

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

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

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

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

For **B4**

B6

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
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Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



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

Hi Alex,

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

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

Dimensions: 12.5" x 12.5" x 10.5"

Weight: 1.7 lbs

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

Overnight Shipping-Return Shipping label for the box:

Dimensions: 12.5" x 12.5" x 10.5"

Projected weight: 2.75 lbs.

Contents: Dog food, no hazardous materials

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

Thank you,

Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer

U.S. Food & Drug Administration

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Office of Research

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**U.S. FOOD & DRUG
ADMINISTRATION**



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

The dog was euthanized? What does ARF stand for?

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

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

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

Sarah Nemser M.S.

U.S. Food & Drug Administration
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P

Please consider the environment before printing this email

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

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

B5

B5

B5

B5

B5

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

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

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

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

A "PDF" report by name "1039540-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "1039540-attachments.zip" and is attached to this email notification.

Below is the summary of the report

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

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

B6

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

B6

Product information

Individual Case Safety Report Number: 1039540

Product Group: Pet Food

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

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

Submission Type: Initial

Report Type: Both

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Sender information

B6

Owner information

B6

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

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

Jennifer L. A. Jones, DVM

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Vet-LIRN Final Case Report

A. Case Identification:

Case Number: 800.218

Vet-LIRN Director: Renate Reimschuessel, VMD, PhD

Program: Vet-LIRN

Division Code: HFV – 500

Other Investigators:

Jennifer Jones, DVM
Sarah Nemser, MS
Olgica Ceric, DVM, PhD
Jake Guag, MPH
David Rotstein, DVM, MPH
Lee Anne Palmer, VMD, MPH
Lauren Carey, DVM

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Vet-LIRN
OS&C CERT
OS&C DVPS
OS&C DVPS

B. Descriptive Title of Case:

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

Address of Vet-LIRN Program Office:

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

C. Initiation and Completion Date:

Initiation Date: 7/13/2017

Completion Date: 8/22/2017

Final Report Submission Date:

Case Summary

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

Signalment:

- [REDACTED] 7 yr MC Miniature Schnauzer
- [REDACTED] B6 2 yr MC Miniature Schnauzer-deceased

Signs: syncopal episodes, dyspnea, cough, heart failure

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

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

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

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

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

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

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

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

References:

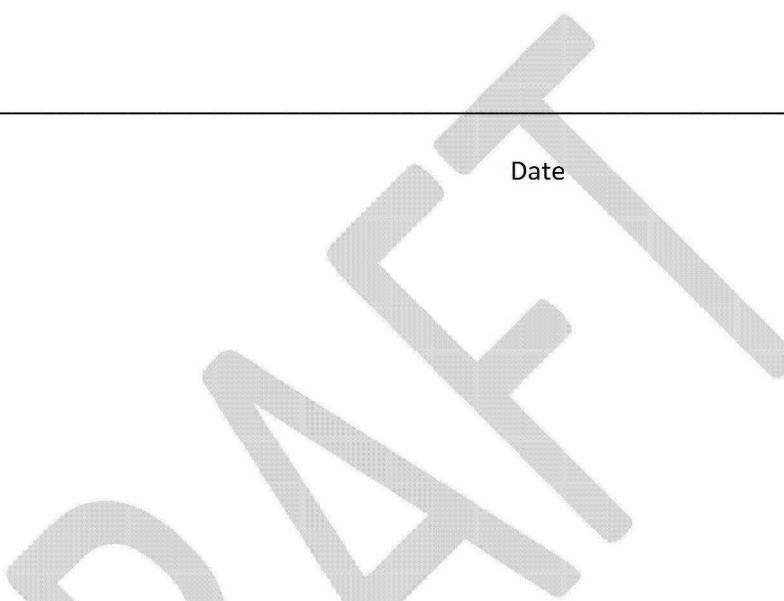
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2. Borde D, Calvert CA, Darien BJ, Guerrero J, and Wall M. Acquired Heart and Blood Vessel Disorders in Dogs. *Merck Veterinary Manual*. Found at: <http://www.merckvetmanual.com/dog-owners/heart-and-blood-vessel-disorders-of-dogs/acquired-heart-and-blood-vessel-disorders-in-dogs>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

Supplemental Information:

SIGNATURES

Deputy Director OR

Date



Director OR

Date



Vet-LIRN Director

Date

Document properties

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