (kg)	B6
----------------------	-------------	-----------

Patient History

12/13/2018 10:44 AM	Appointment	B6
12/27/2018 12:24 PM	Appointment	
01/02/2019 10:00 AM	UserForm	
01/02/2019 10:17 AM	Vitals	
01/02/2019 10:21 AM	Treatment	
01/02/2019 11:06 AM	Purchase	
01/02/2019 11:06 AM	Purchase	
01/02/2019 11:42 AM	UserForm	
01/02/2019 11:45 AM	Purchase	
01/02/2019 11:45 AM	Purchase	
01/02/2019 12:14 PM	Email	

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

Canine Golden Retriever Cream

B6

1/10/2019

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, DACVIM (Cardiology)

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/>

B6

B6 Female
Canine Golden Retriever Cream
B6

1/10/2019

Dear None

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

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

Thank you,

B6 DVM, DACVIM (Cardiology)

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

B6

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

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

Below is the summary of the report:

EON Key: EON-388255

ICSR #: 2067176

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

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

Product information

Individual Case Safety Report Number: 2067176

Product Group: Pet Food

Product Name: Acana Heritage Poultry dry

Description: **B6** presented to the UF Cardiology Service for a 5 month history of progressive exercise intolerance and increased respiratory rate and effort. Patient was diagnosed with Dilated Cardiomyopathy. She has been rechecked once 5/15/19 - clinically stable but no improvement noted on echocardiogram. Her blood taurine results were discordant so she has been on supplementation

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

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

Sender information

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

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

<https://eon.fda.gov/eon//browse/EON-388255>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=405432>

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Report Details - EON-388255	
ICSR:	2067176
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-05-20 10:58:30 EDT
Reported Problem:	Problem Description: B6 presented to the UF Cardiology Service for a 5 month history of progressive exercise intolerance and increased respiratory rate and effort. Patient was diagnosed with Dilated Cardiomyopathy. She has been rechecked once 5/15/19 - clinically stable but no improvement noted on echocardiogram. Her blood taurine results were discordant so she has been on supplementation
	Date Problem Started: 02/14/2019
	Concurrent Medical Problem: Yes
	Pre Existing Conditions: <div style="text-align: center; font-size: 2em; font-weight: bold;">B6</div>
	Outcome to Date: Stable
Product Information:	Product Name: Acana Heritage Poultry dry
	Product Type: Pet Food
	Lot Number:
	Product Use Information:
	Description: 2 cups dry food fed twice per day Patient also has been receiving deer antlers once per week since Aug 2015 as treats/chews.
	First Exposure Date: 08/01/2015
	Last Exposure Date: 02/14/2019
	Time Interval between Product Use and Adverse Event: 3 Years
	Product Use Stopped After the Onset of the Adverse Event: Yes
	Adverse Event Abate After Product Stop: Unknown
	Product Use Started Again: No
	Perceived Relatedness to Adverse Event: Possibly related
	Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:	
Purchase Location Information:	
Animal Information:	Name: B6
	Type Of Species: Dog

	Type Of Breed: Shepherd Dog - German
	Gender: Female
	Reproductive Status: Intact
	Pregnancy Status: Not Pregnant
	Lactation Status: Not lactating
	Weight: 36 Kilogram
	Age: 4 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information: Owner Information provided: No
Healthcare Professional Information:	Practice Name: University of Florida
	Contact: Name: Darcy Adin
	Phone: (614) 582-9798
	Other Phone: B6
	Email: adind@ufl.edu
	Address: 2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
Sender Information:	Name: Darcy Adin
	Address: 2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
	Contact: Phone: 6145829798
	Other Phone: B6
	Email: adind@ufl.edu
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
Reported to Other Parties: None	
Additional Documents:	

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

B6

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

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

Below is the summary of the report:

EON Key: EON-388253

ICSR #: 2067174

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

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

Product information

Individual Case Safety Report Number: 2067174

Product Group: Pet Food, Other

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Blue Buffalo Large Breed Adult		
Paul Newman Dog Biscuits, various		
Spring Hill Fish Oil		

Sender information

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

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

<https://eon.fda.gov/eon//browse/EON-388253>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=405430>

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Report Details - EON-388253

ICSR: 2067174
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-05-20 10:54:51 EDT

Reported Problem:

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

Date Problem Started: [B6]

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6] was diagnosed with dilated cardiomyopathy two years prior to presentation at UF Cardiology and had been previously stable on [B6] for the past two years. [B6] also underwent [B6] in the past for a [B6]. [B6] was also on [B6] of unknown dose and frequency and Spring Hill Fish Oil 1 pill per day.

Outcome to Date: Died Euthanized

Date of Death: [B6]

Product Information:

Product Name: Spring Hill Fish Oil

Product Type: Other

Lot Number:

Product Use Information: **Description:** 1 pill daily as supplement

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Paul Newman Dog Biscuits, various

Product Type: Pet Food

Lot Number:

Product Use Information: **Description:** used as treats patient also received fat free greek yogurt once per day since 2015 and raw carrots as treats
First Exposure Date: 01/01/2010

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Blue Buffalo Large Breed Adult

Product Type: Pet Food

Lot Number:

Product Use Information: **Description:** 2 cups dry fed twice per day
First Exposure Date: 12/31/2007
Last Exposure Date: [B6]
Time Interval: 9 Years

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

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

Additional Documents:

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

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

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

Below is the summary of the report:

EON Key: EON-388245

ICSR #: 2067168

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

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

Product information

Individual Case Safety Report Number: 2067168

Product Group: Pet Food

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

Description: A few days before B6 was seen by UF Cardiology, he presented to a specialty clinic for a minor orthopedic complaint, at which time an ECG revealed an abnormal rhythm. On 3/10, B6 became inappetent and vomited twice. On 3/11, patient presented to primary care veterinarian, and on 3/12, patient presented to an emergency clinic where thoracic radiographs revealed mild to moderate cardiomegaly. He was referred to cardiology on 3/13, where he was diagnosed with Dilated Cardiomyopathy. Anorexia resolved after 2 weeks.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
N and D Venison and Quinoa dry		
Honest Kitchen Turkey dehydrated		
Taste of the Wild Prey (Angus, Beef, and Lentils)		

Sender information

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

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

<https://eon.fda.gov/eon//browse/EON-388245>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=405422>

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

Report Details - EON-388245

ICSR: 2067168
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-05-20 10:45:10 EDT

Reported Problem:

Problem Description: A few days before **B6** was seen by UF Cardiology, he presented to a specialty clinic for a minor orthopedic complaint, at which time an ECG revealed an abnormal rhythm. On 3/10, **B6** became inappetant and vomited twice. On 3/11, patient presented to primary care veterinarian, and on 3/12, patient presented to an emergency clinic where thoracic radiographs revealed mild to moderate cardiomegaly. He was referred to cardiology on 3/13, where he was diagnosed with Dilated Cardiomyopathy. Anorexia resolved after 2 weeks.

Date Problem Started: 03/13/2019

Concurrent Medical Problem: Yes

Pre Existing Conditions: **B6**

Outcome to Date: Stable

Product Information:

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

Product Type: Pet Food

Lot Number:

Product Use Information:

Description: 3/4 cup fed twice per day

First Exposure Date: 03/13/2018

Last Exposure Date: 03/13/2019

Time Interval between Product Use and Adverse Event: 1 Years

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

Adverse Event Abate After Product Stop: Unknown

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Possibly related

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

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: N and D Venison and Quinoa dry

Product Type: Pet Food

Lot Number:

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

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

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

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

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

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

Below is the summary of the report:

EON Key: EON-388246

ICSR #: 2067170

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

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

Product information

Individual Case Safety Report Number: 2067170

Product Group: Pet Food, Other

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Natural Balance Venison, Sweet Potatoes		
Dr. Lyon's dental treat (mint)		
Pedigree chicken and rice		
Cosequin DS		

Sender information

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

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

<https://eon.fda.gov/eon//browse/EON-388246>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=405423>

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

Report Details - EON-388246

ICSR: 2067170
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-05-20 10:48:05 EDT

Reported Problem:
Problem Description: B6 ws referred to UF Cardiology after her primary care veterinarian noted a Grade 2/6 left systolic murmur. She has been slowing down some over the past year, but still runs and plays regularly. B6 has a B6 Patient was diagnosed with primary mitral regurgitation with systolic dysfunction.
Date Problem Started: 04/03/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:
Product Name: B6
Product Type: Other
Lot Number:
Product Use Information: Description: 1/2 tablet once daily as joint supplement
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Smart Bones Smart Sticks (peanut butter)
Product Type: Pet Food
Lot Number:
Product Use Information: Description: 5 inch treat given once per week
First Exposure Date: 01/01/2016
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Dr. Lyon's dental treat (mint)
Product Type: Pet Food
Lot Number:
Product Use Information: Description: 3 inch treat fed once per week
First Exposure Date: 01/01/2018
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Pedigree chicken and rice
Product Type: Pet Food
Lot Number:
Product Use Information: Description: 1/4 cup fed once per day
First Exposure Date: 01/01/2012

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

	Number of Animals Reacted:	1																
	Owner Information:	Owner Information provided: No																
	Healthcare Professional Information:	<table border="1"> <tr> <td data-bbox="677 252 889 288">Practice Name:</td> <td data-bbox="894 252 1523 288">University of Florida</td> </tr> <tr> <td data-bbox="677 295 889 332">Contact:</td> <td data-bbox="894 295 1523 332">Name: Darcy Adin</td> </tr> <tr> <td></td> <td data-bbox="894 338 1523 375">Phone: (614) 582-9798</td> </tr> <tr> <td></td> <td data-bbox="894 381 1523 418">Other Phone: B6</td> </tr> <tr> <td></td> <td data-bbox="894 424 1523 461">Email: adind@ufl.edu</td> </tr> <tr> <td data-bbox="677 467 889 504">Address:</td> <td data-bbox="894 467 1523 633">2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States</td> </tr> </table>	Practice Name:	University of Florida	Contact:	Name: Darcy Adin		Phone: (614) 582-9798		Other Phone: B6		Email: adind@ufl.edu	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States				
Practice Name:	University of Florida																	
Contact:	Name: Darcy Adin																	
	Phone: (614) 582-9798																	
	Other Phone: B6																	
	Email: adind@ufl.edu																	
Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States																	
Sender Information:	<table border="1"> <tr> <td data-bbox="380 648 662 692">Name:</td> <td data-bbox="672 648 1523 692">Darcy Adin</td> </tr> <tr> <td data-bbox="380 698 662 871">Address:</td> <td data-bbox="672 698 1523 871">2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States</td> </tr> <tr> <td data-bbox="380 877 662 920">Contact:</td> <td data-bbox="672 877 1523 920">Phone: 6145829798</td> </tr> <tr> <td></td> <td data-bbox="672 927 1523 963">Other Phone: B6</td> </tr> <tr> <td></td> <td data-bbox="672 970 1523 1006">Email: adind@ufl.edu</td> </tr> <tr> <td data-bbox="380 1013 662 1071">Permission To Contact Sender:</td> <td data-bbox="672 1013 1523 1071">Yes</td> </tr> <tr> <td data-bbox="380 1078 662 1136">Preferred Method Of Contact:</td> <td data-bbox="672 1078 1523 1136">Email</td> </tr> <tr> <td data-bbox="380 1142 662 1200">Reported to Other Parties:</td> <td data-bbox="672 1142 1523 1200">None</td> </tr> </table>	Name:	Darcy Adin	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States	Contact:	Phone: 6145829798		Other Phone: B6		Email: adind@ufl.edu	Permission To Contact Sender:	Yes	Preferred Method Of Contact:	Email	Reported to Other Parties:	None	
Name:	Darcy Adin																	
Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States																	
Contact:	Phone: 6145829798																	
	Other Phone: B6																	
	Email: adind@ufl.edu																	
Permission To Contact Sender:	Yes																	
Preferred Method Of Contact:	Email																	
Reported to Other Parties:	None																	
Additional Documents:																		

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

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

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

Below is the summary of the report:

EON Key: EON-388256

ICSR #: 2067173

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

AE Date	03/19/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		
Age	7 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2067173

Product Group: Pet Food, Other

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Dasuquin (Nutramax) Glucosamine, MSM, Chonroitin, ASU		
Origins 6 Fish Grain Free dry		

Sender information

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

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

<https://eon.fda.gov/eon//browse/EON-388256>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=405433>

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Report Details - EON-388256

ICSR: 2067173
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-05-20 10:51:47 EDT

Reported Problem:

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

Date Problem Started: 03/19/2019

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6

Outcome to Date: Stable

Product Information:

Product Name: Dasuquin (Nutramax) Glucosamine, MSM, Chondroitin, ASU

Product Type: Other

Lot Number:

Product Use Information: **Description:** joint supplement daily

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Origins 6 Fish Grain Free dry

Product Type: Pet Food

Lot Number:

Product Use Information: **Description:** 2 cups fed twice per day

First Exposure Date: 03/01/2013

Last Exposure Date: 03/19/2019

Time Interval between Product Use and Adverse Event: 6 Years

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

Adverse Event Abate After Product Stop: Unknown

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Possibly related

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

Manufacturer:

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

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

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

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

Below is the summary of the report:

EON Key: EON-388254

ICSR #: 2067175

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

AE Date	02/20/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Cattle Dog - Australian (blue heeler, red heeler, Queensland cattedog)		
Age	10 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2067175

Product Group: Pet Food, Other

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

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Spring Valley Fish, Flax, and Borage Oil		
Milkbone peanut flavor dry mini treats		
Pure Balance Salmon and Potato dry		
Good Morning Healthy Joints		

Sender information

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

To view this PFR Event, please click the link below:
<https://eon.fda.gov/eon//browse/EON-388254>

To view the PFR Event Report, please click the link below:
<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=405431>

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Report Details - EON-388254

ICSR: 2067175
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-05-20 10:56:29 EDT

Reported Problem:

Problem Description: Patient presented to the UF Cardiology Service after roughly two weeks of coughing. When coughing initially started, patient was seen by primary care veterinarian and was treated with [REDACTED] B6. On 2/19/19, [REDACTED] B6 presented to his primary care veterinarian again. He had cyanotic mucous membranes, an enlarged heart, and pulmonary edema. Patient was referred to UF and was diagnosed with Dilated Cardiomyopathy.

Date Problem Started: 02/20/2019

Concurrent Medical Problem: Yes

Pre Existing Conditions: Patient was diagnosed with [REDACTED] B6 at that time. Patient also receives Spring Valley Fish, Flax, and Borage Oil once daily and Good Morning Healthy Joints twice daily.

Outcome to Date: Stable

Product Information:

Product Name: Good Morning Healthy Joints
Product Type: Other
Lot Number:
Product Use Information: Description: supplement given twice daily
Manufacturer /Distributor Information:
Purchase Location Information:

Product Name: Spring Valley Fish, Flax, and Borage Oil
Product Type: Other
Lot Number:
Product Use Information: Description: supplement given once daily
Manufacturer /Distributor Information:
Purchase Location Information:

Product Name: Milkbone peanut flavor dry mini treats
Product Type: Pet Food
Lot Number:
Product Use Information: Description: used as treats
First Exposure Date: 01/01/2012
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information:

Product Name: 4Health Salmon and Potato canned

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

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Animal Information:

Name: **B6**

Type Of Species: Dog

Type Of Breed: Cattle Dog - Australian (blue heeler, red heeler, Queensland cattledog)

Gender: Male

Reproductive Status: Neutered

Weight: 24 Kilogram

Age: 10 Years

Assessment of Prior
Health: Fair

Number of Animals
Given the Product: 1

Number of Animals
Reacted: 1

Owner Information: Owner Information provided: No

Healthcare Professional Information: Practice Name: University of Florida

Contact: Name: Darcy Adin

Phone: (614) 582-9798

Other Phone: **B6**

Email: adind@ufl.edu

Address: 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States

Sender Information:

Name: Darcy Adin

Address: 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States

Contact: Phone: 6145829798

Other Phone: **B6**

Email: adind@ufl.edu

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Email

Reported to Other
Parties: None

Additional Documents:

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

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

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

Below is the summary of the report:

EON Key: EON-388244

ICSR #: 2067171

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

AE Date	03/19/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	American Pit Bull Terrier		
Age	7.5 Years		
District Involved	PFR-[B6]DO		

Product information

Individual Case Safety Report Number: 2067171

Product Group: Pet Food

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Sam's Club Chicken Jerky		
Nudges Chicken Jerkey		
Red Barn Bully sticks and slices		
Nubs Chicken Treats		

Sender information

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

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

<https://eon.fda.gov/eon//browse/EON-388244>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=405421>

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Report Details - EON-388244

ICSR: 2067171
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-05-20 10:49:42 EDT

Reported Problem:
Problem Description: B6 presented to UF Cardiology for evaluation of a heart murmur and arrhythmia discovered by his primary care veterinarian. B6 had a recent history of a progressively worsening cough. On ECG, B6 had intermittent ventricular premature complexes (right bundle branch block). B6 was diagnosed with mitral regurgitation with systolic dysfunction.
Date Problem Started: 03/19/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: History of B6 issues, but no other relevant medical history. Patient is on Heartgard and Seresto collar as preventatives.
Outcome to Date: Stable

Product Information:

Product Name:	Nudges Chicken Jerkey
Product Type:	Pet Food
Lot Number:	
Product Use Information:	Description: 2-3 slices fed 2-3 times per day as a treat
	First Exposure Date: 02/01/2019
Manufacturer /Distributor Information:	
Purchase Location Information:	
Product Name:	Nubs Chicken Treats
Product Type:	Pet Food
Lot Number:	
Product Use Information:	Description: one bone once per day as a treat
	First Exposure Date: 10/01/2017
Manufacturer /Distributor Information:	
Purchase Location Information:	
Product Name:	Sam's Club Chicken Jerky
Product Type:	Pet Food
Lot Number:	
Product Use Information:	Description: fed as treats 2-3 slices, 2-3 times per day
	First Exposure Date: 01/01/2018
Manufacturer /Distributor Information:	
Purchase Location Information:	
Product Name:	Red Barn Bully sticks and slices
Product Type:	Pet Food
Lot Number:	
Product Use Information:	Description: treats - 1 stick per day
	First Exposure Date: 08/01/2018

		Date:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Taste of the Wild Pacific Salmon Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	Description:	2 cups fed once per day
		First Exposure Date:	01/01/2017
		Last Exposure Date:	03/19/2019
		Time Interval between Product Use and Adverse Event:	2 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	American Pit Bull Terrier	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	35.9 Kilogram	
	Age:	7.5 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	No
	Healthcare Professional Information:	Practice Name:	University of Florida
		Contact Name:	Darcy Adin

		Phone: (614) 582-9798
		Other Phone: B6
		Email: adind@ufl.edu
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States

Sender Information:	Name:	Darcy Adin
	Address:	2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States
	Contact:	
	Phone:	6145829798
	Other Phone:	B6
	Email:	adind@ufl.edu
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: Norris, Anne; DeLancey, Siobhan; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren; Nemser, Sarah; Glover, Mark; Ceric, Olgica; Jones, Jennifer L
Sent: 7/12/2018 8:50:07 PM
Subject: historical DCM case-FW: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free); [B6] EON-359051
Attachments: 2051919-report.pdf

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Thursday, July 12, 2018 4:48 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; usha.gulati@doveltech.com
Subject: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free); [B6] [B6] EON-359051

A PFR Report has been received and PFR Event [EON-359051] has been created in the EON System.

A "PDF" report by name "2051919-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-359051

ICSR #: 2051919

EON Title: PFR Event created for Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free); 2051919

AE Date	02/12/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1

Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Saluki		
Age	12 Years		
District Involved	PFE B6 DO		

Product information

Individual Case Safety Report Number: 2051919

Product Group: Pet Food

Product Name: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free)

Description: In CY 2012, my Saluki **B6** was part of a targeted cardiac study conducted at Michigan State University. As part of the study, **B6** wore a Holter vest and received an echocardiogram. The results of his screening indicated no heart issues/defects - his heart was healthy. On February 12, 2018 **B6** was diagnosed by both my vet and a veterinary cardiologist as having congestive heart failure, severely advanced dilated cardiomyopathy, heart arrhythmia and a grossly enlarged left heart ventricle (left ventricle was nearly 2x it's normal size while the right ventricle was normal sized). He was placed on a host of cardiac medications that helped improve his quality of life for several weeks, but the disease had progressed too far. On **B6** we made the decision to euthanize him. Prior to his diagnosis in February 2018, **B6** was aging gracefully and was an overall healthy, active dog. He developed a cough one morning and upon vet check we received the shocking diagnosis. For several years we had been feeding **B6** Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Grain-Free dog food. Occasionally we alternated between this food and the chicken based grain free dog food (same brand). Purchased in large 35 lb bags at Costco. Neither the cardiologist who diagnosed **B6** nor the team at MSU were able to explain to me why it was that he developed such serious, severe heart disease at age 11/12 after being cardiac cleared in CY 2012. **B6** did have two litter-mates who died very young from arrhythmia (they died under the age of four); but the rest of the dogs in the litter were heart healthy as was **B6**. I read the FDA report issued today, July 12, 2018 (FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease) with great shock and sadness. Based upon what I have read and my own experience with my dog, I am extremely concerned that the Kirkland brand grain-free dog food I have used for years (containing peas, potatoes and potato starch as high-content ingredients), may have led to to my dog's severe heart disease, suffering and eventual death. Until he awoke with a cough that morning in February 2018, we had no indication whatsoever that he was so sick with advanced heart disease. The FDA report encouraged pet owners to report cases of DCM in dogs suspected of having a link to diet - this is why I am reaching out to you today regarding my experience. If **B6** records regarding his heart disease from my vet, MSU or the cardiologist will be helpful in your research to identify/confirm that these grain-free diets are a contributing factor or are the root cause of DCM in these dogs, please let me know. Thank you.

Submission Type: Initial

Report Type: Both

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

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
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Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free)		
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Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-359051>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=375675>

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Report Details - EON: B6	
ICSR:	2051919
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-12 16:40:22 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	<p>Problem Description: In CY 2012, my Saluki B6 was part of a targeted cardiac study conducted at Michigan State University. As part of the study, B6 wore a Holter vest and received an echocardiogram. The results of his screening indicated no heart issues/defects - his heart was healthy. On February 12, 2018, B6 was diagnosed by both my vet and a veterinary cardiologist as having congestive heart failure, severely advanced dilated cardiomyopathy, heart arrhythmia and a grossly enlarged left heart ventricle (left ventricle was nearly 2x it's normal size while the right ventricle was normal sized). He was placed on a host of cardiac medications that helped improve his quality of life for several weeks, but the disease had progressed too far. On B6 we made the decision to euthanize him. Prior to his diagnosis in February 2018, B6 was aging gracefully and was an overall healthy, active dog. He developed a cough one morning and upon vet check we received the shocking diagnosis. For several years we had been feeding B6 Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Grain-Free dog food. Occasionally we alternated between this food and the chicken based grain free dog food (same brand). Purchased in large 35 lb bags at Costco. Neither the cardiologist who diagnosed B6 nor the team at MSU were able to explain to me why it was that he developed such serious, severe heart disease at age 11/12 after being cardiac cleared in CY 2012. B6 did have two litter-mates who died very young from arrhythmia (they died under the age of four); but the rest of the dogs in the litter were heart healthy as was B6. I read the FDA report issued today, July 12, 2018 (FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease) with great shock and sadness. Based upon what I have read and my own experience with my dog, I am extremely concerned that the Kirkland brand grain-free dog food I have used for years (containing peas, potatoes and potato starch as high-content ingredients), may have led to to my dog's severe heart disease, suffering and eventual death. Until he awoke with a cough that morning in February 2018, we had no indication whatsoever that he was so sick with advanced heart disease. The FDA report encouraged pet owners to report cases of DCM in dogs suspected of having a link to diet - this is why I am reaching out to you today regarding my experience. If B6 records regarding his heart disease from my vet, MSU or the cardiologist will be helpful in your research to identify/confirm that these grain-free diets are a contributing factor or are the root cause of DCM in these dogs, please let me know. Thank you.</p> <p>Date Problem Started: 02/12/2018</p> <p>Concurrent Medical Problem: Yes</p> <p>Pre Existing Conditions: In CY 2014, B6 had B6 which was cured by neutering.</p> <p>Outcome to Date: Died Euthanized</p> <p>Date of Death: B6</p>
Product Information:	<p>Product Name: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free)</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Package Type: BAG</p> <p>Package Size: 35 Pound</p> <p>Possess Unopened Product: No</p> <p>Possess Opened Product: No</p> <p>Stored in a plastic dog food bin (sealed lid) in hall closet.</p>

	Storage Conditions:	
	Product Use Information:	Description: Fed daily for several years to my dog.
		First Exposure Date: 05/01/2016
		Last Exposure Date: B6
		Time Interval between Product Use and Adverse Event: 2 Years
		Product Use Stopped After the Onset of the Adverse Event: No
		Perceived Relatedness to Adverse Event: Probably related
		Other Foods or Products Given to the Animal During This Time Period: Yes
	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: Costco (bought in-store and online)
		Address: B6 United States
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Saluki	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 60 Pound	
	Age: 12 Years	
	Assessment of Prior Health: Good	
	Number of Animals Reacted: 1	
	Owner Information:	
	Healthcare Professional Information:	Practice Name: B6
		Contact: Name: B6 Phone: B6
		Address: B6 United States
		Type of Veterinarian: Primary/regular veterinarian
		Date First Seen: 04/12/2018
		Permission to Release Records to FDA: Yes
		Practice Name: B6

		Contact:	Name:	B6
			Phone:	
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	02/12/2018	
		Permission to Release Records to FDA:	Yes	
Sender Information:	Name:			
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
		Email:		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
	Reported to Other Parties:	None		
Additional Documents:				

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Rotstein, David; DeLancey, Siobhan; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren; Nemser, Sarah; Glover, Mark; Ceric, Olgica; Jones, Jennifer L
Sent: 7/12/2018 9:00:34 PM
Subject: RE: historical DCM case-FW: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free); [B6] EON-359051

Thanks, Dave. That's a sad one.

From: Rotstein, David
Sent: Thursday, July 12, 2018 4:50 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: historical DCM case-FW: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free); [B6] EON-359051

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: PFR Event [<mailto:pfpreventcreation@fda.hhs.gov>]
Sent: Thursday, July 12, 2018 4:48 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; usha.gulati@doveltech.com
Subject: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free); [B6] [B6] EON-359051

A PFR Report has been received and PFR Event [EON-359051] has been created in the EON System.

A "PDF" report by name "2051919-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-359051

ICSR #: 2051919

EON Title: PFR Event created for Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free); 2051919

AE Date	02/12/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Saluki		
Age	12 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2051919

Product Group: Pet Food

Product Name: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free)

Description: In CY 2012, my Saluki **B6** was part of a targeted cardiac study conducted at Michigan State University. As part of the study, **B6** wore a Holter vest and received an echocardiogram. The results of his screening indicated no heart issues/defects - his heart was healthy. On February 12, 2018, **B6** was diagnosed by both my vet and a veterinary cardiologist as having congestive heart failure, severely advanced dilated cardiomyopathy, heart arrhythmia and a grossly enlarged left heart ventricle (left ventricle was nearly 2x it's normal size while the right ventricle was normal sized). He was placed on a host of cardiac medications that helped improve his quality of life for several weeks, but the disease had progressed too far. On **B6** we made the decision to euthanize him. Prior to his diagnosis in February 2018, **B6** was aging gracefully and was an overall healthy, active dog. He developed a cough one morning and upon vet check we received the shocking diagnosis. For several years we had been feeding **B6** Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Grain-Free dog food. Occasionally we alternated between this food and the chicken based grain free dog food (same brand). Purchased in large 35 lb bags at Costco. Neither the cardiologist who diagnosed **B6** nor the team at MSU were able to explain to me why it was that he developed such serious, severe heart disease at age 11/12 after being cardiac cleared in CY 2012. **B6** did have two litter-mates who died very young from arrhythmia (they died under the age of four); but the rest of the dogs in the litter were heart healthy as was **B6**. I read the FDA report issued today, July 12, 2018 (FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease) with great shock and sadness. Based upon what I have read and my own experience with my dog, I am extremely concerned that the Kirkland brand grain-free dog food I have used for years (containing peas, potatoes and potato starch as high-content ingredients), may have led to to my dog's severe heart disease, suffering and eventual death. Until he awoke with a cough that morning in February 2018, we had no indication whatsoever that he was so sick with advanced heart disease. The FDA report encouraged pet owners to report cases of DCM in dogs suspected of having a link to diet - this is why I am reaching out to you today regarding my experience. If **B6** records regarding his heart disease from my vet, MSU or the cardiologist will be helpful in your research to identify/confirm that these grain-free diets are a contributing factor or are the root cause of DCM in these dogs, please let me know. Thank you.

Submission Type: Initial

Report Type: Both

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

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free)		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-359051>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=375675>

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Report Details - EON-359051

ICSR:	2051919
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-12 16:40:22 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In CY 2012, my Saluki [B6] was part of a targeted cardiac study conducted at Michigan State University. As part of the study, [B6] wore a Holter vest and received an echocardiogram. The results of his screening indicated no heart issues/defects - his heart was healthy. On February 12, 2018, [B6] was diagnosed by both my vet and a veterinary cardiologist as having congestive heart failure, severely advanced dilated cardiomyopathy, heart arrhythmia and a grossly enlarged left heart ventricle (left ventricle was nearly 2x it's normal size while the right ventricle was normal sized). He was placed on a host of cardiac medications that helped improve his quality of life for several weeks, but the disease had progressed too far. On [B6] we made the decision to euthanize him. Prior to his diagnosis in February 2018, [B6] was aging gracefully and was an overall healthy, active dog. He developed a cough one morning and upon vet check we received the shocking diagnosis. For several years we had been feeding [B6] Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Grain-Free dog food. Occasionally we alternated between this food and the chicken based grain free dog food (same brand). Purchased in large 35 lb bags at Costco. Neither the cardiologist who diagnosed [B6] nor the team at MSU were able to explain to me why it was that he developed such serious, severe heart disease at age 11/12 after being cardiac cleared in CY 2012. [B6] did have two litter-mates who died very young from arrhythmia (they died under the age of four); but the rest of the dogs in the litter were heart healthy as was [B6]. I read the FDA report issued today, July 12, 2018 (FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease) with great shock and sadness. Based upon what I have read and my own experience with my dog, I am extremely concerned that the Kirkland brand grain-free dog food I have used for years (containing peas, potatoes and potato starch as high-content ingredients), may have led to to my dog's severe heart disease, suffering and eventual death. Until he awoke with a cough that morning in February 2018, we had no indication whatsoever that he was so sick with advanced heart disease. The FDA report encouraged pet owners to report cases of DCM in dogs suspected of having a link to diet - this is why I am reaching out to you today regarding my experience. If [B6] records regarding his heart disease from my vet, MSU or the cardiologist will be helpful in your research to identify/confirm that these grain-free diets are a contributing factor or are the root cause of DCM in these dogs, please let me know. Thank you.
	Date Problem Started:	02/12/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	In CY 2014 [B6] had [B6] which was cured by neutering.
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	35 Pound
	Possess Unopened Product:	No
	Possess Opened Product:	No

Stored in a plastic dog food bin (sealed lid) in hall closet.

Storage Conditions:			
Product Use Information:	Description:	Fed daily for several years to my dog.	
	First Exposure Date:	05/01/2016	
	Last Exposure Date:	B6	
	Time Interval between Product Use and Adverse Event:	2 Years	
	Product Use Stopped After the Onset of the Adverse Event:	No	
	Perceived Relatedness to Adverse Event:	Probably related	
	Other Foods or Products Given to the Animal During This Time Period:	Yes	
Manufacturer /Distributor Information:			
Purchase Location Information:	Name:	Costco (bought in-store and online)	
	Address:	B6 United States	
Animal Information:			
Name:	B6		
Type Of Species:	Dog		
Type Of Breed:	Saluki		
Gender:	Male		
Reproductive Status:	Neutered		
Weight:	60 Pound		
Age:	12 Years		
Assessment of Prior Health:	Good		
Number of Animals Reacted:	1		
Owner Information:			
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
	Address:	B6 United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	04/12/2018	
	Permission to Release Records to FDA:	Yes	
Practice Name:	B6		

	Contact:	Name:	B6
		Phone:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	02/12/2018	
	Permission to Release Records to FDA:	Yes	

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

Additional Documents:

Pets Name	Diet	Diagnosis	Breed	Age	Sex	How long on diet	Taurine
	Deceased	Dilated cardiomyopathy, Congestive heart failure, Ventricular premature contractions, Ventricular tachycardia (short runs)	Dobe	5y	Fs	5y – entire life	B6
	Kirkland Natures Domain Turkey meal and sweet potato	Dilated Cardiomyopathy Congestive Heart Failure,	Boxer	Fs	Fs	4 years	
B6	deceased	Dilated Cardiomyopathy B6	Golden Ret	12	Mi		
	Orijen dog food	*Allergic to Grains* Dilated Cardiomyopathy	Pointer	7	fs	4y	
	Orjien Freeze Dried The real Meat Company Air Dired	Dilated Cardiomyopathy <i>Already sending to Dr. Stern at UC Davis and Dr. Jones</i>	Golden	5y	MI	Meat Comp (grain free) Started 7-29-18	B6
	Blue Buffalo Salmon & Potato	DCM	Bichon mix	12y	mn		
	Go - from Canada	Dilated Cardiomyopathy, Atrial Fibrillation, Congestive Heart Failure (historically) DCM-r/o idiopathic or secondary to the grain free diet	G Dane	4y	mn		
	Perform Ultra Grain Free lamb and rice	Occult Dilated Cardiomyopathy B6	golden				
	Blue buffalo senior	DCM	Dane	8y	mi	2 years	
	Instinct Raw Boost Lamb GF – now on Blue Buffalo. Beef heart for taurine BID	Dilated Cardiomyopathy--Occult, Ventricular Premature Contractions	Dobe	8y	mn	For a short time (2 bags)	B6
		Dilated Cardiomyopathy, Congestive Heart Failure, Atrial Fibrillation, Syncope	golden	9y	fs		
	Alpha dog grain free chicken	Dilated Cardiomyopathy, Subaortic Stenosis (SAS), Aortic Insufficiency	Dogue de Bordeaux	6y	mn		
Unknown brand	DCM	beagle	14y	Mn	14y		

B6

B6

Blue Wilderness	DCM	Lab	9	MN	
Natures Recipe Can	Dilated cardiomyopathy, Early left congestive heart failure	Beagle/ Border collie	12	MN	2y
Blue buffalo	Dilated cardiomyopathy, afib	Dobe	8	MI	
Unsure Changed to NonGF 4 months ago	Dilated cardiomyopathy, Pulmonary hypertension, Sinus tachycardia, Congestive heart failure	labradoodle	11y	mn	11y (whole life)
Blue Wilderness chicken (dry and canned)	Dilated cardiomyopathy, Pulmonary hypertension, Ventricular premature contractions (frequent), Congestive heart failure	Lab mix	2y	MN	2y – whole life

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Rotstein, David; Jones, Jennifer L; Carey, Lauren
Sent: 8/24/2018 6:03:17 PM
Subject: RE: FYI-poss case-FW: canine taurine levels and DCM
Attachments: B6 2015 genetics DCM.PDF

Please note

B5

Age of onset can also affect prognosis. There is a juvenile form of DCM in Portuguese water dogs, where age of onset is measured in weeks from birth [43, 44], while in most other cases age of onset is measured in years [45].

From: Rotstein, David
Sent: Friday, August 24, 2018 1:12 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: FYI-poss case-FW: canine taurine levels and DCM

Thanks -we will watch for it

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Jones, Jennifer L
Sent: Friday, August 24, 2018 1:10 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: FYI-poss case-FW: canine taurine levels and DCM

B6

Portuguese Water dogs

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



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Friday, August 24, 2018 11:02 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FW: canine taurine levels and DCM

FYI – subsequent email indicated dogs were eating Acana. I reinforced the importance of reporting.

I'm rechecking 2 of our dogs today so will send updates.

I got the box for food and will send that Monday
Thanks
Lisa

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

From: [REDACTED] B6
Sent: Friday, August 24, 2018 8:27 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: canine taurine levels and DCM

Hello Dr. Freeman,

I own a four year old Potuguese Water Dog who whelped a litter of pups last year. One of those puppies recently died suddenly from DCM at 15 mo. I alerted the other puppy owners and several have had heart ultrasounds on their dogs. Another puppy has mild DCM and another has a little valve leakage but no DCM. Both my bitch and the sire of this litter, and their sires and dams were tested for JDCM at [REDACTED] B6 and all were normal 1-1.

So, my question is, could this be diet related? I am going to contact the FDA with this information, but thought I'd investigate also.

Thank you for your time,

[REDACTED] B6

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Palmer, Lee Anne; Rotstein, David; Carey, Lauren
Sent: 8/24/2018 6:11:05 PM
Subject: RE: FYI-poss case-FW: canine taurine levels and DCM

Yes indeed, these dogs get a juvenile form of DCM. Contrary to most other breeds that get adult onset! Thanks, Lee Anne J

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



From: Palmer, Lee Anne
Sent: Friday, August 24, 2018 2:03 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: FYI-poss case-FW: canine taurine levels and DCM

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CVM Vet-LIRN Liaison
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Subject: FYI-poss case-FW: canine taurine levels and DCM

B6

Portuguese Water dogs

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Veterinary Medical Officer
Tel: 240-402-5421



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Board Certified Veterinary Nutritionist™
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Tufts University
www.petfoodology.org

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B6

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 8/1/2018 1:20:04 PM
Subject: FW: heart disease and grain-free nutrition

FYI-from Dr. Adin.
Possible PFR-DCM

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

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

From: Jones, Jennifer L
Sent: Wednesday, August 01, 2018 9:19 AM
To: 'Darcy Adin' <dbadin@ncsu.edu>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: heart disease and grain-free nutrition

Thank you, Dr. Adin.
If the owner believes the dogs' illness was related to the food, he can submit the pet food report to FDA:

<https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm>

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

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

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, July 25, 2018 4:26 PM
To: **B6**
Subject: Re: heart disease and grain-free nutrition

H: **B6**

I am so sorry for your loss! Yours is a familiar story that has been lived by others. It sounds like your pups could have been similarly affected like some other dogs that we have seen and reported.

I would be happy to look at their records and this may indeed help us. Did either of them have an echocardiogram performed? Sending the information to this email would be best.

Thank you for reaching out,
Take care
Darcy

> On Jul 25, 2018, at 4:07 PM, **B6**

>

> Hello,

>

> I read about your study in the NY Times (I am sure that you are inundated with similar messages today). My family has a case that you may be interested in. We had two Boston Terriers that, although were three years apart in age, developed severe heart disease in parallel. We finally had to put them down this past fall (they were ages 9 and 12).

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> The dogs had been perfectly healthy (other than the allergies). We had extensive testing done (xrays on both, an mri on the younger one). We would be happy to have the vet send their information to you if it would be helpful. Incidentally, we

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> If not, I completely understand (and sorry for the bother), but I wanted to reach out in case you are looking for other related case.

>

> Best,

[B6]

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 8/1/2018 1:21:13 PM
Subject: RE: heart disease and grain-free nutrition

Will be on the look out. thanks

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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

From: Jones, Jennifer L
Sent: Wednesday, August 01, 2018 9:20 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: FW: heart disease and grain-free nutrition

FYI-from Dr. Adin.
Possible PFR-DCM

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

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

From: Jones, Jennifer L
Sent: Wednesday, August 01, 2018 9:19 AM
To: 'Darcy Adin' <dbadin@ncsu.edu>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
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Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

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>

> If not, I completely understand (and sorry for the bother), but I wanted to reach out in case you are looking for other related case.

>

> Best,

> [B6]

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Peloquin, Sarah
Sent: 8/2/2018 2:03:25 AM
Subject: Re: heart disease and grain-free nutrition

Thank you Jennifer - I suggested that to the owners so hopefully they will do that. I reviewed one of the dogs echocardiogram report, and while it says CHF due to degenerative mitral valve disease, the numbers indicate significant myocardial failure which is consistent with DCM.

Thanks for all your work with this.
Take care
Darcy

> On Aug 1, 2018, at 9:18 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

>

> Thank you, Dr. Adin.

> If the owner believes the dogs' illness was related to the food, he can submit the pet food report to FDA:

>

> <https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm>

>

>

> Jennifer Jones, DVM

> Veterinary Medical Officer

> Tel: 240-402-5421

>

>

> -----Original Message-----

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> Sent: Wednesday, July 25, 2018 4:26 PM

> To: B6

> Subject: Re: heart disease and grain-free nutrition

>

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>> **B6**

From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Katherine.Huebner@fda.hhs.gov
CC: Ceric, Olgica
Sent: 8/7/2019 7:08:24 PM
Subject: FW: VET LIRN updates for AVMA?
Attachments: Vet-LIRN update for AVMA-08-07-2019-v1.docx; Vet-LIRN update for AVMA-08-07-2019-v1.pdf

Katherine
Olga forward your message to me.
Here is Vet-LIRN's update

I'm including the word file in case you want to incorporate into a CVM group document

Please let me know if you need additional info or if something isn't clear.

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: Ceric, Olgica
Sent: Friday, August 2, 2019 6:48 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: Fwd: VET LIRN updates for AVMA?

See below

From: Huebner, Katherine <Katherine.Huebner@fda.hhs.gov>
Date: August 1, 2019 at 10:51:59 PM GMT+2
To: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: VET LIRN updates for AVMA?

Hi Olga,

I will be heading to the AVMA council meeting for public health on behalf of Diana Link this September to provide CVM updates. Are there any updates that you would like me to share about Vet LIRN? Updates will be provided verbally and in writing, and may be shared with others outside the group. If you have any new updates since Diana last summary (see attached), please send to me by August 22.

Thanks!

Katherine (Kate) Huebner, VMD
Veterinary Medical Officer

Center for Veterinary Medicine
Office of Surveillance and Compliance
Division of Surveillance - Medical Review Team
U.S. Food & Drug Administration
Tel: 240-402-4347
katherine.huebner@fda.hhs.gov

Withheld in Full as B5

Withheld in Full as B5

From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Rotstein, David; Queen, Jackie L; Carey, Lauren; Palmer, Lee Anne
CC: Jones, Jennifer L; Nemser, Sarah; Ceric, Olgica; Reimschuessel, Renate
Sent: 8/29/2018 12:54:31 PM
Subject: RE: 800.267 EON-358522 [B6] Halo GF
Attachments: [B6] hx.pdf

Update: one more mrx attached for prior hx of repeated [B6]

From: Peloquin, Sarah
Sent: Tuesday, August 28, 2018 8:31 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: 800.267 EON-358522 [B6] Halo GF

Interview +/- food pending
Will ask if necropsy was performed

[B6] - 4 yr MN Great Dane
No rDVM mrx per O
h/o [B6], no other existing health conditions per cardio mrx; eats GF Halo

[B6] ER visit for tachycardia; coughing, vomiting, and leth x1 week; PE: irregular heart rhythm, intermittent dropped pulses, harsh bilat BV sounds; EKG à tachycardia, absent/buried p waves, irregular RR interval; tFAST pleural fluid, minimal LV contract, incr LA size; aFAST peritoneal fluid à transferred to Tufts

[B6] Tufts: HR 210-230, grade 2/6 murmur, weak pulses; echo à severe dilated LV w/ marked decr contract, thin LV walls, mod dilation LA, mild thicken mitral valve, trace pleural effusion, mild ascites, dilated hep vessels, FS 4.51% à DCM with secondary CHF, A-fib; WB tau [B6] started [B6]
BID

[B6] recheck at Tufts; not eating well, lethargic; gallop, murmur 2/6; echo à large volume ascites, no pleural/pericard effusion; EKG à a-fib, HR 220, rare VPCs; abdominocentesis removed 3.2 L straw fluid; BW showed elevated kidney values; added [B6]
Died at home [B6]

From: Rotstein, David
Sent: Monday, July 9, 2018 9:13 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: more DCMFW: Halo grain-free dry food (exact variety unknown): Lisa Freeman - EON-358522

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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From: PFR Event [<mailto:pfreventcreation@fda.hhs.gov>]
Sent: Monday, July 09, 2018 9:00 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; **B6**
Subject: Halo grain-free dry food (exact variety unknown): Lisa Freeman - EON-358522

A PFR Report has been received and PFR Event [EON-358522] has been created in the EON System.

A "PDF" report by name "2051557-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-358522
ICSR #: 2051557
EON Title: PFR Event created for Halo grain-free dry food (exact variety unknown); 2051557

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

Product information

Individual Case Safety Report Number: 2051557
Product Group: Pet Food
Product Name: Halo grain-free dry food (exact variety unknown)
Description: DCM and CHF Taurine not measured
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Halo grain-free dry food (exact variety unknown)		

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:

<https://eon.fda.gov/eon//browse/EON-358522>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=375146>

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From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Rotstein, David; Carey, Lauren; Palmer, Lee Anne; Queen, Jackie L
CC: Reimschuessel, Renate; Jones, Jennifer L; Ceric, Olgica
Sent: 9/28/2018 1:40:35 PM
Subject: RE: 800.267 EON-365002 [B6] multi
Attachments: EON-365002 owner interview 9.28.2018.pdf

Owner interview attached
Food pending (RR Nutrish)
Will request prior mrx from rdvm

From: Peloquin, Sarah
Sent: Thursday, September 20, 2018 1:02 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: 800.267 EON-365002 [B6] multi

Interview +/- food pending
Normal tau

[B6] - 6 yr MN Great Dane

Prior Mhx: [B6]

2/17/18: rdvm visit for coughing/gagging at home; pulse ox 98%, BW unremarkable, T4 wnl (1.9); non-synch fem pulses, tachycardic w/ irregular rhythm; 4DX neg; EKG à A fib; rec ASAP cardio consult

[B6] cardio consult; 2/6 L sys murmur, weak arterial pulse, irregular tachycard, mild dyspnea, norm BV sounds; rads à mod-marked gen cardiomegaly, pulm vasc/parenchyma consistent with decomp CHF and cardio pulm edema; EKG à A-fib w/ rapid ventric resp rate, HR 250; echo à thin LV wall w/ marked decr contract and dilation, dilated RV/RA, mod dil LA, trace pleural effusion, FS 19.93%; dx DCM, CHF, A fib; hosp overnight for telemetry à VPCs and non-sustained V tach; sent home with [B6]

[B6] ref 0-900)

9/10/18: recheck cardio, doing well at home home coughs 1-2x/day, e/d well, good exercise tolerance; grade 3/6 holosys murmur, fair arterial pulse, irregularly irregular rhythm, normal resp; echo à thin LV walls with progressively incr LV size and marked decr contract, marked LA dil, dilated RA/RV, FS 16.73%; EKG à A fib w/ rapid ventric resp rate, HR 200, rare isolated VPCs; incr [B6] rec recheck echo 4-6 mos

Diet history: Blue Seal Natural 26 puppy-14 mos; Nature's Variety Instinct Raw Boost chicken 14 mos-January 2018; Rachael Ray Nutrish chicken/veggies January 2018-present; Nutro GF chicken/lentil/SP January 2018--?

From: Rotstein, David
Sent: Wednesday, September 12, 2018 8:11 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM case-also fed Rachel Ray-FW: Nature's Variety Instinct Raw Boost Chicken dry: Lisa Freeman - EON-365022

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: PFR Event <preventioncreation@fda.hhs.gov>
Sent: Wednesday, September 12, 2018 8:09 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; **B6**
Subject: Nature's Variety Instinct Raw Boost Chicken dry: Lisa Freeman - EON-365022

A PFR Report has been received and PFR Event [EON-365022] has been created in the EON System.

A "PDF" report by name "2054861-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 "2054861-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-365022

ICSR #: 2054861

EON Title: PFR Event created for Nature's Variety Instinct Raw Boost Chicken dry, Rachel Ray Nutrish Chicken and Veggie dry; 2054861

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

Product information

Individual Case Safety Report Number: 2054861

Product Group: Pet Food

Product Name: Nature's Variety Instinct Raw Boost Chicken dry, Rachel Ray Nutrish Chicken and Veggie dry

Description: DCM and CHF. Owner was feeding Natures Variety until ~1/8/18 then switched to Rachel Ray. Presented to ER for coughin [B6] DCM and CHF diagnosed (with atrial fibrillation). Taurine not measured and diet not changed. Re-evaluated 9/10/18 and no improvement. Whole blood taurine pending and owner is switching diet. Owner does not have the Nature's Variety but will hold onto the Rachel Ray. She is happy to answer any additional questions

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Nature's Variety Instinct Raw Boost Chicken dry		
Rachel Ray Nutrish Chicken and Veggie 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:

<https://eon.fda.gov/eon//browse/EON-365022>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issuelid=381781>

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through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Burkholder, William
Sent: 5/19/2018 1:06:27 AM
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Burkholder, William

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

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

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

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

B5

Bill

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

From: Palmer, Lee Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

B5

I also cleaned up and **B5** (added a few things). Thanks – hope we can figure this one out!

Lee Anne

From: Jones, Jennifer L

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

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

B5

Any other ideas or suggestions?

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Hartogensis, Martine

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

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

Martine

From: Jones, Jennifer L

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

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

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

B5

B5

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



From: Hartogensis, Martine

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

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

Yes, excellent work!

B5

B5

Thanks in advance!
Martine

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

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

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

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

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

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

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

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

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

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

From: DeLancey, Siobhan

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

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

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

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

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

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

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

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

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

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

B5

B5

From: Hartogensis, Martine

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

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

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

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L

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

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

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

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

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



U.S. FOOD & DRUG
ADMINISTRATION



From: Rotstein, David

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

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

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

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

B5

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

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

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

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

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

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

This is very interesting.

B5

B5

Martine

From: Palmer, Lee Anne

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

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

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

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

B5

From: Rotstein, David

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

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

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

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

Lee Anne,

This is fantastic.

B5

B5

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

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

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

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

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

B5

B5

From: Rotstein, David

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

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

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

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

Sounds very intriguing!!!

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

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

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

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

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

B5

B5

From: Hartogensis, Martine

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

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

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

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

Awesome, thank you Dave!

Martine

From: Rotstein, David

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

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

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

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

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

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

Good Afternoon,

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

Just some basic information:

B5

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

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

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison

CVM OSC/DC/CERT

7519 Standish Place

240-506-6763 (BB)



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From: Hartogensis, Martine

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

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

Subject: RE: DCM

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

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.

Jen

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



From: Rotstein, David

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

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

Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Hartogensis, Martine

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

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

Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

Might be a good opportunity for us to partner with some cardiology folks....

Martine

From: Rotstein, David

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

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

Subject: Re: DCM

Martine

B5

B5

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

Dave

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

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

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

Subject: DCM

Hi Dave!

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

Martine

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Carey, Lauren; Glover, Mark; Queen, Jackie L; Palmer, Lee Anne; Rotstein, David
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 9/10/2018 11:45:21 AM
Subject: RE: 800.267-DCM Cluster-EON-351879- **B6** Freeman-vet-Blue Buffalo Basics salmon and potato dry food - regular and grain-free
Attachments: T_20735.pdf

FYI-Updated Tau-WB: **B6** now.

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



From: Jones, Jennifer L
Sent: Wednesday, May 09, 2018 8:37 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-DCM Cluster-EON-351879- **B6** Freeman-vet-Blue Buffalo Basics salmon and potato dry food - regular and grain-free

MRx summary-part of DCM cluster;

B6 7 yr MC Doberman Pinscher Mix

Presenting complaint 4/3/2018: vaccines, no concerns à start **B6** à recheck 4/4: diarrhea 5x today, diarrhea/urination in house after starting the drugs, vet gave **B6** & **B6**

PE 4/3: crt 2 sec, arrhythmia-irregularly irregular, short stretches of tachycardia, Gr II/VI murmur, clear lungs & eupneic, mild flank alopecia
-4/4: HR 170, irregularly irregular rhythm, Gr II/VI left apical pansystolic murmur, moderate synchronous pulses

Labs: **4/4 Echo:** moderate DCM (LV > RV), mod LA dilation, Afib

4/4 ECG: Afib

Whole blood Tau: 29 (at some point done)-unclear when

4/19 Nutrition Consult: mild muscle loss, BCS 5.5/9; Current diet-Blue Buffalo Basics-rotate between regular & grain free Salmon & SP dry kibble, adds Merrick dry food (during winter when weight loss), feeds boiled meat and rice during bouts of diarrhea, Stewards freeze dried beef liver treats; takes Omega 3 fish oil, just began **B6** takes Rx with Natural balance or Merricks canned food (varied flavors), occ Pill Pockets-grain free;

Prior Mhx: **B6**

B6

B6

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



From: Carey, Lauren
Sent: Monday, April 23, 2018 12:11 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: FW: Blue Buffalo Basics salmon and potato dry food - regular and grain-free:: Lisa Freeman - EON-351879

PFR created for the DCM RFR.

From: PFR Event [<mailto:pfpreventcreation@fda.hhs.gov>]
Sent: Monday, April 23, 2018 10:45 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; **B6**
Subject: Blue Buffalo Basics salmon and potato dry food - regular and grain-free:: Lisa Freeman - EON-351879

A PFR Report has been received and PFR Event [EON-351879] has been created in the EON System.

A "PDF" report by name "2046277-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 "2046277-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-351879

ICSR #: 2046277

EON Title: PFR Event created for Blue Buffalo Basics salmon and potato dry food - regular and grain-free;; 2046277

AE Date	04/03/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Doberman Pinscher		

Age	7 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2046277

Product Group: Pet Food

Product Name: Blue Buffalo Basics salmon and potato dry food - regular and grain-free:

Description: Reported as RFR (EON-351747). FDA CVM resubmitting as PFR. 7 year old castrated male Doberman pinscher with DCM. Has been eating Blue Buffalo Basics salmon and potato dry food since 2012 (rotates between regular and grain free version of this diet). Recently, diagnosed with DCM and whole blood taurine was 29 nmol/ml. Started on cardiac medications by RDVM and just started taurine and fish oil (may also start [B6]). Unclear if taurine deficiency-related DCM or related to current concerns with "grain free" diets. DCM and taurine deficiency Owner has bag of food that she's keeping until we hear from you. RDVM is [B6]

Submission Type: Initial

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

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

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 Basics salmon and potato dry food - regular and grain-free:		

Sender information

Lisa Freeman
 200 Westboro Rd
 North Grafton, MA 01536
 USA

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

<https://eon.fda.gov/eon//browse/EON-351879>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=368267>

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: Joshua A Stern <istern@ucdavis.edu>
To: [REDACTED] **B6**
CC: Reimschuessel, Renate
Sent: 8/17/2018 2:40:11 PM
Subject: Re: Diet and Taurine Table - [REDACTED] **B6** EON-359970

I believe the FDAs link which I typically share provides plenty of information and direction for clients.

<https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm>

Thanks for your continued work on this issue Dr. Reimschuessel.

Best

Josh

Joshua Stern, DVM, PhD, DACVIM (Cardiology)
Associate Professor of Cardiology
Department of Medicine & Epidemiology
University of California Davis; CCAH Room 258
[REDACTED] **B6** cell (530) 752.2475 office
istern@ucdavis.edu

Associate Editor - Journal of Veterinary Cardiology
www.journals.elsevier.com/journal-of-veterinary-cardiology

On Aug 17, 2018, at 7:10 AM, [REDACTED] **B6** <[REDACTED] **B6**> wrote:

Dr. Reimschuessel,

We are getting more cases reported in our Facebook groups of low taurine, DCM, and deaths caused by DCM. I feel we need to have a stand alone file that will provide people with detailed information on how to submit their case to the FDA. We have the portal address you provided, but do you have an existing document we could post that explains the process, what to expect, what records they need to have ready, how they will be contacted, etc.?

Thank you for anything you can provide to us. I have copied Dr. Stern on this message.

[REDACTED] **B6**

On Wed, Aug 1, 2018 at 6:53 AM, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov> wrote:

Dear [REDACTED] **B6**

Thank you very much for providing the link and the information.

I would encourage you to ask the contributing owners (or general site users) to report their cases to FDA, using the portal link below.

It is important to have their information officially recorded and documented by FDA.

A consumer report can be submitted through the Safety Reporting Portal:

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

Again, thank you for sharing the links to your data.

Dr. Reimschuessel

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: [B6] [mailto:[B6]]
Sent: Wednesday, August 1, 2018 9:33 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: Diet and Taurine Table - [B6] EON-359970

Dr. Reimschuessel,

My name is [B6] and I was contacted by [B6] regarding our online Diet and Taurine Table. The "Diet and Taurine Table" is available for online viewing to members of the "Taurine Deficiency in Golden Retrievers" and "Taurine-Deficient Dilated Cardiomyopathy" FaceBook groups, however, anyone with the link to the table is able to view it. For security, the table is maintained outside of Facebook in a dedicated Google Drive account. No one has access to modify the table except myself.

The purpose of the "Diet and Taurine Table" allows dog owners the opportunity to share information about taurine levels, taurine-deficient Dilated Cardiomyopathy (DCM) and the food their dogs were fed prior to testing. It is not intended to show how dogs with low taurine, DCM or Congestive Heart Failure (CHF) were medically treated. All dogs submitted must have been taurine tested by a licensed laboratory. Taurine test results in either the LOW or NORMAL range are accepted.

Every Friday I create a PDF snapshot of the table that is printer-friendly. I think that may have been what [B6] sent you. The online table will provide you more information.

To view the online table, please use this link:

B6

Owners complete an online questionnaire and their responses are automatically entered into the table. Here is the link to the online submission form that feeds the table:

<https://goo.gl/forms/0dnUZ6nosuR9DHRR2>

If you have any questions regarding the form, please let me know. It is simply a spreadsheet and all the data can be extracted to a .csv file.

Thank you,

B6

B6

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Rotstein, David; Norris, Anne; Hartogensis, Martine; Jones, Jennifer L; Burkholder, William; Reimschuessel, Renate
CC: DeLancey, Siobhan
Sent: 8/13/2018 7:04:20 PM
Subject: RE: Food Safety News Query: DCM follow-up

I think that's very good, Anne. I support your approach. J

From: Rotstein, David
Sent: Monday, August 13, 2018 3:02 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

That will work!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Norris, Anne
Sent: Monday, August 13, 2018 3:01 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

B5

Please advise if you see anything you'd recommend changing.

Thanks,
Anne

B5

From: Palmer, Lee Anne
Sent: Monday, August 13, 2018 10:55 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

Hi – just a few additional comments.

From: Hartogensis, Martine
Sent: Monday, August 13, 2018 10:51 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

Added to #3.

From: Carey, Lauren
Sent: Monday, August 13, 2018 10:28 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

My comments below.

From: Jones, Jennifer L
Sent: Monday, August 13, 2018 9:45 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>;

Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

My comments below.

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



From: Norris, Anne
Sent: Monday, August 13, 2018 9:34 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Food Safety News Query: DCM follow-up

Good morning!

B5

B5

Thanks,
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: 240-704-0579
Anne.Norris@fda.hhs.gov



From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Hartogensis, Martine; Carey, Lauren; Jones, Jennifer L; Burkholder, William; Reimschuessel, Renate; Rotstein, David
CC: DeLancey, Siobhan
Sent: 8/13/2018 7:01:06 PM
Subject: RE: Food Safety News Query: DCM follow-up

B5

Please advise if you see anything you'd recommend changing.

Thanks,
Anne

B5

From: Palmer, Lee Anne
Sent: Monday, August 13, 2018 10:55 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

Hi – just a few additional comments.

From: Hartogensis, Martine
Sent: Monday, August 13, 2018 10:51 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

Added to #3.

From: Carey, Lauren

Sent: Monday, August 13, 2018 10:28 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Food Safety News Query: DCM follow-up

My comments below.

From: Jones, Jennifer L

Sent: Monday, August 13, 2018 9:45 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

Subject: RE: Food Safety News Query: DCM follow-up

My comments below.

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



From: Norris, Anne

Sent: Monday, August 13, 2018 9:34 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

Subject: Food Safety News Query: DCM follow-up

Good morning!

B5

B5

Thanks,
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration

O: 240-402-0132

M: 240-704-0579

Anne.Norris@fda.hhs.gov



From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Carey, Lauren; Jones, Jennifer L; Norris, Anne; Burkholder, William; Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 8/13/2018 2:51:27 PM
Subject: RE: Food Safety News Query: DCM follow-up

Added to #3.

From: Carey, Lauren
Sent: Monday, August 13, 2018 10:28 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

My comments below.

From: Jones, Jennifer L
Sent: Monday, August 13, 2018 9:45 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

My comments below.

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



From: Norris, Anne
Sent: Monday, August 13, 2018 9:34 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Food Safety News Query: DCM follow-up

Good morning!

B5

B5

Thanks,
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: 240-704-0579
Anne.Norris@fda.hhs.gov



From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Jones, Jennifer L; DeLancey, Siobhan; Hartogensis, Martine; Burkholder, William; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Peloquin, Sarah
CC: Ceric, Olgica; Reimschuessel, Renate
Sent: 12/7/2018 1:13:58 PM
Subject: RE: FYI-DCM Article-FW: article

Thanks!

From: Jones, Jennifer L
Sent: Friday, December 7, 2018 8:07 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: FYI-DCM Article-FW: article

From Dr. Adin.

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



From: ADIN,DARCY BRITTAIN <adind@ufl.edu>
Sent: Friday, December 07, 2018 7:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: article

Hi Jen,

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

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

Take care
Darcy

Darcy B. Adin, DVM, Diplomate ACVIM (Cardiology)
Clinical Associate Professor, Cardiology
University of Florida
College of Veterinary Medicine
PO Box 100136
2015 SW 16th Ave
Gainesville, FL 32608
(352) 294-8606

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Reimschuessel, Renate; Joshua A Stern; Peloquin, Sarah
CC: [REDACTED] B6
Sent: 9/19/2018 5:42:34 PM
Subject: RE: Necropsy on nutritionally mediate DCM case

Thank you, Josh. I contacted [REDACTED] B6 yesterday, and we're coordinating the tissue collection/histopathology.
Many thanks for referring her to us!!

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



From: Reimschuessel, Renate
Sent: Wednesday, September 19, 2018 1:08 PM
To: Joshua A Stern <jstern@ucdavis.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: [REDACTED] B6
Subject: RE: Necropsy on nutritionally mediate DCM case

Thank you so much for assisting in our investigation
Drs. Jones and Peloquin can help you with logistics of shipping and billing.

Again – we really appreciate your work.
Dr. Reimschuessel

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: Joshua A Stern <jstern@ucdavis.edu>
Sent: Wednesday, September 19, 2018 12:24 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: [REDACTED] B6
Subject: Necropsy on nutritionally mediate DCM case

Hi - I was contacted about a dog with DCM that was eating a suspect diet and was euthanized. I advised on necropsy procedure and the clinician did this and collected samples. They now need to make contact with you about the process. They are CC'd on this email.

B6

Best

Josh

Joshua Stern, DVM, PhD, DACVIM (Cardiology)
Associate Professor of Cardiology
Department of Medicine & Epidemiology
University of California Davis; CCAH Room 258
B6 cell (530) 752.2475 office
jstern@ucdavis.edu

Associate Editor - Journal of Veterinary Cardiology
www.journals.elsevier.com/journal-of-veterinary-cardiology

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Burkholder, William; Rotstein, David; Hartogensis, Martine; Palmer, Lee Anne
CC: Reimschuessel, Renate; Carey, Lauren; DeLancey, Siobhan; Norris, Anne
Sent: 8/9/2018 3:28:26 PM
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

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



From: Burkholder, William
Sent: Thursday, August 09, 2018 11:25 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

Oh, oh, oh, my head is hurting, but

B5

These are my initial ideas and are not absolutes by any stretch of the imagination. They are only advanced for consideration, debate and modification.

From: Jones, Jennifer L
Sent: Thursday, August 09, 2018 10:49 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne

<Anne.Norris@fda.hhs.gov>

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

Thoughts?

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



From: Rotstein, David

Sent: Thursday, August 09, 2018 10:47 AM

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

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

From: Burkholder, William <William.Burkholder@fda.hhs.gov>

Date: August 9, 2018 at 10:45:04 AM EDT

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

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

From: Jones, Jennifer L

Sent: Thursday, August 09, 2018 10:36 AM

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

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

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Burkholder, William

Sent: Thursday, August 09, 2018 10:26 AM

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

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

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

Lots of people and organizations have guidelines on how to choose a pet food.

B5

B5

From: Jones, Jennifer L

Sent: Thursday, August 09, 2018 8:16 AM

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

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

Subject: Vet-LIRN call w/ Vet Cardiologists on 8/8

An update-we had a call w/ Drs. Darcy Adin (NCSU-cardiologist), Lisa Freeman (Tufts-nutritionist), **B6**

B6

cardiologist), and Joshua Stern (UC Davis-cardiologist, Golden Retriever study).

B5

Jennifer L. A. Jones, DVM

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



From: Burkholder, William </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8D5FDA60A4814BD290D84BD28A2A9292-BBURKHOL>
To: Jones, Jennifer L; Hartogensis, Martine; Rotstein, David; Palmer, Lee Anne
CC: Reimschuessel, Renate; Carey, Lauren; DeLancey, Siobhan; Norris, Anne
Sent: 8/20/2018 2:52:00 PM
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

Looks good to me, Jen.

Bill

From: Jones, Jennifer L
Sent: Monday, August 20, 2018 7:00 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

Thank you, Bill.

I've revised the **B5** statement to be:

B5

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



From: Burkholder, William
Sent: Monday, August 13, 2018 4:28 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

B5

Bill

William J. Burkholder, DVM, PhD, DACVN
Leader, Nutrition and Labeling Team I, HFV-228

Division of Animal Feeds
Center for Veterinary Medicine
7519 Standish Place
Rockville, Maryland 20855
Phone: 240-402-5900
Fax: 240-453-6882
E-mail: william.burkholder@fda.hhs.gov



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FDA-CVM-FOIA-2019-1704-017619

immediately at william.burkholder@fda.hhs.gov.

From: Jones, Jennifer L
Sent: Monday, August 13, 2018 11:51 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

I agree.

B5

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



From: Hartogensis, Martine
Sent: Monday, August 13, 2018 11:00 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

Hi,

Just seeing these emails.

B5

B5

Something worth considering....

Martine

From: Jones, Jennifer L
Sent: Thursday, August 09, 2018 11:28 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

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



From: Burkholder, William
Sent: Thursday, August 09, 2018 11:25 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

Oh, oh, oh, my head is hurting, but

B5

These are my initial ideas and are not absolutes by any stretch of the imagination. They are only advanced for consideration, debate and modification.

From: Jones, Jennifer L
Sent: Thursday, August 09, 2018 10:49 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

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



From: Rotstein, David
Sent: Thursday, August 09, 2018 10:47 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

From: Burkholder, William <William.Burkholder@fda.hhs.gov>

Date: August 9, 2018 at 10:45:04 AM EDT

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

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

On the surface I think the suggestion is reasonable, but t

B5

B5

From: Jones, Jennifer L

Sent: Thursday, August 09, 2018 10:36 AM

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

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

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

B5

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



From: Burkholder, William

Sent: Thursday, August 09, 2018 10:26 AM

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

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

Subject: RE: Vet-LIRN call w/ Vet Cardiologists on 8/8

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B5

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From: Jones, Jennifer L

Sent: Thursday, August 09, 2018 8:16 AM

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

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

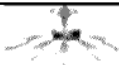
Subject: Vet-LIRN call w/ Vet Cardiologists on 8/8

An update-we had a call w/ Drs. Darcy Adin (NCSU-cardiologist), Lisa Freeman (Tufts-nutritionist) B6
B6 and Joshua Stern (UC Davis-cardiologist, Golden Retriever study).

B5

Jennifer L. A. Jones, DVM

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



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Norris, Anne; Palmer, Lee Anne; Rotstein, David; Reimschuessel, Renate; Edwards, David; Hartogensis, Martine; Burkholder, William; DeLancey, Siobhan
CC: Carey, Lauren; Lovell, Randall A; Ceric, Olgica; Nemser, Sarah; Conway, Charlotte; Atkinson, Krisztina Z; Hodges, April
Sent: 6/11/2018 4:05:55 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 800.267 Procedure Rationale-v2.docx; 800.267-draft-Sample Testing Procedures-v4.doc

Good morning everyone,

B5

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

Thank you,
Jen

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



From: Norris, Anne
Sent: Tuesday, May 22, 2018 9:24 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining.

B5

B5

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 9:13 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

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

B5

From: Norris, Anne

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

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

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

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

B5

B5

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:39 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

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

If we go forward, I would recommend

B5

B5

From: Rotstein, David

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

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

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

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

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

Anne,

Agreed.

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Norris, Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

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

B5

From: Jones, Jennifer L

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

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

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

B5

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



From: Rotstein, David

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

To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

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

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Reimschuessel, Renate

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

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

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

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

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

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

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

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

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

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

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

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

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

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

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

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

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

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David

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

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

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

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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

From: Hartogenesis, Martine

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

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

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

Thanks Bill and your concerns are noted!

B5

Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

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

Martine

From: Burkholder, William

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

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

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

B5

B5

Bill

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

From: Palmer, Lee Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

Thanks, Jen, very interesting issue!

B5

B5

I also cleaned up and (**B5** added a few things). Thanks – hope we can figure this one out!

Lee Anne

From: Jones, Jennifer L

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

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

B5

B5

Any other ideas or suggestions?

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



From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

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

Martine

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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



From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!

B5

B5

Thanks in advance!

Martine

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

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

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

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

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

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

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

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

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

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

From: DeLancey, Siobhan

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

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

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

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

As luck would have it, I'm at CE today listening to B6 talk about nutrition and

cardiomyopathies. See attached slide.

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

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

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

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

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

B5

B5

From: Hartogenesis, Martine

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

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

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

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

Excellent work Jen!!

B5

B5

Martine

From: Jones, Jennifer L

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

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

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

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

B5

B5

Please see the PPT for the rationale/summary

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



From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

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

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting;

B5

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

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

Just some basic information:

B5

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

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

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

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

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

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

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



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

Might be a good opportunity for us to partner with some cardiology folks....

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

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

Dave

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

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

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

Subject: DCM

Hi Dave!

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

Martine

Vet-LIRN Final Case Report

A. Case Identification:

Case Number: 800.218

Vet-LIRN Director: Renate Reimschuessel, VMD, PhD

Program: Vet-LIRN

Division Code: HFV – 500

Other Investigators:

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

B. Descriptive Title of Case:

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

Address of Vet-LIRN Program Office:

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

C. Initiation and Completion Date:

Initiation Date: 7/13/2017
Completion Date: 8/22/2017
Final Report Submission Date: 11/1/2017

Case Summary

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

Signalment:

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

Signs: syncopal episodes, dyspnea, cough, heart failure

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

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

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

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

Response: Vet-LIRN collected medical records for review and leftover open product (Kangaroo flavor) for taurine, **B5** testing.

Results: The food tested negative **B5** The food taurine level (0.26% estimated Dry Matter Basis) was above the minimum level in cats (no AAFCO minimum for dogs). The food carnitine level is 0.0077% estimated on a Dry Matter Basis. There is no AAFCO carnitine minimum for dogs or cats. It is unclear whether or not the food carnitine is low, normal, or high.

Conclusion: Dilated cardiomyopathy (DCM) can be caused by a variety of etiologies including, genetic² (breed related), toxic^{3,4} [B5]

[B5] and nutritional deficiency¹ (e.g. taurine, protein restricted diets with stones, carnitine deficiency). The two genetically unrelated dogs were fed the same foods and began to experience clinical signs approximately the same time. The medical records indicate infectious disease and nutritional deficiency are unlikely etiologies. [B6] records indicated elevated liver enzymes and CK values, which could support a hepatotoxic and myotoxic (cardio +/- muscle) exposure. Because [B6] presented six months after [B6] it is unknown if [B6] also had elevated liver enzymes when [B6] was ill. The history also suggested no exposure to doxorubicin or domoic acid. Vet-LIRN tested the leftover bag of food from [B6] illness time (June 2017), but not from January, when both dogs were initially ill. A test for [B5] was not available.

The cause of the two dogs' DCM is unclear, but is likely an environmental toxin exposure. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that [B5] taurine, or [B5] levels in the food caused the dogs' illness.

References:

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

Supplemental Information:

01-800.218-EON-323515-	B6	CC: Consumer Complaint
02-800.218-EON-323515-		MedRec: Medical Records
03-800.218-EON-323515-		Results: Testing Results
04-800.218-EON-323515-		Summary: Vet-LIRN Summary

SIGNATURES

Deputy Director OR Date

Director OR Date

Vet-LIRN Director Date

Report Details - EON-323515			
ICSR:	2023228		
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:	2017-07-11 17:06:59 EDT		
Reported Problem:	Problem Description:	<p>Please note: Dr. Jennifer Jones was consulted prior to submission of this report. She would like to be involved in the case review 3 week history of cough treated unsuccessfully with [B6] 3 day history of inappetence and vomiting prior to presentation to NCSU emergency service for dyspnea. Radiographs showed severe pulmonary edema and echocardiogram showed severe Dilated Cardiomyopathy. There was an initial response to diuretic therapy however, he declined and was placed on the ventilator for respiratory support and continued CHF treatment. Attempts to wean off the ventilator were unsuccessful and aquaphoresis was performed. He continued to decline despite aggressive therapy and was euthanized. Infectious disease testing was negative and taurine and carnitine analysis showed adequate levels. Necropsy initially did not reveal a cause for DCM and supported alveolar injury (possibly ventilator related). A re-</p> <div style="border: 1px dashed black; padding: 10px; text-align: center; font-size: 2em; font-weight: bold;">B6</div> <p>[B6] had been fed California Naturals Adult - both kangaroo with lentils and venison with lentils along with Milo's kitchen treats. We have samples of these foods from 6/17 but not the original bags from when he was presented 2/17. These samples were provided at the time his housemate, [B6] (unrelated, older miniature schnauzer) also presented with severe DCM and CHF. I will enter this dog as a separate affected patient. Both dogs had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation [B6] had clinical signs at the time [B6] was treated, but didn't present with CHF for several months), we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure.</p>	
	Date Problem Started:	[B6]	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Euthanized	
	Date of Death:	[B6]	
	Product Information:	Product Name:	Alternated between: -California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe
		Product Type:	Pet Food
		Lot Number:	
UPC:		not available	
Package Type:		BAG	
Package Size:		26 Pound	
Purchase Date:		06/01/2017	
Possess Unopened Product:		No	
Possess Opened Product:		Yes	
Storage Conditions:		In a cabinet, in the original bag	
Product Use Information:	Description:	twice daily feeding The sample we have is from 6/17, however, we do not have food samples from 2/17 when both dogs started with clinical signs.	
	Time Interval between Product	2 Years	

Use and Adverse Event:	
Product Use Stopped After the Onset of the Adverse Event:	No
Perceived Relatedness to Adverse Event:	Possibly related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:	
Purchase Location Information:	Address: United States

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Schnauzer - Miniature
Gender:	Male
Reproductive Status:	Neutered
Weight:	8.2 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: North Carolina State University, College of Veterinary Medicine
	Contact: Name: Darcy Adin Phone: (919) 513-6694 Other Phone: B6 Email: dbadin@ncsu.edu
	Address: 1060 William Moore Dr Raleigh New York 27607 United States
	Practice Name: North Carolina State University College of Veterinary Medici
	Contact: Name: B6 Phone: 9195136694

		Other Phone: B6
	Practice Name:	North Carolina state University, College of Veterinary Medic
	Contact:	Name: B6
		Phone: B6
		Other Phone: B6
Sender Information:	Name:	Darcy Adin
	Address:	1060 William Moore Dr Raleigh New York 27607 United States
	Contact:	Phone: 9195136694
		Other Phone: B6
		Email: dbadin@ncsu.edu
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Manufacturer
Additional Documents:		

B6Fax: Admin
Fax: ReferralSmall Animal
Large Animal**B6**

Client B6	Patient B6 SCHNAUZER MC BLACK CANINE	Case # 212267 8.2 kg	Attending DVM Student Discharging DVM Referring DVM	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 ½ year old male castrated Miniature Schnauzer who presented the NCSU ER on **B6** for labored breathing and was subsequently transferred to **B6** Cardiology. **B6** initially developed a cough three weeks ago; Dr. **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 **B6**. Kennel cough was suspected as the underlying cause of his cough and **B6** were prescribed. On **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 was concern for aspiration pneumonia on his radiographs. Nebulization was performed and subcutaneous fluids, **B6** were administered for treatment. While in-hospital, **B6** regurgitated. On **B6**, **B6** had improvement in respiratory effort but he still was not eating; subcutaneous fluids, **B6** were performed again on an outpatient basis. The day of presentation **B6**, Dr. **B6** syringe fed **B6** but as she attempted he immediately regurgitated. **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 **B6** for further care and ventilation if indicated.

B6 has a history of developing coffee brown urine, sometimes with clumping, after strenuous activity when it is hot outside. The discolored urine typically develops after the activity and lasts 24-36 hours before clearing up. A urinalysis was performed and **B6** primary veterinarian detected crystals in the urine. **B6** diet was changed to an unknown diet to decrease the amount of crystals prevent stone formation; this diet was ultimately discontinued. Other than this, prior to the coughing that began 3 weeks ago, **B6** was a normal, healthy dog with no significant medical history. He previously had no respiratory signs or changes in drinking/appetite/urination/defecation. **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):

Weight: 8.0 kg BCS: 5/9
T: 100.2 F
P: 160 bpm
R: 64 breaths/min
MMs/CRT: pale pink / <2 sec
Attitude: Alert, responsive
Hydration: Adequate

EENT/Oral: No ocular discharge noted, clear ear canals AU, no crusting/erythema noted; moist/flat nasal planum, no nasal discharge noted

PLN: No peripheral lymphadenopathy noted

CV/R: Grade I-II/VI left apical systolic murmur, femoral pulses hypokinetic but synchronous; jugular venous distention present; normal, albeit tachycardic, rhythm auscultes; dyspneic, inspiratory crackles in all lung fields on bilateral auscultation

GI/GU: Abdomen tense but non-painful on palpation; cranial abdominal organomegaly noted; no obvious fluid wave or masses noted
MSK: Appropriate and symmetrical musculing; ambulatory with no observed lameness; full ortho exam not performed due to patient's status

INTEG: Clean hair coat, no evidence of ectoparasites

NEURO: Mentally appropriate, intact cranial nerve reflexes, limited exam performed due to patient's status

Main Diagnostics **B6**

1. Big 4 - Glu: 135, Azo: 15-20, PCV: 40%, TS: 5.0 g/dL
2. Venous blood gas: pH 7.34, PCO2 46, lactate 2.4, HCO3 24.8
3. CBC - WBC 9.4, PCV 45, Seg 7.9, Band 0.18, Plt 157
4. Chemistry - BUN 19, creat 0.4, Phos 6.2, K 4.9, Na 140, TP 4.2
5. Blood Pressure - 90 mmHg systolic via Doppler
6. Urinalysis (post-lasix) - USG 1.011, otherwise unremarkable
7. Cardiac Troponin I - 0.79
8. Bap GM - pending
9. Vector borne panel - pending
10. Taurine levels - pending
11. Carnitine Levels - pending
12. Echocardiogram - Severely dilated and hypocontractile left and right ventricles, severely dilated left and right atria. Changes consistent with DCM (primary vs. secondary) vs. myocarditis vs. pacing-induced vs. other

Main Diagnostics **B6**

1. Chemistry - Gluc 225, BUN 29, Creat 0.7, phos 11.7, TP 5.0, ALT 53, CK 709, K 3.3, Cl 95, Na 144
2. Chest radiographs (9:15 AM) - final report pending - Severe generalized cardiomegaly with biventricular heart failure; improved from rDVM radiographs taken prior to presentation
3. Chest radiographs (5:00 PM) - final report pending - Progressive severe diffuse alveolar pattern consistent with worsening cardiogenic pulmonary edema; cannot exclude ventilator - induced lung injury and/or pneumonia

Main Diagnostics **B6**

1. CBC - WBC 9.9, Plt (clumping), PCV 44, Seg 8.0, Band 0.7
2. Chem - Gluc 136, BUN 12, Creat 0.7, Phos 4.6, ALT 88, CK 13,621, K 4.3, Na 151, Cl 109, AST 577
3. Coag - PT 9.1, PTT 14, Dimer 189, Fib 539, INR 1.09
4. Chest radiographs (1:30 AM, immediately post-ultrafiltration) - final report pending - markedly improved pulmonary infiltrates consistent with improved cardiogenic edema; residual interstitial to patchy alveolar pattern, decreased caudal cava size consistent with hypovolemia
5. Chest radiographs (11:00 AM) - final report pending - overall improved pulmonary pattern with persistent and in some areas slightly more condensed interstitial to patchy alveolar pattern. Consistent with continued improvement of congestive heart failure with possible concurrent bronchopneumonia; left lateral image shows suspected hiatal hernia

Main Diagnostics **B6**

1. CBC - WBC 6.8, PCV 39, Prot 6.9, Seg 4.2, Band 0.54, Toxic Neut Mild, Plt 97
2. Chem - Gluc 165, BUN 37, Creat 0.9, Phos 8.1, ALT 147, AST 1006, CK 35,930, Na 135, K 3.8, Cl 90
3. Urine Creat - 27.9
4. Urine Sodium - pending
5. Chest radiographs (10:00 AM) - final report pending - markedly progressive alveolar pattern consistent with significantly worsened cardiogenic edema; cannot exclude less likely differentials such as ARDS, ALI, hemorrhage, PTE, and pneumonia
6. ECG - suspect atrial tachycardia

Main Therapeutics Throughout Hospitalization (PO medications given through NG tube)

B6

Brief Daily Summary:

B6 **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** 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 bolus of B6 was given he was immediately placed on a B6 CRI at 1mg/kg/hr and B6 at 5mcg/kg/min quickly uptitrated to 10mcg/kg/min. After 4-6 hours of clinical worsening and the suspicion for respiratory fatigue, mechanical ventilation was recommended to the owner and pursued. Recheck radiographs (first rads performed at B6) after being on ventilation and continued CHF treatment showed continued severe pulmonary infiltrates but significantly improved compared to rDVM rads prior to any intervention. Because of this improvement we continued with aggressive CHF management and mechanical ventilation. Throughout the day he started to show some worsening clinically while on the ventilator and recheck radiographs were performed around 4:30PM. These radiographs showed worsening of the pulmonary infiltrates despite aggressive therapy. B6 At that time aquapheresis was discussed with the owner and pursued. This was from approximately 7PM-1AM (including setup and moving the patient. This procedure was performed successfully with no significant complications.

B6 Immediately after aquapheresis therapy recheck radiographs were performed (approximately 1:30AM) which showed a marked improvement in terms of pulmonary infiltrates. An interstitial to alveolar pattern persisted, mostly ventrally distributed, but was significantly improved. He was maintained on mechanical ventilation until approximately 5-6:00 AM when he was slowly weaned off ventilation and extubated. He handled this quite well and while sedated as the medications wore off, he clinically was markedly improved from presentation. His congestive heart failure medications were continued at aggressive doses (B6 at 15-20mcg/kg/min, B6 had continued to be at 1mg/kg/hr CRI since presentation, B6 was approximately 0.52mg/kg PO TID etc.). Recheck radiographs were performed around 2:00PM which showed an overall improvement in the pulmonary pattern, although a ventrally distributed alveolar pattern persisted and in some areas were slightly worse. We continued therapy for CHF and the patient was already being covered for pneumonia with meropenem (this antibiotic was chosen based on the patient's recent history of many antibiotics given including B6). He continued to do well until acutely worsening was seen during the owner visit approximately 4:00PM (20 minutes into the visit) where his respiratory rate/effort declined. He was given another bolus of B6 on top the CRI, butorphanol, and an increase in B6. He was able to relax and showed slight improvement, although was unable to breathe as comfortably as prior to the episode. He remained tachycardic throughout the night but otherwise normal.

B6 He remained tachycardic throughout the night at approximately 180bpm and the following morning he showed signs of atrial tachycardia at a rate of 190bpm. He was weaned off his dobutamine and started on diltiazem boluses followed by a CRI which resolved the atrial tach and a sinus tach at 150bpm persisted. He clinically was worse than the day before and repeat chest radiographs were performed that showed severe worsening of his pulmonary infiltrates. After discussion with the owner, we elected to continue even more aggressive diuretic therapy (multiple boluses of B6 on top of the 1mg/kg/hr CRI he had been on almost since presentation) but by 3:00 PM after only further worsening the decision for euthanasia was made. The owners elected for necropsy with private cremation.

I am sorry for the loss of your patient. Both B6 and Dr. B6 were absolutely wonderful to work with. If you have any questions at all, please do not hesitate to call us at B6

B6

B6

Fax: Admin
Fax: Referral

Small Animal
Large Animal

B6

Client B6	Patient B6 SCHNAUZER MC GRAY&WHITE CANINE	Case # 216605 9.9 kg	Attending DVM Student Discharging DVM Referring DVM	B6
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B6

Discharge Status: UNDETERM
NED

CASE SUMMARY:

HISTORY:

B6 a 7 year old male castrated Schnauzer, was presented to **B6** on **B6** for episodes of collapse. **B6** first collapse episode was in Mid February; he was described to fall over for 6 seconds with no loss of consciousness, and he immediately returned to normal after. **B6** had another collapse episode two weeks later, which looked the same and lasted the same amount of time as the first. **B6** next episode of collapse was **B6** after a two hour hike, when he collapsed and screamed, which lasted for six seconds, and he was normal after. **B6** experienced another collapse a week after, he whined, it lasted six seconds, and was normal after. A week after that, **B6** had another collapse episode, where a puppy ran towards him, **B6** tried to run with him, stopped, got wobbly, stood still, and was normal after a few seconds, but did not fall to the floor. **B6** also reports that he is panting more than usual. He had a good appetite for treats, but seems more reluctant to eat his food since February. He does eventually eat his food if mixed in with some treats. **B6** is fed California Natural, Kangaroo or Venison flavor. There has been no change with **B6** urination or defecation, and is otherwise healthy. **B6** is up to day on flea and tick preventative with a three month **B6** given on 5/2/17, but is not up to day on Heartworm preventative with Heartgard last given on 4/26/17.

B6

CV/R: No murmur or arrhythmia auscultated, femoral pulses strong and synchronous, normal bronchovesicular lung sounds noted on bilateral auscultation

B6

B6

3. Echocardiogram: Moderately to severely decreased LV ejection fraction, LV cavity size is severely increased, severely dilated LA, moderate to severe mitral valve regurgitation, anterior and posterior leaflets mild thickened due to endocardiosis, mild tricuspid regurgitation, moderately elevated pulmonary artery systolic pressure. Diagnosis: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspect dilated cardiomyopathy
4. ECG: regular sinus rhythm, complexes suggest LV enlargement, tall R waves
5. Thoracic radiographs: Severe left-sided cardiomegaly with moderate left atrial enlargement, unstructured interstitial pattern, and mild lobar venous distention: most consistent with left-sided congestive heart failure. ***Final report pending***
6. Urinalysis (cytocentesis): USG 1.019, protein negative, quiet sediment

Pending Lab Results:

1. Taurine
2. Carnitine
3. Vector borne panel

- 4. BAPGM
- 5. Troponin-I
- 6. T4
- 7. Toxoplasma
- 8. Neospora
- 9. Chagas
- 10. Complete amino acids

TREATMENTS:

B6

ASSESSMENT:

Thank you for bringing **B6** in to see us! He is a very cute and sweet boy. **B6** presented to us today for evaluation of progressive episodes of collapse. On physical exam today, **B6** was stable, but he had mildly increased breath sounds noted in all lung fields. During more excitable moments, **B6** showed increased respiratory effort with an abdominal component to his breathing pattern. We consulted with the **B6** Cardiology Service, who performed an ECG and echocardiogram. 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 **B6** 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. Please monitor **B6** for signs of worsening of his heart failure such as increased exercise intolerance, labored breathing, increased coughing or fainting. Call **B6** Cardiology or your referring veterinarian if any of these signs occur. Also, please start taking respiratory rates when **B6** is resting. This number should improve on his medications and remain less than 40 at rest. Please contact us or his primary care veterinarian if his respiratory rate or effort are worsening or you have any other concerns.

INSTRUCTIONS FOR CARE OF YOUR PET:

Medications:

B6

Activity / Cautions:

Please keep **B6** quiet until his recheck exam in several weeks. **B6** should be able to regulate his own energy level at home and be taken out for short bathroom breaks.

Diet:

Please continue **B6** current diet for the next several weeks. After this, he should be transitioned to a new meat-based commercial diet. We recommend that you consider one of the larger pet food brands (i.e. Royal Canin, Hills, Iams, Purina). Avoid salty treats, such as hot dog or jerky treats.

Monitoring:

1. Please monitor **B6** for signs of cardiac decompensation. This would include lethargy, cough, difficulty breathing (increased respiratory rate/effort), worsened abdominal distension, and episodes of collapse or fainting.

2. Please monitor [B6] resting respiratory rate. In order to do this, you can count the number of times that [B6] breathes in 15 seconds and multiply this number by 4 to get the number of breaths per minute. If you notice that this number is increasing or that it is consistently greater than 35-40 breaths per minute, then you should have [B6] evaluated by a veterinarian. A mobile app (Cardalis) is available to record instant rates and trends in respiratory rates.

PLAN FOR RE-EVALUATION OF YOUR PET:

Please call the Cardiology Service tomorrow to schedule an appointment for [B6] during the week of July 10th. You can schedule this appointment by calling [B6]. Please bring a sample of [B6] current diet to this appointment for possible testing. He will also likely have a blood pressure, chest radiographs, and a renal panel performed during this appointment to re-evaluate his heart failure.

If you have any questions or concerns before this appointment, please have [B6] re-evaluated by your primary care veterinarian or the [B6] Emergency Service. [B6] may need recheck bloodwork and chest X-rays prior to this appointment if he is not doing well. He also may need medication adjustments and potentially hospitalization.

In order to help expedite medication refills, please visit us online at [B6] and select [B6]

[B6] [B6] [B6]

SMALL ANIMAL EMERGENCY SERVICE TEAM:

Faculty: [B6]

Residents/Fellows: [B6]

Interns: [B6]

Supervisor: [B6]

Technicians: [B6]

Client Services: [B6]

Referring Veterinarians - please visit us online at [B6] and fill out our RDVM Feedback Survey!

The following instructions were provided at discharge

CLINICIAN: [B6]

Date: [B6]

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] Emergency Service 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

Activity / Cautions:

Please keep **B6** quiet until his recheck exam in several weeks. **B6** should be able to regulate his own energy level at home and be taken out for short bathroom breaks.

Diet:

Please continue **B6** current diet for the next several weeks. After this, he should be transitioned to a new meat-based commercial diet. We recommend that you consider one of the larger pet food brands (i.e. Royal Canin, Hills, Iams, Purina). Avoid salty treats, such as hot dog or jerky treats.

Monitoring:

1. Please monitor **B6** for signs of cardiac decompensation. This would include lethargy, cough, difficulty breathing (increased respiratory rate/effort), worsened abdominal distension, and episodes of collapse or fainting.
2. Please monitor **B6** resting respiratory rate. In order to do this, you can count the number of times that **B6** breathes in 15 seconds and multiply this number by 4 to get the number of breaths per minute. If you notice that this number is increasing or that it is consistently greater than 35-40 breaths per minute, then you should have **B6** evaluated by a veterinarian. A mobile app (Cardalis) is available to record instant rates and trends in respiratory rates.

PLAN FOR RE-EVALUATION OF YOUR PET:

Please call the Cardiology Service tomorrow to schedule an appointment for **B6** during the week of July 10th. You can schedule this appointment by calling **B6**. Please bring a sample of **B6** current diet to this appointment for possible testing. He will also likely have a blood pressure, chest radiographs, and a renal panel performed during this appointment to re-evaluate his heart failure.

If you have any questions or concerns before this appointment, please have **B6** re-evaluated by your primary care veterinarian or the **B6** Emergency Service. **B6** may need recheck bloodwork and chest X-rays prior to this appointment if he is not doing well. He also may need medication adjustments and potentially hospitalization.

IF YOU HAVE ANY QUESTIONS OR PROBLEMS, PLEASE CALL THE SMALL ANIMAL EMERGENCY SERVICE AT **B6**

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

B6

Fax: Admin
Fax: Referral

Small Animal **B6**
Large Animal

Discharge Comments

Client B6	Patient B6 SCHNAUZER MC GRAY&WHITE CANINE	Case # 216605 9.9 kg	Attending DVM Student Discharging DVM Referring DVM	B6
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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 **B6** cardiology service for re-evaluation of dilated cardiomyopathy. At his prior visit, **B6** presented to our Small Animal Emergency on **B6** 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 **B6** SAES. Collapse episodes were preceded by excitement or exertion. He was discharged **B6** with **B6** **B6** house mate, **B6** unfortunately passed away from DCM and CHF in **B6**. 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 **B6** **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** 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

CV/R: Grade 2/6 left apical systolic murmur, no arrhythmias auscultated, femoral pulses strong and synchronous, normal bronchovesicular lung sounds noted on bilateral auscultation- no crackles or wheezes, eupneic

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 potassium, while normal, is at the low end of the range, and because this may have some long term benefit through anti-aldosteronism. 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

[B6] taurine and carnitine assessments were normal, making supplementation unlikely to be beneficial. Other supplements with theoretical but unstudied benefits are included below. These are not likely to be harmful and no interactions with his medications are anticipated.

1. [B6] 5 grams (1 scoop) daily.
2. Coenzyme Q10 (as ubiquinol not ubiquinone) 100 mg capsules: give 1 capsule 2-3 times daily
3. Fish oil 450 mg of EPA and DHA per day. This is an approximate dose and can be rounded up or down depending on the fish oil chosen. Nature Made and Nordic Naturals are high quality brands.

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 [B6] 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 [B6] 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 [B6](#) and select [B6](#)

NOTE: If your pet is in need of emergency aid and you are not able to get to the [B6](#) 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 - [B6](#)

Student - [B6](#)

Referring Veterinarians - please visit us online at [B6](#) and fill out our RDVM Feedback Survey!

Certificate of Analysis

Food and Drug Administration - CVM - Invoice Denise Durham

8401 Muirkirk Rd.
Laurel Maryland 20708 United States

Sample Name:	800.218	Covance Sample:	6406524
Project ID	FDA_CVM-20170804-0007	Receipt Date	04-Aug-2017
PO Number	HHSF223201610005I/HHSF22301002T	Receipt Condition	Ambient temperature
Sample Serving Size	100 g	Login Date	04-Aug-2017
		Online Order	20

Analysis	Result
L-Carnitine *	
L-Carnitine	69900 ppb
Taurine	
Taurine	231 mg/Serving Size

Method References	Testing Location
-------------------	------------------

L-Carnitine (CARNITNE_S)	Covance Laboratories - Madison
STAREY ET AL.: JOURNAL OF AOAC INTERNATIONAL VOL. 91, NO.1, 2008. (Modified).	

Taurine (TAUR_LC_S)	Covance Laboratories - Madison
R. Schuster, "Determination of Amino Acids in Biological, Pharmaceutical, Plant and Food Samples by Automated Precolumn Derivatization and HPLC", Journal of Chromatography., 1988, 431, 271-284, Henderson, J.W., Ricker, R.D. Bidlingmeyer, B.A., Woodward, C., "Rapid, Accurate, Sensitive, and Reproducible HPLC Analysis of Amino Acids, Amino Acid Analysis Using Zorbax Eclipse-AAA columns and the Agilent 1100 HPLC," Agilent Publication, 2000, and Barkholt and Jensen, "Amino Acid Analysis: Determination of Cysteine plus Half-Cystine in Proteins after Hydrochloric Acid Hydrolysis with a Disulfide Compound as Additive," Analytical Biochemistry, 177, 318-322 (1989).	

Testing Location(s)	Released on Behalf of Covance by
---------------------	----------------------------------

Covance Laboratories - Madison

Covance Laboratories Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

Edward Ladwig - Director



2918.01

These results apply only to the items tested. This certificate of analysis shall not be reproduced, except in its entirety, without the written approval of Covance.

* This analysis is not ISO accredited.



Texas A&M Veterinary Medical Diagnostic Laboratory
 483 Agronomy Road
 College Station TX 77840
 Phone: (979) 845-3414 Fax: (979) 845-1794

Report Date: 8/4/2017

Final Report

Date Received: 8/4/2017

Case Coordinator: **B6**

Accession No: **B6**

JENNIFER JONES, DVM
 8401 MUIRKIRK RD.
 LAUREL MD 20708

Phone: (240) 402-5421
 Fax: (301) 210-4685
 Email: jennifer.jones@fda.hhs.gov

Associated Parties

Vet Practice	TAMU Veterinary Pathobiology	Account #: A02336	B6
	Jennifer Jones, DVM		8401 Muirkirk Rd. Laurel, MD 20708 (240) 402-5421

Customer Requests

Specimens Submitted: 1 bag,
 Customer Test Request: Please test dog food product for **B5**

History

Please see previous email.

Lab Findings

Toxicology

Specimen	Test Name	Method	Basis	Toxicology Result	Units
Dog food - 800.218 - 1	B5	ELISA	As received basis	None Detected, < 5	ppm
B5 was not detected in this sample at the detection limit of 5 ppm. - B6 PhD, DABT, Veterinary Toxicologist /kk					

Client Report History

Report Type	Delivery Method	Sent To	Date Sent
Final	Email	jennifer.jones@fda.hhs.gov	8/4/2017 3:59 PM

Accession Number: **B6**

Final (8/4/2017)

Page 1 of 1

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Lisa Freeman
Sent: 8/4/2018 3:29:06 AM
Subject: Follow up call?

Hi Dr. Jones,

Dr. Freeman and I are wondering if your group would be willing to have another conference call as a follow-up to discuss the nutritionally based DCM cases? As you know, since the release of the FDA statement, there has been much discussion among the public and the veterinary community, and we thought it could be useful to reconvene.

Thank you for your thoughts!
Darcy

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Peloquin, Sarah; Jones, Jennifer L
Sent: 5/11/2019 12:38:23 AM
Subject: for review: ACVP presentation-DCM
Attachments: CARDIAC FINDINGS IN DOGS WITH EXPOSURE TO GRAIN 5-10-2019.docx

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Nemser, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC1EB8D2F5944ECAA02F40E225C2054-SNEMSER>
To: Jones, Jennifer L
Sent: 4/4/2018 1:42:15 PM
Subject: FW: 800.261-Zignature Kangaroo Formula: [B6] EON-350158
Attachments: EON-350158 [B6] case summary-4.4.2018.doc

I am not getting original emails about cases. Am I not on the emails?

S

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: **240-402-0892**

fax: **301-210-4685**
sarah.nemser@fda.hhs.gov

From: Jones, Jennifer L
Sent: Wednesday, April 04, 2018 9:32 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.261-Zignature Kangaroo Formula: [B6] EON-350158

MRx summary below. We are purchasing store-bought product for Tau, Met, Cys testing. A previous case without food had a Cocker Spaniel-same Zignature Essentials Food, low Tau on labwork. If the Food results are negative, we may need to consider Tau/Cys/Met inhibitors in the food or breed-related AA handling deficiencies causing the DCM

MRx summary:

Presenting complaint 10/27 to rDVM: developed a cough on 10/25, cough for 3-4 days, not lethargic, normal eating/drinking, no vomiting or diarrhea, worse when lying down, dog didn't cough while in clinic except for a tracheal cough when pulling on the leash à treated with hydroxyzine, doxycycline, hydrocodone à stopped all 3 drugs [B6] b/c cough worsened à to ER on [B6] after coughing up pink tinged foam; no lethargy, continues to eat and drink; UTD on vaccines and HWP, no drugs à treat with [B6]
Tau, L-carnitine and **vet recommended a diet change** à labwork done 11/14 à to rDVM 11/16: doing well à recheck 2/26/18: intermittent cough, related to excitement, change diet to RC Early Cardiac à on recheck improved à suspect Tau responsive DCM-mild, suspect cough secondary to bronchial or primary respiratory disease à recheck 3/13: resting RR 16 rpm, minimal coughing only when excited, since switching to cardiac food BMs are dense and tenesmus, owner is weaning dog off [B6]
PE 10/27 @ rDVM: numerous [B6] no audible murmur or arrhythmia, shallow breathing
PE [B6] @ specialist: LS-OU, HR 100 bpm, mild [B6] disease, Gr II/VI, left apical protosystolic murmur, questionable mild inc bronchovesicular sounds bilaterally, [B6] mildly tense cranial abdominal palpation

PE 11/16 @ rDVM: mild underbite, H/L wnl

PE 2/26: Gr III/VI pansystolic, PMI MV, reg rhythm with S3 gallop, HR 130, BCS 6/9, hepatomegaly

PE 3/13: T 99.9F, RR 56, HR 124 bpm, Gr III/VI murmur, rest nsf

Labs: 10/27 CBC: Lym 1.01 (1.05-5.1)

-3/13: Lym 1044 (1060-4950), Plt 615 (143-448), Plt inc on direct
10/27 Chem: ALP 440 (23-212), GGT 30 (0-11), rest nsf
-11/14: Glu 51 (70-143), Glob 4.7 (2.5-4.5), ALP 621, GGT 31
-3/13: Na:K 27, ALP 2243 (5-180), GGT 117 (0-13)

B6

BP 100 (based on Echo)
-2/26: 155 mg Hg, direct measurement
-3/13: 130-140 mmHg, direct measurement
11/3 Tau-blood: 168 (200-350)
3/13 UA: 1.010, pH 5
3/13 TT4: 0.8 (1-4)

Rads 10/27: generalized cardiomegaly, left atrial enlargement, slight left auricular bulge, increased sternal contact & rounded heart, dorsal tracheal deviation, prominent pulmonary vasculature with questionably mild inc interstitial opacity in caudal-dorsal lungs, suggesting early CHF/PE

B6 Echo: severe LV hypertrophy, mild-mod MV regurgitation, mod-sev LA dilation, mild TV regurg, mild RV & RA dilation, mod-sev lower systolic function values

-2/26: mild LV dilation, mild MV regurg, normal LA, mild TV regurg, normal RV & RA, low normal systolic functional indices of LV

B6 ECG: normal sinus rhythm

Prior MHx: 7/2017: doing well at home-occasionally coughs, several **B6** no murmur or cough on tracheal palpation; 10/23/2017-vaccines, doing well per O, no murmur ausculted, not been getting HWP consistently,

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



From: Jones, Jennifer L

Sent: Tuesday, March 27, 2018 3:40 PM

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-350158

Yes-let's take a look! I think we should check taurine, cysteine, methionine, and beta-alanine. I'm curious if those

B5

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



From: Palmer, Lee Anne

Sent: Tuesday, March 27, 2018 3:25 PM

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

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: FW: Zignature Kangaroo Formula: **B6** - EON-350158

In case of interest – taurine level low?

From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]

Sent: Tuesday, March 27, 2018 3:20 PM

To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification
<HQPetFoodReportNotification@fda.hhs.gov> B6

Subject: Zignature Kangaroo Formula; B6 EON-350158

A PFR Report has been received and PFR Event [EON-350158] has been created in the EON System.

A "PDF" report by name "2044632-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 "2044632-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350158

ICSR #: 2044632

EON Title: PFR Event created for Zignature Kangaroo Formula; 2044632

AE Date	10/31/2017	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	13 Years		
District Involved	PFR; B6		

Product information

Individual Case Safety Report Number: 2044632

Product Group: Pet Food

Product Name: Zignature Kangaroo Formula

Description: At the time of diagnosis B6 was a 13 year old female spayed Labrador retriever who had been maintained on a Zignature Kangaroo formula. She presented with a history of a progressive cough which, prior to presentation, became productive and she coughed up a small volume of pink foam (possible pulmonary edema). On examination she had a 2/6 left apical systolic heart murmur and on echo diagnosed with advanced dilated cardiomyopathy with severe left ventricular dilation, moderate to severe left ventricular systolic dysfunction, and moderate to severe left atrial dilation. Thoracic radiographs were suspicious for early congestive heart failure. A whole blood taurine level was submitted and was low at B6 She was treatment with B6

B6 taurine and l-carnitine and her diet was changed to Royal Canin Early Cardiac. At her recheck in 2/26/18, B6 heart had improved significantly with now mild dilated cardiomyopathy with normalized left atrial dimensions, mild left ventricular dilation and low normal left ventricular systolic function. The B6 was able to be discontinued at this time.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature Kangaroo Formula		

Sender information

B6

USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-350158>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=366527>

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

Vet-LIRN Case Summary Document

Vet-LIRN Case Number:	
EON/CC #:	EON-350158
Owner LAST Name:	B6
Vet LAST Name:	B6
Vet-LIRN Initiation Date:	3/28/2018
MedRec: Requested:	Received with Complaint
MedRec: Received:	
MedRec: Significant finding:	
Vet-LIRN Tests (planned):	
Vet-LIRN Test Results:	
Result Interpretation:	
IF NFA, justification:	

COMPLAINT Narrative: At the time of diagnosis [B6] was a 13 year old female spayed Labrador retriever who had been maintained on a Zignature Kangaroo formula. She presented with a history of a progressive cough which, prior to presentation, became productive and she coughed up a small volume of pink foam (possible pulmonary edema). On examination she had a 2/6 left apical systolic heart murmur and on echo diagnosed with advanced dilated cardiomyopathy with severe left ventricular dilation, moderate to severe left ventricular systolic dysfunction, and moderate to severe left atrial dilation. Thoracic radiographs were suspicious for early congestive heart failure. A whole blood taurine level was submitted and was low at 168. She was treatment with [B6] and her diet was changed to Royal Canin Early Cardiac. At her recheck in 2/26/18, [B6] heart had improved significantly with now mild dilated cardiomyopathy with normalized left atrial dimensions, mild left ventricular dilation and low normal left ventricular systolic function. The [B6] was able to be discontinued at this time.

Signalment: [B6] 13 yr FS Lab

Signs: productive, progressive cough

Food Product: Zignature Kangaroo Formula

Plan:

- MRx
- Open product for Tau, Cysteine, Methionine, +/- Beta-Alanine

MRx summary:

Presenting complain [B6] **to rDVM:** developed a cough on [B6] cough for 3-4 days, not lethargic, normal eating/drinking, no vomiting or diarrhea, worse when lying down, dog didn't cough while in clinic except for a tracheal cough when pulling on the leash → treated with [B6] [B6] → stopped all 3 drugs [B6] b/c cough worsened → to ER of [B6] after coughing up pink tinged foam; no lethargy, continues to eat and drink; UTD on vaccines and HWP, no drugs → treat with [B6] and **vet recommended a diet change** → labwork done 11/14 → to rDVM 11/16: doing well → recheck 2/26/18: intermittent cough, related to

excitement, change diet to RC Early Cardiac → on recheck improved → suspect Tau responsive DCM-mild, suspect cough secondary to bronchial or primary respiratory disease → recheck 3/13: resting RR 16 rpm, minimal coughing only when excited, since switching to cardiac food BMs are dense and tenesmus, owner is weaning dog off **B6**

PE **B6** @ rDVM: **B6** no audible murmur or arrhythmia, shallow breathing

PE **B6** @ specialist: LS-OU, HR 100 bpm; **B6** Gr II/VI, left apical protosystolic murmur, questionable mild inc bronchovesicular sounds bilaterally; **B6**

PE **B6** @ rDVM: mild underbite, H/L wnl

PE 2/26: Gr III/VI pansystolic, PMI MV, reg rhythm with S3 gallop, HR 130, BCS 6/9,

hepatomegaly

Labs:

B6

Rads **B6** generalized cardiomegaly, left atrial enlargement, slight left auricular bulge, increased sternal contact & rounded heart, dorsal tracheal deviation, prominent pulmonary vasculature with questionably mild inc interstitial opacity in caudal-dorsal lungs, suggesting early CHF/PE

B6 **Echo:** severe LV hypertrophy, mild-mod MV regurgitation, mod-sev LA dilation, mild TV regurg, mild RV & RA dilation, mod-sev lower systolic function values

B6 mild LV dilation, mild MV regurg, normal LA, mild TV regurg, normal RV & RA, low normal systolic functional indices of LV

B6 **ECG:** normal sinus rhythm

Prior MHx: 7/2017: doing well at home-occasionally coughs, several SQ masses, no murmur or cough on tracheal palpation; **B6** vaccines, doing well per O, no murmur ausculted, not been getting HWP consistently,

An article about beta-alanine: <https://academic.oup.com/alcalc/article/36/1/29/138000>

B5

I emailed the vet to request the full MRx and see if lot/best by information available for the leftover food.

4/4/2018

JJ-Vet sent the full MRx available and does not have any leftover food. We will purchase the food for testing. A dog from a previous case without food (800.218-**B6**) Cocker Spaniel with Low Tau and also eating Zignature Essentials Kangaroo.

MRx added to above summary.

Document properties

Author: Reimschuessel, Renate
Company: US FDA
Template: Normal.dotm
Page count: 2
Paragraph count: 55
Line count: 106
Word count: 783
Character count (spaces excluded): 4356
Character count (spaces included): 5116

From: Burkholder, William </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=BBURKHOL>
To: Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Atkinson, Krisztina Z; Glover, Mark; Rotstein, David; Lambkin, Sonya; Queen, Jackie L
Sent: 9/13/2017 3:50:58 PM
Subject: FW: Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

FYI. DAF had a call from a consultant on this topic about 2-3 weeks ago. The consultant would not divulge the manufacturer(s) or brand(s)

From: American College of Veterinary Nutrition [mailto:ACVN-L@lists.psu.edu] On Behalf Of [REDACTED]
Sent: Wednesday, September 13, 2017 11:44 AM
To: ACVN-L@LISTS.PSU.EDU
Subject: FW: Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

My [REDACTED] account was denied...

From: [REDACTED] [mailto:[REDACTED]]
Sent: Wednesday, September 13, 2017 11:43 AM
To: American Academy of Veterinary Nutrition; American College of Veterinary Nutrition
Cc: [REDACTED]
Subject: Re: Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

Hi all,

We (at [REDACTED]) have also recently diagnosed a dog ([REDACTED]) with taurine-deficiency DCM that was eating an Acana diet (duck & pear). Since the company reports AA% on their website, I calculated the methionine-cysteine to be 0.2 g/100 kcal (AAFCO min 0.16/100 kcal). It is a diet high in legumes. Max cruder fiber calculated to be 1.7 g/100 kcal.

Does anyone else have cases? If so, should we combine to write up a case series? Feel free to email me directly ([REDACTED]).

Thanks,

[REDACTED] DVM, DACVIM, DACVN

On Wed, Sep 13, 2017 at 11:35 AM, [REDACTED] [REDACTED] wrote:
Hello [REDACTED],

2 decades ago, I was involved in the project trying to understand the dog epidemic of HCM mostly associated with lamb and rice diets.

We were never able to give a complete explanation (ie, when we reproduced the diet, we were not able to induce taurine deficiency to a degree that would be harmful to the dogs.)

We believe that the issue was due to the combination of:

- Not enough bioavailable methionine/cystine in the diet (poor quality lamb meal, low level of protein)
- Impaired recycling of bile acids (rice bran, ...)

Thus in dogs, to correct taurine deficiency you can also use methionine and this is probably better. Indeed methionine is not only a precursor of taurine but also glutathione, choline, carnitine, ... (see presentation of Bab Backus at ACVIM a few years ago)

I would be interested in getting guaranteed analysis and ingredient list of diets associated with the issue.

B6

De : American Academy of Veterinary Nutrition [mailto:AAVN-L@lists.psu.edu] **De la part de**

B6

Envoyé : mercredi 13 septembre 2017 17:18

À : AAVN-L@LISTS.PSU.EDU

Objet : Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

Hi Everyone:

This was sent to me and I thought it would be good to share with everyone. Two decades ago, we discovered that protein-restricted diets not supplemented with taurine could induce reversible DCM in healthy dogs. In addition, it has been known since the 1990's that Cocker spaniels with DCM benefit from taurine (and carnitine) supplementation, and a study done by AMC and UC Davis in the 1990's also showed that some Golden Retrievers with DCM had taurine deficiency. There now appears to be an association with taurine deficiency induced DCM in Golden Retrievers consuming grain free diets. The attachment provides some guidelines regarding client education and what to do diagnostically with Golden Retrievers with DCM.

Thanks,

B6

This email was sent on behalf of the College of Agricultural Sciences, The Pennsylvania State University, Ag Administration Building, University Park, PA 16802. For any questions or problems, contact the [list administrator](#) or [Ag Communications and Marketing](#).

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From: Burkholder, William </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=BBURKHOL>
To: Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Atkinson, Krisztina Z; Glover, Mark; Rotstein, David; Lambkin, Sonya; Queen, Jackie L
Sent: 9/13/2017 4:11:36 PM
Subject: FW: Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

FYI from Tufts.

From: American College of Veterinary Nutrition [mailto:ACVN-L@lists.psu.edu] **On Behalf Of** Freeman, Lisa
Sent: Wednesday, September 13, 2017 11:55 AM
To: ACVN-L@LISTS.PSU.EDU
Subject: Re: Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

It's not just Acana so be on the lookout!

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

From: American College of Veterinary Nutrition [mailto:ACVN-L@lists.psu.edu] **On Behalf Of** [REDACTED] **B6**
Sent: Wednesday, September 13, 2017 11:44 AM
To: ACVN-L@LISTS.PSU.EDU
Subject: FW: Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

My [REDACTED] **B6** account was denied...

From: [REDACTED] **B6** [mailto:[REDACTED] **B6**]
Sent: Wednesday, September 13, 2017 11:43 AM
To: American Academy of Veterinary Nutrition; American College of Veterinary Nutrition
Cc: [REDACTED] **B6**
Subject: Re: Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

Hi all,

We (at [REDACTED] **B6**) have also recently diagnosed a dog ([REDACTED] **B6**) with taurine-deficiency DCM that was eating an Acana diet (duck & pear). Since the company reports AA% on their website, I calculated the methionine-cysteine to be 0.2 g/100 kcal (AAFCO min 0.16/100 kcal). It is a diet high in legumes. Max cruder fiber calculated to be 1.7 g/100 kcal.

Does anyone else have cases? If so, should we combine to write up a case series? Feel free to email me directly ([REDACTED] **B6**)

Thanks,
[REDACTED] **B6**, DVM, DACVIM, DACVN

On Wed, Sep 13, 2017 at 11:35 AM, [B6] wrote:
Hello [B6]

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I would be interested in getting guaranteed analysis and ingredient list of diets associated with the issue.

[B6]

De : American Academy of Veterinary Nutrition [mailto:AAVN-L@lists.psu.edu] **De la part de** [B6]
Envoyé : mercredi 13 septembre 2017 17:18
À : AAVN-L@LISTS.PSU.EDU
Objet : Association with Grain Free Diets and Taurine Deficiency Induced DCM in Golden Retrievers

Hi Everyone:

This was sent to me and I thought it would be good to share with everyone. Two decades ago, we discovered that protein-restricted diets not supplemented with taurine could induce reversible DCM in healthy dogs. In addition, it has been known since the 1990's that Cocker spaniels with DCM benefit from taurine (and carnitine) supplementation, and a study done by AMC and UC Davis in the 1990's also showed that some Golden Retrievers with DCM had taurine deficiency. There now appears to be an association with taurine deficiency induced DCM in Golden Retrievers consuming grain free diets. The attachment provides some guidelines regarding client education and what to do diagnostically with Golden Retrievers with DCM.

Thanks,

[B6]

Park, PA 16802. For any questions or problems, contact the [list administrator](#) or [Ag Communications and Marketing](#).

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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'
CC: Peloquin, Sarah; Ceric, Olgica
Sent: 8/16/2019 11:19:05 AM
Subject: FW: Brief update on cardiomyocyte idea (and metabolomics)

FYI

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



From: Jones, Jennifer L
Sent: Friday, August 16, 2019 6:39 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Pohl, Aurelie <Aurelie.Pohl@fda.hhs.gov>
Subject: RE: Brief update on cardiomyocyte idea (and metabolomics)

Excellent. I'll reach out to RR. We have some blood or plasma samples, but only from cases and not from every case.

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



From: Palmer, Lee Anne
Sent: Thursday, August 15, 2019 12:31 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Pohl, Aurelie <Aurelie.Pohl@fda.hhs.gov>
Subject: Brief update on cardiomyocyte idea (and metabolomics)

Hi all – just a brief update for you and then more info and meetings ahead where we all can be involved!

B5

B5

B5 Anyway – it sounds like another avenue we could pursue that may give us some additional info.

Interesting things to consider:

1

B5

2.
3.

B5

I'll set up a meeting with all of us, and with Marilyn sometime soon... please let me know if you have interest/questions/concerns based on the little I've relayed here.

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Acting Director, Division of Veterinary Product Safety

Center for Veterinary Medicine

Office of Surveillance and Compliance

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Nemser, Sarah </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS /CN=SARAH.YACHETTI>
To: Rotstein, David
CC: CVM Vet-LRN-OR
Sent: 3/3/2015 5:15:59 PM
Subject: FW: CASe coming to you through the portal for Purina Beneful

Dave,

Please let us know when this case comes through.

Sarah

Sarah Nemser M.S.

tel: 240-402-0892

sarah.nemser@fda.hhs.gov

From: [REDACTED] [mailto:[REDACTED]]
Sent: Tuesday, March 03, 2015 12:13 PM
To: Reimschuessel, Renate; Nemser, Sarah
Subject: CASe coming to you through the portal for Purina Beneful

Hi all,

I referred a client to you today. This person had a dog that died of cardiomyopathy according to the post-mortem done here at [REDACTED]. The owner thinks it is related to the dog food she was feeding. I suggested she start a case through the pet food reporting portal and you all could determine if you wanted to pursue more testing. I doubt there is any relation between the food and the condition, but I don't know enough about the case. We do have tissues here and also can provide the post-mortem report if the owner requests if of us. The owner's name is [REDACTED] and the dog was a Doberman.

Cindy

[REDACTED]

[REDACTED]

From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: Peloquin, Sarah
CC: Jones, Jennifer L
Sent: [REDACTED] 1:22:32 PM
Subject: FW: [REDACTED]

Hi Sarah,

I got an email from Tufts. Since Jen is [REDACTED] could you please follow up this? I don't have detail info, so searched [REDACTED] and found info in \\wsdc-isilon1\cvm-vetlim\$\6-CASES\800.267-EON-Multi-DCM-Cluster\2-Cases\05-Testing In Progress\cc-297-EON-380743-[REDACTED] Wellness-eng bull\emails (I think it is related to this case but not guarantee)

I can ship the shipping materials, but need to know

1. If we will follow up this
2. If so, which samples (fix or frozen) they will collect and what is size/weight of the samples.
3. If we need to ship formalin to the Vet, etc

Thanks
Jake

From: Tufts Veterinary Clinical Nutrition Service <vetnutrition@tufts.edu>
Sent: [REDACTED]
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: [REDACTED] <[REDACTED]@tufts.edu>
Subject: [REDACTED]

Dear Jennifer and Jake

I just heard from Dr. [REDACTED] the primary care vet for [REDACTED] She is the dog from the household in which at least 3 dogs were affected with diet-associated DCM. This was the first case from the household which was identified when she came in for congestive heart failure.

The owners contacted him and said they will be bringing her in today to be euthanized for worsening heart failure. He's volunteered to get heart and liver samples as he did from [REDACTED] Jake – could you send him shipping materials? His email is

[REDACTED]

Thanks very much
Lisa

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

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: 8.5 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

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

Report Details - EON-380742

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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: 8.5 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

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

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: Scalera, Alexander
Sent: 11/2/2016 3:22:29 PM
Subject: FW: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Alex, for PO 6.
You can call the number below to pay with VISA.
Thanks,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Wednesday, November 02, 2016 10:47 AM
To: Jones, Jennifer L
Subject: FW: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi Jennifer
Please see message below re: using Visa for this invoice
Thanks
Lisa

From: [redacted] B6
Sent: Wednesday, November 02, 2016 9:53 AM
To: [redacted] B6
Subject: FW: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi [redacted] B6

This went to medical records and they forwarded it to me. Visa is fine. She can just call with the number. [redacted] B6

Thanks,

[redacted] B6

From: [redacted] B6
Sent: Wednesday, November 02, 2016 9:43 AM
To: [redacted] B6
Subject: FW: FDA case follow up-EON-285648-Freeman-Nature's Vareity

See email below from Dr. Freeman.

[redacted] B6

B6

From: Freeman, Lisa
Sent: Tuesday, November 01, 2016 6:42 PM
To: B6
Subject: Fwd: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi B6 How should I respond? This is for the reimbursement for B6 blood culture that we talked about a couple weeks ago by the Fda. Thanks. Lisa

Sent from my iPhone

Begin forwarded message:

From: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
Date: November 1, 2016 at 3:08:43 PM EDT
To: "Freeman, Lisa" <Lisa.Freeman@tufts.edu>
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good afternoon Lisa,

My accountant asked if you're able to be reimbursed by credit (VISA) or if a check was needed?

Thank you,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer

From: Jones, Jennifer L
Sent: Monday, October 31, 2016 7:32 AM
To: 'Freeman, Lisa'
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Sounds great! Thank you, Lisa.
Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it's been submitted.

Jennifer Jones, DVM
Veterinary Medical Officer

From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Friday, October 28, 2016 3:36 PM
To: Jones, Jennifer L
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Thanks very much.

I'm going to have another one for you. 3 unrelated dogs in a family who've developed dilated cardiomyopathy. Supposedly on a commercial vegan diet and then small company's dog food. Once I get more details, I'll submit that one.

Best,

Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Tufts University

From: Jones, Jennifer L [<mailto:Jennifer.Jones@fda.hhs.gov>]
Sent: Friday, October 28, 2016 3:07 PM
To: Freeman, Lisa
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Varsity

Good afternoon Lisa,

Thank you for sending the invoices. I'll submit them for repayment.
I'll be on the look-out for the Medical records and the final blood culture result.
We will send the results of the food testing as soon as they are received. As a head's up, they usually take a few weeks.

Thank you again for your help with the investigation.
Kind regards and enjoy your weekend,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer

From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Friday, October 28, 2016 10:01 AM
To: Jones, Jennifer L
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Varsity

Dear Jennifer

Please see attached for an invoice, as well as the receipt for shipping and the invoice that includes the blood culture.

So far, the blood culture is negative but I'll send the final report when it's available.

We're getting written permission for release of records from the owner and will send those asap

Will I be updated on the results of the food analysis? That will be helpful information for treating this dog since she's not doing especially well

Thanks

Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Tufts University

From: Jones, Jennifer L [<mailto:Jennifer.Jones@fda.hhs.gov>]
Sent: Friday, October 21, 2016 11:15 AM
To: Freeman, Lisa
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Varsity

Good morning Dr. Freeman,

Thank you for the update. We will look for the medical records to arrive.

In the meantime, please move forward with the Listeria blood culture at IDEXX. Please send a copy of the results when finished and an invoice for the blood collection/shipping/Listeria testing.

For the open product testing, an instruction document and pre-filled out laboratory submission forms are attached. Please include those in the shipment. After shipping, please send an invoice for the shipping materials and shipping.

Please email or call with any questions.
Thank you kindly,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer

From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Friday, October 21, 2016 10:24 AM
To: Nemser, Sarah; Ceric, Olgica
Cc: Reimschuessel, Renate; Jones, Jennifer L
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Variety

Dear Sarah

I got information from Dr. Ceric on submitting a blood culture for Listeria but not any information on submitting the food for analysis.

I'm traveling this week but can submit an estimate for blood testing on Monday

Kind regards,
Lisa

From: Nemser, Sarah [<mailto:Sarah.Nemser@fda.hhs.gov>]
Sent: Friday, October 21, 2016 10:22 AM
To: Ceric, Olgica; Freeman, Lisa
Cc: Reimschuessel, Renate; Jones, Jennifer L
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Variety

Dr. Freeman,

I wanted to follow up on this case

Dr. Ceric is out of office due to

B6

In her email below she stated that she would provide information on sending the food to the Ohio laboratory. Please let us know if that information was provided, if not we can follow up.

Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

Sarah Nemser M.S.
Vet-LIRN Network Coordinator
tel: **240-402-0892**
fax: **301-210-4685**
sarah.nemser@fda.hhs.gov

From: Ceric, Olgica
Sent: Wednesday, October 19, 2016 2:09 PM
To: Freeman, Lisa
Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

If IDEXX can test blood, that would be the fastest way to get it to the lab. We will reimburse you for the charges, but we will need an estimate first, in order to prepare purchase order.

As for the food, we can test it at our network lab in Ohio, I'll send you instructions in a separate email.

We will reimburse you for the shipping charges. You'll just need to submit invoice (one for blood testing and shipping), once you ship the sample.

Olgica Ceric, DVM, PhD
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
tel: 240-402-5419
fax: 301-210-4685
e-mail: olgica.ceric@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Wednesday, October 19, 2016 1:43 PM
To: Ceric, Olgica
Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi all
We just got a blood sample from the dog (just so happened she was coming in for a recheck today so I was fortunate to catch her primary clinician before the dog left). We typically submit our blood cultures to IDEXX. I'm on the phone right now to see if they can test for Listeria. If not, can you tell me where to submit?

We do not have the ability to easily test the food for Listeria so if you could send details on that as well, I'd appreciate it

The owner did give permission to get records sent. I'm traveling through Friday but can get those submitted to you on Monday

I'll get someone to submit samples as soon as you provide info on labs, etc
Thanks
Lisa

From: Ceric, Olgica [<mailto:Olgica.Ceric@fda.hhs.gov>]
Sent: Wednesday, October 19, 2016 10:10 AM
To: Freeman, Lisa
Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Dr. Freeman,

Thank you for the prompt response.

Do you have in-house lab available for testing the food? If so, please let me know the testing estimate.

Once you get approval from the owner to release medical records, please email them, or fax to: 301-210-4685.

Regarding Listeria, perhaps you could ask the owner if they are willing to submit blood for testing when you contact them regarding medical records? I understand your concerns regarding antibiotics, but we'd like to do it just in case.

Please reply to all when responding, my responses might be delayed since I'll be on leave part day by the end of the week.

Thank you,

Olgica Ceric, DVM, PhD
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
tel: 240-402-5419
fax: 301-210-4685
e-mail: olgica.ceric@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Tuesday, October 18, 2016 7:28 AM
To: Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Varsity

Dear Olgica

We're happy to get permission from owners for medical records and I can get food submitted for testing next week

My question is on the blood culture. I'm not sure when the dog will be coming back in (she was discharged late last week) and am wondering if Listeria could be cultured if dog has been on antibiotics for >1 week

Thanks

Lisa

From: Ceric, Olgica [<mailto:Olgica.Ceric@fda.hhs.gov>]
Sent: Monday, October 17, 2016 1:03 PM
To: Freeman, Lisa
Cc: Nemser, Sarah; Jones, Jennifer L
Subject: FDA case follow up-EON-285648-Freeman-Nature's Varsity

Good morning Dr. Freeman,

We received your consumer complaint and would like to request the following:

- a copy of full medical records for the dog
- blood culture for Listeria
- open bag testing for Listeria and Salmonella

FDA will pay for the testing.

We have a network of veterinary diagnostic laboratories and could send samples to one of them, unless your lab has the capabilities?

Please email (preferred) or fax (301) 210-4685 us the medical records. Please send the full medical history-not just for this illness event.

Attached are a copy of our network procedures. They describe how veterinarians help with our case investigations. I also attached an owner friendly version.

Sincerely,

Olgica Ceric, DVM, PhD

Veterinary Medical Officer

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704

Laurel, Maryland 20708

tel: 240-402-5419

fax: 301-210-4685

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

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

From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: Jones, Jennifer L
Sent: 1/29/2018 9:20:50 PM
Subject: FW: Food collection kit [B6] 800.218

I forgot to ship this one. I will ship it by Wed.

Sorry!

From: Jones, Jennifer L
Sent: Wednesday, January 24, 2018 7:05 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Food collection kit [B6] 800.218

Jake, Please send a kit when you have time-F:\6-CASES\800.218-EON-Multi-Ca Naturals-Zignature-DCM\EON-Mult [B6] Multi foods [B6] Cases\3-samples

Jennifer L. A. Jones, DVM

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



From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: Rotstein, David
Sent: 6/10/2016 5:41:34 PM
Subject: FW: [B6] History
Attachments: 3293_001.pdf.html

EON-266814 [B6] ase for Taurine testing. List of food bought. Looks like GF Chicken Adult was most prevalent.

Jennifer Jones, DVM
Veterinary Medical Officer

From: [B6]
Sent: Friday, June 10, 2016 1:39 PM
To: Jones, Jennifer L
Subject: Fw: [B6] History

Hello Dr. Jones,

Thank you for speaking with me yesterday. As promised, here is the list of purchases from the [B6] store. Please note that we purchased a few Merrick cans of cat food before we knew about the taurine issue (we were trying to get [B6] to eat anything at that point). Let me know if you require any further information or have additional questions.

Thank you.

[B6]

From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: Jones, Jennifer L
Sent: 9/20/2018 8:53:26 PM
Subject: FW: UC Davis control - Follow up
Attachments: Normal_dog_20Nov17.xls

Got something with some issues. I don't know whether you can use it or not...

From: [REDACTED] **B6**
Sent: Thursday, September 20, 2018 4:50 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: UC Davis control - Follow up

Hi Jake,

I have added the data run with the new analyzers (see attachment). The data between were run by the old analyzer and can only be viewed, but not be analyzed because the configure differences of the old and new systems. I spent whole Tuesday working on it (even though I got more than 200 samples the day) with no luck. I have to ask the manufacture for help during some training class in future.

My apology again.

Kind Regards,

[REDACTED] **B6**

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, September 17, 2018 7:07 AM
To: [REDACTED] **B6**
Subject: RE: UC Davis control - Follow up

Hi [REDACTED] **B6**

I know you had the issues and busy. I was wondering when we can get AA results for the control urine samples? Do you think you can send the results by this Fri (09/21)? We would like to include that data for the AAVLD presentation.

Thanks
Jake

From: [redacted] **B6**
Sent: Monday, September 10, 2018 6:51 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>; Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: UC Davis control - Follow up

Hi Jake,

I didn't use the shipping slip you generated because we don't have the labels (Dry Ice) from UPS, plus I don't have my car with me today (I used drove to the down town UPS office to drop off package) . So I used our Fedex Account and arranged a pickup service from our address.

Attached is the Round 17 results. Sorry for taking so long to get them done because two sudden issues. First is that our analyzer was done, and it took more than a month to replace it with a new one. The second issue is that we have been receiving 70-114 clinic samples each day since the golden Retriever DCM issue was brought out early August, which has been huge extra burden to the lab. Hope it will not have too much negative impact on your project progress.

Kind Regards,

[redacted] **B6**

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, September 10, 2018 1:20 PM
To: [redacted] **B6**
Subject: RE: UC Davis control - Follow up

[redacted] **B6**

Thank you for the information. Attached please find the return shipping label.

Gentle reminder: Please do not seal the insulated box lid and cardboard box. Dry ice is needed to be evaporated.

Please put 'Address of Consignor', 'Address of Consignee', 'Exempt specimen', 'Dry Ice Hazard Label', 'UN 1845' with 4.0lb dry ice weight on a side of box.

Please provide sample inventory form. I will fill out and provide you

Fust follow up: When I can expect to get data?

Thank you
Jake

From: [redacted] **B6**

Sent: Monday, September 10, 2018 4:08 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: UC Davis control - Follow up

Dry ice: 4 Lbs.

Thanks,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, September 10, 2018 12:33 PM
To: **B6**
Subject: RE: UC Davis control - Follow up

Hi **B6**
What is the weight of dry ice?

Jake

From: **B6**
Sent: Monday, September 10, 2018 3:03 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>; Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: UC Davis control - Follow up

The package size: 11x9.5x8 inch

The package weight: 2370 g with dry ice

There are only three samples #100, 101, 102

Thanks,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Friday, September 7, 2018 11:32 AM
To: **B6**
Subject: RE: UC Davis control - Follow up

No problem.

Please provide me below information so I can generate a return shipping label.

1. Total box weight
2. Dry ice weight
3. Size of box (H x L x W)

Thanks

Jake

From: [redacted] **B6**

Sent: Friday, September 7, 2018 1:08 PM

To: Guag, Jake <Jake.Guag@fda.hhs.gov>; Andrea Fascetti <ajfascetti@ucdavis.edu>

Subject: Re: UC Davis control - Follow up

Hi Jake,

I am really sorry for the postpone of sample shipping and data reporting. I will come this weekend to analyze and organize the data and send to you. And I will ship the urine samples to you Monday for sure.

Thanks and have nice weekend,

[redacted] **B6**

From: Guag, Jake <Jake.Guag@fda.hhs.gov>

Sent: Friday, September 7, 2018 8:47 AM

To: [redacted] **B6**

Subject: RE: UC Davis control - Follow up

Hi [redacted] **B6**

Just follow up. When do you plan to ship the urine and provide amino acid data?

Thanks

Jake

From: Guag, Jake

Sent: Friday, August 24, 2018 4:31 PM

To: [redacted] **B6**

Subject: RE: UC Davis control - Follow up

Great! Thank you so much.

Just provide me information of

1. Total box weight

2. Dry ice weight
3. Size of box (H x L x W)

Thanks
Jake

From: [REDACTED] **B6**
Sent: Friday, August 24, 2018 3:57 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: UC Davis control - Follow up

Hi Jake,

I will ship the sample to you Monday. I will pack it and send the weight to you, so you can generate a slip and email to me.

We just finished the amino acid analysis. I will try to organize the data and send to you next week.

Have a nice weekend,

[REDACTED] **B6**

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Friday, August 24, 2018 9:32 AM
To: [REDACTED] **B6**
Subject: RE: UC Davis control - Follow up

Hi [REDACTED] **B6**,

I would like to get the last control urine sample. Do you need a shipping box? I can ship one to you.

Any updates about the amino acid results?

Thanks
Jake

From: [REDACTED] **B6**
Sent: Friday, August 10, 2018 12:18 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>; Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: UC Davis control - Follow up

Hi Jake,

Yes, we got the last control urine sample. Shall I ship it to you Monday?

We have the amino acid results for normal dog urine up to #75. Do we have a dead line for the results? Our analyzer was crashed and it took us one and half month to get it replaced with a new one. Sorry about the delaying.

Have a nice weekend,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>

Sent: Friday, August 10, 2018 6:25 AM

To: **B6**

Subject: UC Davis control - Follow up

Hi **B6**

Just follow up. We expect to get one more UC Davis control urine sample by Sep 2018. Did you collect the urine sample?

Also, I was wondering if you have amino acid quantification results for the recent controls.

Thanks

Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

**DOCUMENT
PRODUCED IN NATIVE**

From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: Jones, Jennifer L
Sent: 8/20/2019 11:36:43 AM
Subject: FW: Vet-LIRN urine sample collection - plan
Attachments: ND-urine samples.xlsx

For your record.

Jake

From: [REDACTED] **B6**
Sent: Monday, August 19, 2019 8:17 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Vet-LIRN urine sample collection - plan

Hi Jake,

Attached is the updated Normal Dog urine sample information. The highlighted rows with red color are the samples shipped today. I will update and email you the questionnaires tomorrow.

Thanks for your arrangement,

[REDACTED] **B6**

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, August 19, 2019 11:50 AM
To: [REDACTED] **B6**
Subject: RE: Vet-LIRN urine sample collection - plan

Thanks. [REDACTED] **B6**
Same to you. If you will have vacation soon, then have a great time J

Jake

From: [REDACTED] **B6**
Sent: Monday, August 19, 2019 2:41 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Vet-LIRN urine sample collection - plan

Thanks Jake. Are you arranging a vacation soon? If so, I wish you a great vacation time!

Kind Regards,

[REDACTED] **B6**

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, August 19, 2019 11:35 AM
To: [REDACTED] **B6**
Subject: RE: Vet-LIRN urine sample collection - plan

Hi [REDACTED] **B6**
Attached please find the return shipping label.

Please DO NOT seal the box, so the dry ice can be evaporated.
Please put all 5 labels I included in the box in one side (Exempt Animal Specimen, shipper's label, recipient label, dry ice label (diamond shape, STP-830), and UN1845 label).
Please fill out shipper's information (you) and recipient's information (mine).
Please write down 7Kg on the UN1845 label.
Please also include sample inventory sheet.

Thanks
Jake

From: [REDACTED] B6
Sent: Monday, August 19, 2019 1:38 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Vet-LIRN urine sample collection - plan

Hi, Jake,

This time we only have samples from 95-110. The package weight is 9330 gram in total with 7000 gram dry ice.

Thanks,

[REDACTED] B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, August 19, 2019 6:12 AM
To: [REDACTED] B6
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: RE: Vet-LIRN urine sample collection - plan

Hi [REDACTED] B6

Please let me know the total weight of the box with samples by 3:30 ET today. I will generate a return shipping label.

Thanks
Jake

From: Guag, Jake
Sent: Monday, August 12, 2019 2:44 PM
To: [REDACTED] B6
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: RE: Vet-LIRN urine sample collection - plan

I see. No prob!
You can ship the samples next week. Just let me know when you ready. I will generate a return shipping label.

Thanks
Jake

From: [REDACTED] B6
Sent: Monday, August 12, 2019 2:34 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: Vet-LIRN urine sample collection - plan

Hi Jake,

Sorry, we can't do it this week.

Thanks,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, August 12, 2019 8:37 AM
To: **B6**
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: RE: Vet-LIRN urine sample collection - plan

Hi **B6**

Can you ship the samples either Aug. 13th or 14th?
If not, please let me know. I will block 20th.

Also, please provide me total weight of the box. I will generate a return shipping label and email you. I already know size of the box (email attached) and only need a final weight.

Thanks
Jake

From: **B6**
Sent: Monday, August 12, 2019 11:23 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>
Subject: Re: Vet-LIRN urine sample collection - plan

Hi Jake,

Sorry to let you know that I can not ship the urine samples to you today as one of my coworkers can't come today (I just got the message this morning). I will ship them to you on 19th according to the original plan.

I apologize for the inconvenience.

Kind Regards,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, August 6, 2019 7:19 AM
To: **B6**
Subject: RE: Vet-LIRN urine sample collection - plan

Great!
Could you please provide me how many urine samples you plan to ship to me? Estimate number is fine. I will aliquot the samples and just want to check how long I need to block my calendar.

It would be great help if you ship the samples to me on Aug 13th, so I can get them on 14th. However, shipping of Aug 12th is fine as well. Please let me know when you plan to ship.

Thanks
Jake

From: [REDACTED] **B6**
Sent: Monday, August 5, 2019 6:35 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Vet-LIRN urine sample collection - plan

Hi Jake,
I will do that. If there is urgent change, I will let you know.

[REDACTED] **B6**

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From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Monday, August 5, 2019 11:41:04 AM
To: [REDACTED] **B6**
Subject: RE: Vet-LIRN urine sample collection - plan

Hi [REDACTED] **B6**

Our project schedule is changed and I can handle your urine samples from next week. I was wondering if you can ship the samples to me on Aug 12th or 13th. Please let me know if you can do that, so I will block my calendar.

Thanks
Jake

From: [REDACTED] **B6**
Sent: Tuesday, July 23, 2019 1:04 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Vet-LIRN urine sample collection - plan

Thanks Jake for the arrangement. [REDACTED] **B6** You can ship the containers any time. But I may not be able to ship the samples back this month. Aug 19th will work better to me. We don't need 15mL tube. We also have ice packs. Secondary containers are needed.

Kind regards and wish you a happy summer,

[REDACTED] **B6**

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, July 23, 2019 7:40 AM
To: [REDACTED] **B6**
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Vet-LIRN urine sample collection - plan

Hi [REDACTED] **B6**

Hope all is well. Jen informed you have collected 103 out of 140 control urine samples. You might collect more now J
We would like to get some of the control samples.

I believe you store collected urine sample in freezer. Do you need 15mL tube? If so, how many tubes you need?
I will include them in the shipping box.
I will ship a large box with multiple ice packs and secondary containers. A secondary container can hold ~12-15

tubes. I am not sure how many secondary containers I will ship, but probably 4-6. So you can send ~50-70 control urine samples to me.

When would be good time to ship box? I can ship box this week or later. You don't need to ship the samples right away, but I would like to have them either week of Jul 29th or Aug 19th.

Please let me know

Thanks

Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

**DOCUMENT
PRODUCED IN NATIVE**

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS /CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Nemser, Sarah; Ceric, Olgica; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Sent: 7/13/2018 1:10:36 PM
Subject: Fwd: Blue Buffalo-Life Protection Formula-Chicken and Brown Rice Recipe-For both ADULT and SENIOR;--Blue Buffalo-FREEDOM - Grain Free-Chicken Recipe-For both ADULT and SENIOR; [B6] EON-359067
Attachments: 2051935-report.pdf

Cardiac

From: PFR Event <ppreventcreation@fda.hhs.gov>
Date: July 12, 2018 at 10:20:20 PM EDT
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [B6]
Subject: Blue Buffalo-Life Protection Formula-Chicken and Brown Rice Recipe-For both ADULT and SENIOR;--Blue Buffalo-FREEDOM - Grain Free-Chicken Recipe-For both ADULT and SENIOR; [B6] EON-359067

A PFR Report has been received and PFR Event [EON-359067] has been created in the EON System.

A "PDF" report by name "2051935-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-359067

ICSR #: 2051935

EON Title: PFR Event created for Blue Buffalo Life Protection Formula Chicken and Brown Rice Recipe For both ADULT and SENIOR; Blue Buffalo FREEDOM - Grain Free Chicken Recipe For both ADULT and SENIOR;; 2051935

AE Date	02/05/2014	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Other
Breed	Schnauzer (unspecified)		

Age	10 Years		
District Involved			

Product information

Individual Case Safety Report Number: 2051935

Product Group: Pet Food

Product Name: Blue Buffalo Life Protection Formula Chicken and Brown Rice Recipe For both ADULT and SENIOR; Blue Buffalo FREEDOM - Grain Free Chicken Recipe For both ADULT and SENIOR;

Description: In 2014, [B6] was diagnosed with early-onset heart failure caused by dilated cardiomyopathy. Prior to this diagnosis, he was in great health. Were able to minimize the effects of the heart failure with meds and prescription diet. Prior to this, [B6] was fed a steady diet of Blue Buffalo - and prior to that, Beneful. Dog's heart became enlarged and ultimately led to his death.

Submission Type: Initial

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

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

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 Formula Chicken and Brown Rice Recipe For both ADULT and SENIOR; Blue Buffalo FREEDOM - Grain Free Chicken Recipe For both ADULT and SENIOR;		

Sender information

[B6]

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

<https://eon.fda.gov/eon//browse/EON-359067>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=375691>

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From: Darcy Adin <dbadin@ncsu.edu>
To: Joshua A Stern [B6] Fries, Ryan C [B6]
CC: Freeman, Lisa; Jones, Jennifer L
Sent: 8/7/2018 11:08:36 AM
Subject: Fwd: hold-FDA call w/ NCSU & Tufts re: DCM

Hi Josh [B6] Ryan and [B6]

I know it is short notice but if any of you are available to conference with Dr. Jones and her group at the FDA, we would love to have you join us tomorrow (wednesday) at 4pm EST to discuss where we are with investigations after the FDA statement release.

Thanks!
Darcy and Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: Mon, Aug 6, 2018 at 10:58 AM
Subject: hold-FDA call w/ NCSU & Tufts re: DCM
To: "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey, Siobhan" <Siobhan.Delancey@fda.hhs.gov>, "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Palmer, Lee Anne" <LeeAnne.Palmer@fda.hhs.gov>, "Carey, Lauren" <Lauren.Carey@fda.hhs.gov>, "Reimschuessel, Renate" <Renate.Reimschuessel@fda.hhs.gov>, "Ceric, Olgica" <Olgica.Ceric@fda.hhs.gov>, "Nemser, Sarah" <Sarah.Nemser@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>, Lisa Freeman <lisa.freeman@tufts.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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren; Peloquin, Sarah; Burkholder, William; Freeman, Lisa; ADIN,DARCY BRITTAIN; Pohl, Aurelie; Norris, Anne; DeLancey, Siobhan
CC: Ceric, Olgica
Sent: 8/13/2019 12:42:31 PM
Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings
Attachments: Histopathologic Findings – Confirmed and Non-Confirmed DCM [Autosaved] [Autosaved].pptx

Please do not forward.

thanks

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERRT
7519 Standish Place
240-506-6763 (BB)



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-----Original Appointment-----

From: Jones, Jennifer L
Sent: Wednesday, July 17, 2019 10:19 AM
To: Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren; Rotstein, David; Peloquin, Sarah; Burkholder, William; Freeman, Lisa; ADIN,DARCY BRITTAIN; Pohl, Aurelie; Norris, Anne; DeLancey, Siobhan
Cc: Ceric, Olgica
Subject: Meeting with Tufts and UFL-discuss ACVIM findings
When: Tuesday, August 13, 2019 8:00 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: virtual meeting

Please forward if I missed anyone.

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Histopathologic
Findings – Confirmed
and Non-Confirmed
DCM

CM & Non-DCM Cases

Cases

- Cases from CVCA and PFRs
- Dogs:
 - 8 DCM based on echo
 - 3 non-DCM:
 - Sudden death
 - Endocardiosis with lung and bladder mass
 - Cardiomegaly with CHF

an

- Full necropsy and histopathologic evaluation
- Cardiac evaluation
 - Adapted Protocol – *Kogia* Cardiomyopathy
 - Weights and measurements
 - Histopathologic Findings
 - DCM
 - 2 types (with overlap)
 - Fatty change (infiltration)-degenerative
 - Wavy fiber-attenuation
- Grid Pathology
 - Individual
 - Population

Cardiomyopathy Types: Tjholm A and Jonsson L. 2005. *Met Pathol* 42: 1-8.



stologic Findings

roup:

- Primary DCM (5/6)
- Secondary DCM (1/6)- infectious

isto- Cardiac

- Cardiomyocyte atrophy and degeneration (5/5)
- Fatty infiltration (steatosis)(4/5)
- Interstitial edema (3/5)
- (mild) interstitial myocarditis (3/5)
- Endocardiosis (5/5)
- Fibrosis (4/5)

isto- Non-Cardiac (associated with cardiac disease)

- Pulmonary edema (3/5)
- Pulmonary fibrosis (3/5)
- Hepatic chronic passive congestion (4/5)

DCM: Gross

B6 **B6** **B6**
B6

B6

B6

B6

B6

Secondary DCM & Non-DCM Cases

B6

Secondary DCM:
Myocarditis

Mesothelioma

Bronchopulmonary Carcinoma (middle pleura) &
Distal bronchi (lower pleura)

From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Freeman, Lisa
Sent: 11/1/2018 7:33:16 PM
Subject: RE: Taurine result - [B6]

Thank you very much, Lisa! And thank you for updating me on [B6] also.

Sarah

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Thursday, November 1, 2018 2:30 PM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: FW: Taurine result - [B6]

Hi Sarah,

This is for a previously submitted dog. Initially had a borderline low level [B6] and mildly reduced contractile function.

Clearly high enough taurine now! We will recheck an echo soon.

Thanks

Lisa

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

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogensis, Martine
CC: Carey, Lauren; Rotstein, David; Jones, Jennifer L; Burkholder, William
Sent: 7/12/2018 3:42:40 PM
Subject: PFI - CVM webinar and premeeting for next week [B6] will need to miss (I had informed Nanette)
Importance: High
Attachments: Information: PFI & CVM Webinar on July 19 (pre-meeting)

Hi – never good timing, but we have an ill-timed [B6] week next week. I let Nanette know last week when the PFI meeting was scheduled. Understandably, she didn't want to move the meeting since it's hard to schedule. I will not be on either Tuesday or Thursday of next week for the meeting. Lauren should be well able to cover anything from our team.

Sorry to miss – thanks and good luck. Looks like an interesting set of questions from PFI...

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



From: Milton, Nanette </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D54DC17348F942F4BF2FEA6A507AF352-NMILTON>
Sent: 7/12/2018 3:26:16 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; McDermott, Patrick <Patrick.McDermott@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: Information: PFI & CVM Webinar on July 19 (pre-meeting)
Start: 7/17/2018 5:30:00 PM
End: 7/17/2018 6:30:00 PM
Show Time As: Free
Recurrence: (none)
Required Attendees: Palmer, Lee Anne; Rotstein, David; McDermott, Patrick; DeLancey, Siobhan; Burkholder, William; Hartogensis, Martine; Norris, Anne; Jones, Jennifer L; Carey, Lauren
Attachments: PFI Questions for CVM Regarding DCM.docx

Hi Nanette,

Please send the attached questions to the CVM folks attending the webinar on the 19th.

Can you set up a pre-meeting from CVM so we can discuss?

Also, let PFI know who will be attending from CVM.

Thanks!
Martine

From: [REDACTED] [mailto:[REDACTED]@petfoodinstitute.org]
Sent: Thursday, July 12, 2018 9:23 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: [REDACTED] [mailto:[REDACTED]@petfoodinstitute.org]
Subject: Information: PFI & CVM Webinar on July 19
Importance: High

Martine,

I wanted to reconfirm the webinar is scheduled for July 19. I'm sharing some questions with you in advance that may be asked by our members. These are the questions that our producer members presented to PFI as we informed them of the DCM incidents. I hope this is helpful to your team.

Please let us know who will be joining the call. We will do the same from our end.

Thank you so much,

[REDACTED]

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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 12/3/2018 2:48:57 PM
Subject: Please send PFRs-FW: Grain Free Diet Study with CVCA

I can't seem to find these. Can you please send? They are part of the DCM CVCA collaboration.

B6

ICSR #: 2058366 submitted 11/2/18
CSR #: 2055989 submitted 10/12/18

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



From: [redacted] <[redacted]@cvcavets.com>
Sent: Monday, December 03, 2018 8:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Grain Free Diet Study with CVCA

We also have [redacted] coming in for his 2 month recheck next week, if you wanted to send 2 boxes for him for shipping the samples.

Please let me know if you have any questions or if I can help with anything else. Have a great day! :)

On Mon, Dec 3, 2018 at 6:49 AM Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning [redacted]

Thank you for the update. Do you have the ICSR number, like a confirmation number, for each report? Also, what day did you submit them? This may help us locate them in the system.

Thanks again,
Jen

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



From: [redacted] <[redacted]@cvcavets.com>
Sent: Friday, November 30, 2018 12:52 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Grain Free Diet Study with CVCA

Good afternoon,

My name is [redacted] I am one of the technicians at CVCA in [redacted]. I had a question for you. I submitted reports for [redacted] and [redacted], but Dr. Rosenthal said that you still needed reports for them. Do you mind letting me know what exactly I needed to do in order to make them complete? Thank you so much for your help. You should be receiving 2 of our boxes next week. Have a great weekend!

--

B6

Registered Veterinary Technician

CVCA - Cardiac Care for Pets

B6

Phone: **B6**

Fax: **B6**

B6@cvcavets.com

Visit our Website: www.cvcavets.com

"Like" our Fan Page: www.facebook.com/CVCAVETS

"Follow us on Instagram: <https://instagram.com/CVCAVETS>

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"Like" our Fan Page: www.facebook.com/CVCAVETS

"Follow us on Instagram: <https://instagram.com/CVCAVETS>

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Carey, Lauren; Palmer, Lee Anne; Reimschuessel, Renate; Rotstein, David; Ceric, Olgica
Sent: 6/7/2018 6:12:10 PM
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan
Attachments: 800.267 Procedure Rationale-v1.docx; 800.267-draft-Sample Testing Procedures-v3.doc

Hi everyone,
Please review again by COB Monday. I'd like to send the document to the larger group (Martine, DAF, communications, etc.) ahead of our Quarterly Center JPT Call (and less JPT these days, more other stuff).
Thanks,
Jen

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



From: Jones, Jennifer L
Sent: Monday, June 04, 2018 6:37 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan

Thank you, everyone. I'll get the edits done and send back out for a final review before sending to the larger group.

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



From: Carey, Lauren
Sent: Friday, June 01, 2018 7:27 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan

No comments from me. Thanks, Jen.

From: Palmer, Lee Anne
Sent: Friday, June 01, 2018 3:12 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan

Hi Jen – I made edits to

B5
B5

bit. Let me know if you have questions about what I've done. Thanks!

From: Jones, Jennifer L
Sent: Friday, May 25, 2018 8:41 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan

Thanks, I'm sending to Martine and the larger group after this group has reviewed.

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



From: Reimschuessel, Renate
Sent: Friday, May 25, 2018 8:40 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan

Rr edits
Other folks may want to review after the items in this version have been addressed

From: Jones, Jennifer L
Sent: Friday, May 25, 2018 8:20 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan

Thank you, Dave.

B5

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



From: Rotstein, David
Sent: Friday, May 25, 2018 8:16 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Action Item: Please Review-800.267-DCM draft testing plan

Jen,

This looks fantastic and is well organized with excellent supportive information.

As for the study design, I think this looks good. The criteria are well-developed.

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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

From: Jones, Jennifer L
Sent: Friday, May 25, 2018 7:33 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: Action Item: Please Review-800.267-DCM draft testing plan

Please review by COB 6/1.

Jennifer L. A. Jones, DVM

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



From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Ask CVM; Carey, Lauren
CC: Jones, Jennifer L
Sent: 6/28/2019 12:35:06 AM
Subject: RE: Additional information regarding study of diet-related dilated cardiomyopathy (DCM) in dogs

That's great news! I know Dr. Adin moved to U of Florida, and so sounds like she's getting some funding (or her group is). This is the type of work that will help us get to the bottom of this, and maybe even provide clues regarding any potential relationship to risks to human health. Thanks!

From: Ask CVM
Sent: Thursday, June 27, 2019 6:52 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: FW: Additional information regarding study of diet-related dilated cardiomyopathy (DCM) in dogs



From: Sharon Albright <Sharon.Albright@akcchf.org>
Sent: Thursday, June 27, 2019 1:14 PM
To: Ask CVM <AskCVM@fda.hhs.gov>
Cc: Diane Brown <Diane.Brown@akcchf.org>; Bradford Brady <Bradford.Brady@akcchf.org>
Subject: Additional information regarding study of diet-related dilated cardiomyopathy (DCM) in dogs

Hello –

Pet owners following the FDA's investigation into the potential link between certain diets and canine dilated cardiomyopathy may be interested to know that the AKC Canine Health Foundation (CHF) is funding a scientific study of diet-associated dilated cardiomyopathy (DCM) in dogs.

With [CHF Grant 02661: Investigation into Diet-Associated Dilated Cardiomyopathy in Dogs](#), a multi-institutional team of veterinary cardiologists and nutritionists will prospectively screen a large population of apparently healthy dogs for DCM and compare cardiac disease measures including ultrasound, blood biomarker and taurine levels, between dogs eating boutique, exotic ingredient, or grain-free diets versus other diets. Results will inform the extent and cause of the recent increase in diet-related dilated cardiomyopathy seen in all breeds of dogs, including mixed breeds and those not usually associated with DCM.

The principal investigator is Dr. Darcy Adin at the University of Florida. Co-investigators and other participating institutions include Drs. Lisa Freeman and John Rush at Tufts University; Dr. Rebecca Stepien at the University of Wisconsin, Madison; Drs. Amara Estrada and Margaret Sleeper at the University of Florida; and Dr. Joshua Stern at the University of California, Davis. These sites are actively recruiting study participants.

CHF invites you to include this information in the Additional Resources section of the latest FDA update and/or the FAQ page related to this matter. Please reach out with any questions. We welcome the opportunity for collaboration to address this important concern in canine health.

Regards,
Sharon

Sharon M Albright, DVM CCRT
Manager of Communications and Veterinary Outreach
919-334-4019
Sharon.Albright@akcchf.org

AKC Canine Health Foundation

Main 888-682-9696

Fax 919-334-4011

PO Box 900061

Raleigh, NC 27675

www.akcchf.org | [Facebook](#)

[Click here to stay up to date with the latest canine health information and research](#)



Vet-LIRN Case Summary Document

Vet-LIRN Case Number:	800.218
EON/CC #:	Multiple
Owner LAST Name:	B6
Vet LAST Name:	B6
Vet-LIRN Initiation Date:	1/23/2018
MedRec: Requested:	already received
MedRec: Received:	
MedRec: Significant finding:	All dogs w/ DCM, 2 Tau wnl, 1 not measured, 1 Tau low
Vet-LIRN Tests (planned):	<ul style="list-style-type: none"> MRx Review Open Product (B6) for Metals and Cys/Met
Vet-LIRN Test Results:	
Result Interpretation:	
IF NFA, justification:	

COMPLAINT Narrative: see xls and multiple PFRs

1/23/2018

JJ-MRx summaries.

The listserv BLUF:

- Diet:
 - Kangaroo: low Tau & Met, high Carn
 - Lentil: Low Cys, Met
- In Cats, plasma Taurine (Tau)
 - falsely increases with damaged WBC and Platelets, short half-life
 - Whole blood Taurine a better measurement b/c longer half-life
 - Skeletal muscle even longer half-life and thought to parallel cardiac muscle Tau content
- From one vet dealing with Golden Retrievers eating designer diets (high quality meats) with pea or lentils-most dogs with low or Low Normal Whole Blood Tau → most recovered with Tau supplementation → Hypothesis: B5

B6 -6 yr FS Lab
 Presenting complaint B6: cough, dyspnea, multiple episodes of collapse, cardiomegaly, suspected CHF; seen by rDVM B6 for cough → by B6 collapse episode-circled, fell over, flopped ~1 min, 2nd less severe episode B6 → continued shortness of breath, easily tires; heartworm negative (B6), eats California Naturals Kangaroo and Lentil with veggies and 2 tbsp canned pumpkin; on B6 and SLIT;

PE **B6**: T 102.7, P 208, R 150, Gr III/VI left apical systolic murmur with gallop, regular tachycardia, quiet heart sounds, localized fine crackles left cranial hilar region with dry cough, poor femoral pulses, mm pale pink; → hospitalized → occ short paroxysms of slow ventricular tachycardia

Labs: **B6**

B6

B6

Echo: sinus tachycardia, DCM with left sided CHF

Whole Blood Tau: **B6** (200-350), >150 not known risk of Tau Deficiency;

ECG: HR 189 bpm, sinus tachycardia, atrial enlargement, LVE

B6 T-Rads: mild decrease in severity of cardiomegaly, resolving cardiogenic edema

B6 8 yr F Lab

Presenting: **B6** ER for heart evaluation, seen week prior (Thurs) for collapse while playing fetch; at vet-atrial fibrillation with mild heart failure; normal sinus rhythm (nsr) on **B6** → **B6** collapse while fetching → nsr with rads showing resolution of HF, CBC/Chem wnl → recheck on **B6**; no episodes of weakness/collapse, last 2-3 anxious and less social b/c storm anxiety; on daily **B6** → recheck **B6** new cough, not frequent, at rest and with excitement/activity; owner transitioning to a new venison food, urinary incontinence

PE **B6**: Gr III to IV/VI left apical holosystolic murmur, sinus arrhythmia, moderate femoral pulses

B6 T 103.1, RR 120, Gr III-IV/VI left apical holosystolic murmur

B6: HR 128, pant, Gr III/VI left apical systolic murmur with wide radiation, fair-moderate femoral pulse

Labs:

B6

Whole Blood Taur: **B6** (200-350) (>150 = no risk for Tau deficiency)

BP: 108 mmHg

B6 90 mmHg

Echo: DCM, Chronic degenerative valve disease, atrial fibrillation, exertional collapse

B6 slight improvement though heart a little larger

heart bigger with decreased contractility,

Telemetry: consistent sinus rhythm/arrhythmia

Renal panel: no results listed

B6 SDMA 18, normal BUN/Ct, mild low Cl wnl

B6 T Rads: mild progression of cardiac enlargement

B6 progressive cardiomegaly

B6: 5 yr FS Lab → genetic niece of **B6**

Presenting complaint **B6** new heart murmur, diagnosed with CHF on **B6** seen by rDVM for heavy breathing and cough; rads and labs showed enlarged heart, CHF → **B6** to ER, increased meds with some improvement → panting and on low sodium Kangaroo and Lentil diet; other dog **B6** is

B6 aunt, urinary incontinence began prior to CHF treatment/diagnosis; less social and active; on **B6** → **B6** tachypneic, coughed up pink tinged fluid, episode of collapse, dry heaving on way to ER → on Venison and Lentil diet → respiratory rate continue to increase despite Lasix CRI → euthanized

PE **B6** HR 150, pant, Gr IV/VI left apical systolic murmur with radiation to right, adequate femoral pulse

Labs: **B6** HR 180, pant, pale pk, Gr IV/VI murmur, fine crackles right dorsal lung fields

BP: 110

Renal Panel: mild inc SDMA (19 ug/dL)

B6

Echo: endocardiosis, DCM
ECG: nsr

B6

T Rads: persistent cardiomegaly with mild decreased severity

B6

generally enlarged, unstructured interstitial pulmonary pattern within right middle and cd lobes, mild enlargement cranial lobar pulmonary veins

B6 4 yr MC Cocker Spaniel

Presenting complaint **B6** evaluation of cardiomegaly and CHF, diagnosed by rads **B6** to rDVM

B6

for week long progressive cough-2x/day with progressive severity; t-rads and labs: CHF; treated with antibiotics and heart meds (concern initially for pneumonia) → improved cough but still occurring; PE **B6**: T 104.4, HR 150, pant, quiet/distant heart sounds with gallop, Gr I/VI systolic murmur on left, fine bilateral crackles, patient shivering so femoral pulse difficult to assess but suspect decreased, palpable jugular pulsation, suspected oral epulis;

B6: HR 178-180, T 102.4, quiet heart sounds, gallop, fair femoral pulses, palpable

hepatomegaly, epidermal collarettes with exudative crust on ventral abdomen

Labs:

B6

B6

Echo: DCM, CHF
ECG: sinus tachycardia, HR ~200
Whole Blood Tau: **B6**(200-350)

T Rads (**B6**): decreased heart size

B5

Document properties

Author: Reimschuessel, Renate
Company: US FDA
Template: Normal.dotm
Page count: 2
Paragraph count: 87
Line count: 135
Word count: 993
Character count (spaces excluded): 5358
Character count (spaces included): 6344

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Nemser, Sarah
CC: CVM Vet-LRN-OR
Sent: 3/3/2015 5:27:01 PM
Subject: RE: CASE coming to you through the portal for Purina Beneful

I'll be on the lookout.

Thanks!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)
240-506-6763 (BB)

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From: Nemser, Sarah
Sent: Tuesday, March 03, 2015 12:16 PM
To: Rotstein, David
Cc: CVM Vet-LRN-OR
Subject: FW: CASE coming to you through the portal for Purina Beneful

Dave,

Please let us know when this case comes through.

Sarah

Sarah Nemser M.S.

tel: 240-402-0892

sarah.nemser@fda.hhs.gov

From: [REDACTED] B6
Sent: Tuesday, March 03, 2015 12:13 PM
To: Reimschuessel, Renate; Nemser, Sarah
Subject: CASE coming to you through the portal for Purina Beneful

Hi all,

I referred a client to you today. This person had a dog that died of cardiomyopathy according to the post-mortem done here at [REDACTED] B6. The owner thinks it is related to the dog food she was feeding. I suggested she start a case through the pet food reporting portal and you all could determine if you wanted to pursue more testing. I doubt there is any relation between the food and the condition, but I don't know enough about the case. We do have tissues here and also can provide the post-mortem report if the owner requests if of us. The owner's name is [REDACTED] B6 and the dog was a Doberman.

[REDACTED] B6

B6

DVM PhD, DABVT

Veterinary Clinical Toxicology

B6

Veterinary Diagnostic Laboratory

B6

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Nemser, Sarah
CC: CVM Vet-LRN-OR
Sent: 3/4/2015 6:28:19 PM
Subject: RE: CASe coming to you through the portal for Purina Beneful

No reports thus far.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-276-9213 (Office and Fax)
240-506-6763 (BB)

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From: Nemser, Sarah
Sent: Tuesday, March 03, 2015 12:16 PM
To: Rotstein, David
Cc: CVM Vet-LRN-OR
Subject: FW: CASe coming to you through the portal for Purina Beneful

Dave,

Please let us know when this case comes through.

Sarah

Sarah Nemser M.S.

tel: 240-402-0892

sarah.nemser@fda.hhs.gov

From: [REDACTED] B6
Sent: Tuesday, March 03, 2015 12:13 PM
To: Reimschuessel, Renate; Nemser, Sarah
Subject: CASe coming to you through the portal for Purina Beneful

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[REDACTED] B6

B6

DVM PhD, DABVT

Veterinary Clinical Toxicology

B6

Veterinary Diagnostic Laboratory

B6

From: Darcy Adin <dbadin@ncsu.edu>
To: Freeman, Lisa
CC: Jones, Jennifer L; adind@ufl.edu
Sent: 11/15/2018 1:00:59 PM
Subject: Re: checking in

Hi Jennifer,
Based on Lisa's times, I could do the 3rd from 9-1 and the 4th from 9-1.
Thanks!
Darcy

On Nov 15, 2018, at 7:55 AM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi Jen
Dec 3 (9-1 or after 3), 4 (anytime), or 5 (10-3) would work for me.
Thanks
Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, November 15, 2018 7:44 AM
To: Darcy Adin <dbadin@ncsu.edu>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: RE: checking in

Good morning Darcy and Lisa,
Yes, let's plan for a meeting after Thanksgiving. When in early December would work well for you?
Thanks,
Jen

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

<[image001.png](#)>



From: Darcy Adin <dbadin@ncsu.edu>
Sent: Wednesday, November 07, 2018 3:20 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: checking in

Hi Jennifer,

I hope you are doing well! I wanted to check in with you to let you know that I have changed affiliations and am now working at the University of Florida (my new email is adind@ufl.edu, copied above).

Dr. Freeman and I wanted to check to see if your group be willing to have a follow up call regarding the dietary induced DCM issue?

Thanks!
Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Adjunct 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
CC: adind@ufl.edu
Sent: 11/15/2018 3:57:36 PM
Subject: RE: checking in

Great! I sent a calendar appointment. Please forward as necessary.
Would you be willing to forward me a copy of the DCM article for JAVMA? I'd like to share it with our communication team. They may get some inquiries after it's release, and it would help them prepare.

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



From: Darcy Adin <dbadin@ncsu.edu>
Sent: Thursday, November 15, 2018 8:01 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; adind@ufl.edu
Subject: Re: checking in

Hi Jennifer,
Based on Lisa's times, I could do the 3rd from 9-1 and the 4th from 9-1.
Thanks!
Darcy

On Nov 15, 2018, at 7:55 AM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi Jen
Dec 3 (9-1 or after 3), 4 (anytime), or 5 (10-3) would work for me.
Thanks
Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, November 15, 2018 7:44 AM
To: Darcy Adin <dbadin@ncsu.edu>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: RE: checking in

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Jen

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

<image001.png>



From: Darcy Adin <dbadin@ncsu.edu>
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To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: checking in

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Dr. Freeman and I wanted to check to see if your group be willing to have a follow up call regarding the dietary induced DCM issue?

Thanks!
Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Adjunct 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
Sent: 11/16/2018 9:23:46 PM
Subject: RE: checking in

Hi Jen
Let me get the final copy from JAVMA and I'll send that to you asap
Thanks and have a great weekend
Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, November 15, 2018 10:58 AM
To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>
Cc: adind@ufl.edu
Subject: RE: checking in

Great! I sent a calendar appointment. Please forward as necessary.
Would you be willing to forward me a copy of the DCM article for JAVMA? I'd like to share it with our communication team. They may get some inquiries after it's release, and it would help them prepare.

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



From: Darcy Adin <dbadin@ncsu.edu>
Sent: Thursday, November 15, 2018 8:01 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; adind@ufl.edu
Subject: Re: checking in

Hi Jennifer,
Based on Lisa's times, I could do the 3rd from 9-1 and the 4th from 9-1.
Thanks!
Darcy

On Nov 15, 2018, at 7:55 AM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi Jen
Dec 3 (9-1 or after 3), 4 (anytime), or 5 (10-3) would work for me.
Thanks
Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, November 15, 2018 7:44 AM
To: Darcy Adin <dbadin@ncsu.edu>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: RE: checking in

Good morning Darcy and Lisa,
Yes, let's plan for a meeting after Thanksgiving. When in early December would work well for you?
Thanks,
Jen

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

<[image001.png](#)>



From: Darcy Adin <dbadin@ncsu.edu>
Sent: Wednesday, November 07, 2018 3:20 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: checking in

Hi Jennifer,

I hope you are doing well! I wanted to check in with you to let you know that I have changed affiliations and am now working at the University of Florida (my new email is adind@ufl.edu, copied above).

Dr. Freeman and I wanted to check to see if your group be willing to have a follow up call regarding the dietary induced DCM issue?

Thanks!
Darcy

--

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

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:25:09 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thank you.

I am going to send these out and also include the information Tuft's sent out to give them a more complete picture of it all.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Hartogensis, Martine
Sent: Tuesday, June 05, 2018 2:23 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi Dave,

Are you talking about the ORA Divisions? If so, great idea and ok with me to send.

Martine

From: Rotstein, David
Sent: Monday, June 04, 2018 12:58 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Rotstein, David
Sent: Thursday, May 24, 2018 10:04 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

Good Morning,

B5

B5

Thank you,

Dave

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Palmer, Lee Anne; Hartogensis, Martine; Burkholder, William; Jones, Jennifer L; Rotstein, David
CC: Conway, Charlotte; Edwards, David; DeLancey, Siobhan; Norris, Anne; Cepeda, Sandra
Sent: 7/13/2018 7:52:58 PM
Subject: RE: Confidential - Information we discussed

We also have two new **B4** product reports. Neither is a DCM case. In 1 case 2 dogs developed right sided heart enlargement (DCM is left-sided, so this more of a pulmonary hypertension type case) and 1 case 1 dog was diagnosed with CHF, unclear what it was secondary to. Not sure how we want to treat non-DCM cardiac cases within the current case groups.

Also not sure if there are any other **B4** we should be checking for.

From: Palmer, Lee Anne
Sent: Friday, July 13, 2018 3:48 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Cepeda, Sandra <Sandra.Cepeda@fda.hhs.gov>
Subject: RE: Confidential - Information we discussed

B4, B5, B6

From: Hartogensis, Martine
Sent: Friday, July 13, 2018 3:27 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Cepeda, Sandra <Sandra.Cepeda@fda.hhs.gov>
Subject: RE: Confidential - Information we discussed

Hi Bill,

Thank you for sending this!

B4, B5

Sandra Cepeda is our new FOIA Officer and **B5**

B5

B4, B5

Martine

From: Burkholder, William
Sent: Friday, July 13, 2018 2:11 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>
Subject: FW: Confidential - Information we discussed

Greetings CVMDCMers and Happy Friday,

B4, B5

Bill

From: B4
Sent: Thursday, July 12, 2018 6:16 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: Confidential - Information we discussed

Confidential
This email and attachments contain
Confidential Business Information/Trade Secret Information

Hi, Bill

B4

B4

B4

Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe	Dog	Terrier - Bull	8 Years	Male	26.3 Kilogram	<p>(b) (6) is an 8 year old intact male Bull Terrier who was first diagnosed with severe degenerative valve disease with moderate decrease in contractility on 8/21/17. At that time, he was started on [REDACTED] B6. Taurine supplementation was recommended but not started. On [REDACTED] he presented to the emergency service for a sudden increase in respiratory rate and effort and was hospitalized for congestive heart failure. Echo findings on 3/22/18 included progressive valve disease and severe, progressive decrease in contractility, the latter of which may either be a component of dilated cardiomyopathy vs secondary to (b) (6) grain free diet (Nature's Recipe Salmon and Yam). Clinically, (b) (6) has been tiring more quickly recently. He has had weight loss (3 kg since 8/2017) despite a good appetite. Prior to his 3/22/18 presentation, he had a 2-3 week history of collapsing/fainting episodes, in which he would go limp and paddle - no loss of bowels. Health history includes allergies/dermatitis - previously on [REDACTED] but otherwise no major illnesses or injuries. I have recommended adjustments to (b) (6) medications as well as taurine supplementation; he will continue the Nature's Recipe Salmon and Yam diet due to significant skin allergies when changing the diet.</p>
Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe	Dog	Spaniel - Cocker /American	13 Years	Female	11.7 Kilogram	<p>A heart murmur was auscultated on a routine exam and patient was diagnosed on 2/26/18 with moderate dilated cardiomyopathy - ruleout idiopathic vs. taurine/amino acid responsive - with moderately decreased left ventricular contractility. Patient is on a grain free diet Nature's Recipe Salmon and Sweet Potato. It is suspected that some grain free diets provide insufficient levels of taurine, contributing to the development of dilated cardiomyopathy. At presentation, (b) (6) had no cough; normal appetite and attitude; no exercise intolerance. Medication management and taurine supplementation was recommended. She will be rechecked in June 2018.</p>

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Hartogensis, Martine; Burkholder, William; Jones, Jennifer L; Palmer, Lee Anne; Rotstein, David
CC: Conway, Charlotte; Edwards, David; DeLancey, Siobhan; Norris, Anne; Cepeda, Sandra
Sent: 7/13/2018 7:44:39 PM
Subject: RE: Confidential - Information we discussed

Can we double check their GF brands? I know they have [REDACTED] but I don't know if that's a complete list.

From: Hartogensis, Martine
Sent: Friday, July 13, 2018 3:27 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Cepeda, Sandra <Sandra.Cepeda@fda.hhs.gov>
Subject: RE: Confidential - Information we discussed

Hi Bill,

Thank you for sending this!

[REDACTED]
B4, B5

Sandra Cepeda is our new FOIA Officer and [REDACTED]
B5

[REDACTED]
B5

[REDACTED]
B4, B5

Martine

From: Burkholder, William
Sent: Friday, July 13, 2018 2:11 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>
Subject: FW: Confidential - Information we discussed

Greetings CVMDCMers and Happy Friday,

[REDACTED]
B4, B5

B4, B5

Bill

From: [REDACTED] **B4**
Sent: Thursday, July 12, 2018 6:16 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: Confidential - Information we discussed

Confidential
This email and attachments contain
Confidential Business Information/Trade Secret Information

Hi, Bill

B4

B4

B4

From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Burkholder, William; Jones, Jennifer L; Palmer, Lee Anne; Rotstein, David; Carey, Lauren
CC: Conway, Charlotte; Edwards, David; DeLancey, Siobhan; Norris, Anne; Cepeda, Sandra
Sent: 7/13/2018 7:26:53 PM
Subject: RE: Confidential - Information we discussed

Hi Bill,

Thank you for sending this!

B4, B5

Sandra Cepeda is our new FOIA Officer and

B5

B5

B4, B5

Martine

From: Burkholder, William
Sent: Friday, July 13, 2018 2:11 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>
Subject: FW: Confidential - Information we discussed

Greetings CVMDCMers and Happy Friday,

B4, B5

B4, B5

Bill

From: **B4**
Sent: Thursday, July 12, 2018 6:16 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: Confidential - Information we discussed

Confidential
This email and attachments contain
Confidential Business Information/Trade Secret Information

Hi, Bill

B4

B4

From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Jones, Jennifer L
Sent: 9/18/2018 2:08:07 PM
Subject: RE: control dog Taurine-urine

Is that the urine that CVCA will be collecting?
How many dogs are in the study so far, with the original requirements?

From: Jones, Jennifer L
Sent: Tuesday, September 18, 2018 9:55 AM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: FW: control dog Taurine-urine

FYI

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



From: Andrea Fascetti <ajfascetti@ucdavis.edu>
Sent: Tuesday, September 18, 2018 8:17 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: control dog Taurine-urine

Hi Jen - Here is B6 email address:

B6

And Josh:

istern@ucdavis.edu

I hope this helps.

Andrea

On Sep 18, 2018, at 1:23 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Andrea,
I got your message about the collaboration with Joshua Stern and B6. We will need to get some documentation first, but otherwise, we'd be happy to share the control urine taurine data. I'm checking to see what agreements we need. Can you please provide B6 email? After I get the documents, I can send them to the group for signature, and then we can share the data.
Thank you for the collaborative opportunity!

B6

Take care,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>
<[image001.png](#)> <[image002.png](#)>

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Norris, Anne; Palmer, Lee Anne; Rotstein, David; Jones, Jennifer L; Peloquin, Sarah; Reimschuessel, Renate; Hartogensis, Martine; Burkholder, William; DeLancey, Siobhan
Sent: 2/21/2019 5:49:04 PM
Subject: RE: DCM paper - Darcy Adin, 2019 Vet Cardiology

Thanks, Anne. The author list is an interesting mix of involved parties.

From: Norris, Anne
Sent: Thursday, February 21, 2019 12:12 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM paper - Darcy Adin, 2019 Vet Cardiology

I've lost track of whether we circulated this paper internally, but sharing because it caught the eye of Phyllis Entis from Food Safety News. She hasn't written about it (at least not yet). One of the authors is Greg Aldrich.

From: Norris, Anne
Sent: Tuesday, February 19, 2019 9:09 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: DCM paper - Darcy Adin, 2019 Vet Cardiology

Thanks!

From: Palmer, Lee Anne
Sent: Tuesday, February 19, 2019 9:05 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: DCM paper - Darcy Adin, 2019 Vet Cardiology

Hi – please forgive me if we have this already, but I think this just came out.

I haven't read it yet.

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



From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Norris, Anne; Palmer, Lee Anne; Murphy, Jeanette
CC: Forfa, Tracey; Jones, Jennifer L; Rotstein, David; DeLancey, Siobhan
Sent: 6/20/2019 3:49:53 PM
Subject: RE: DCM roll-out timing question?

Ok, no problem!

From: Norris, Anne
Sent: Thursday, June 20, 2019 11:49 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

B5

From: Hartogensis, Martine
Sent: Thursday, June 20, 2019 11:38 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

B5

Lee Anne, Jen and Dave may be able to help you with some slides.

Martine

From: Palmer, Lee Anne
Sent: Thursday, June 20, 2019 10:45 AM
To: Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

B5

From: Murphy, Jeanette
Sent: Thursday, June 20, 2019 10:37 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>;
Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: DCM roll-out timing question?

Greetings Ladies

I am at a training this week and am with one of the ORA division reps who got

B5

B5

I am speaking at a conference next Friday (conference is Thurs/Fri) about FSMA updates. The general focus of the conference is research in rendering and pet food for food safety.

B5

B5

shared. And any side bar talking points you want me to have if asked questions.

Jenny

From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Jones, Jennifer L; Rotstein, David
Sent: 6/12/2019 6:40:31 PM
Subject: RE: DCM write-up for June Web Update

Sorry for the delay—I added my changes in blue:

B5

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

From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 2:10 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Excellent, thanks, Dave. I'll wait for Sarah P to reply to make sure our numbers are correct as of 5/31/2019.

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



From: Rotstein, David
Sent: Wednesday, June 12, 2019 10:19 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Works for me!

Thank you!

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

240-506-6763 (BB)



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From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 10:18 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

This looks great, Dave. I'm just going to change the date to B5 Does that still work?

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



From: Rotstein, David
Sent: Wednesday, June 12, 2019 10:05 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Jen,
Please see below.

B5 I can add those if you think it would be helpful.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)



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From: Jones, Jennifer L

Sent: Wednesday, June 12, 2019 7:21 AM

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

Subject: DCM write-up for June Web Update

Importance: High

Good morning team,

B5

Can you get this to me by noon Thursday? I told comm's I'd have the update complete by COB Thursday.

Thank you :)

Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704

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new tel: 240-402-5421

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



**U.S. FOOD & DRUG
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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Peloquin, Sarah; Hodges, April
Sent: 6/12/2019 2:05:17 PM
Subject: RE: DCM write-up for June Web Update

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B5

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