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

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

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

Below is the summary of the report:

EON Key: EON-388255

ICSR #: 2067176

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

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

Product information

Individual Case Safety Report Number: 2067176

Product Group: Pet Food

Product Name: Acana Heritage Poultry dry

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

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

Sender information

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

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

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

Below is the summary of the report:

EON Key: EON-388245
ICSR #: 2067168
EON Title: PFR Event created for Honest Kitchen Turkey dehydrated, N and D Venison and Quinoa dry, Taste of the Wild Prey (Angus Beef and Lentils); 2067168

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

Product information

Individual Case Safety Report Number: 2067168

Product Group: Pet Food

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
N and D Venison and Quinoa dry		
Honest Kitchen Turkey dehydrated		
Taste of the Wild Prey (Angus, Beef, and Lentils)		

Sender information

Darcy Adin

2015 SW 16th Ave

2015 SW 16th Avenue

Gainesville, FL 32608

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think

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

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

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

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

Below is the summary of the report:

EON Key: EON-388244

ICSR #: 2067171

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

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

Product information

Individual Case Safety Report Number: 2067171

Product Group: Pet Food

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Sam's Club Chicken Jerky		
Nudges Chicken Jerkey		
Red Barn Bully sticks and slices		
Nubs Chicken Treats		

Sender information

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

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

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

Jennifer L. A. Jones, DVM

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



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

11-21-2016

PENDING

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

CASE FOLLOW UP

Signed and need to file

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

Submitted for Signature

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

Sent to RR for review

Working on Final Report

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

Pending cases

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

Sarah Nemser M.S.

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Vet-LIRN Network Coordinator

8401 Muirkirk Road, G202, HFV 500

Laurel, Maryland 20708

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

P Please consider the environment before printing this email

Vet-LIRN

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

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

Here's all of the cases:

Note
800.179 No photos

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

B5, B6

dave

800.183-CC146411

by Vet-LIRN

B6

800.183-CC146411-Lung 4X

B6

800.183-CC146411-Lung 10X

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 10/8/2018 7:12:54 PM
Subject: Taste of the Wild Pacific Stream (dry): Lisa Freeman - EON-367849
Attachments: 2055795-report.pdf; 2055795-attachments.zip

A PFR Report has been received and PFR Event [EON-367849] has been created in the EON System.

A "PDF" report by name "2055795-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055795-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367849

ICSR #: 2055795

EON Title: PFR Event created for Taste of the Wild Pacific Stream (dry); 2055795

AE Date	02/02/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	9.76 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055795

Product Group: Pet Food

Product Name: Taste of the Wild Pacific Stream (dry)

Description: DCM and CHF diagnosed 2/2/18. Owner did not change diet after diagnosis. Just rechecked echo and no improvement. Taurine levels pending and will echo other dog in household on same diet to screen.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Pacific Stream (dry)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Hartogensis, Martine; McDermott, Patrick; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Edwards, David; Conway, Charlotte
CC: DeLancey, Siobhan
Sent: 7/12/2018 1:13:44 PM
Subject: DCM Comms going live today at 2:00 pm
Attachments: CVMU_DCM_GrainFree_FINAL.docx; FDA In Brief_DCM_grainfree_FINAL.docx

Hi all,

The DCM comms will be going live at 2:00 pm today! Attached are the final versions. I'll shoot you links when they're live. Thanks so much for everyone's cooperation. Hopefully getting the message out will help us get more/better reports to aid in the investigation.

Anne

Anne Norris

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



From: Joshua A Stern <jstern@ucdavis.edu>
To: Jones, Jennifer L; Reimschuessel, Renate
Sent: 10/19/2018 5:11:29 PM
Subject: DCM question

Hi Jennifer & Renate -

I'm giving a presentation at the ACVIM Cardiology conference (all board certified vet cardiologists will be the audience) and I'm giving an update on our work in golden retrievers. I will however be

B5

B5

I was hoping I could get a tiny bit of general info from you to update my slides. I'm happy to chat by phone if that is easier.

Here a few questions - that I would love to know if you are able to answer:

B5

I really appreciate your help if possible. The cardiologists would love to have a tiny bit more info and I'm in a position to pass this on to a captive audience tomorrow afternoon.

Also I'll be reviewing the recommendations for reporting and necropsy info too - so this will hopefully give the investigation a bit of a boost.

Best

Josh

Joshua Stern, DVM, PhD, DACVIM (Cardiology)
Associate Professor of Cardiology
Department of Medicine & Epidemiology
University of California Davis; CCAH Room 258
B6 (530) 752.2475 office
jstern@ucdavis.edu

Associate Editor - Journal of Veterinary Cardiology
www.journals.elsevier.com/journal-of-veterinary-cardiology

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: [REDACTED] **B6**
CC: Ceric, Olgica; Nemser, Sarah
Sent: 6/7/2016 11:30:46 AM
Subject: FDA Follow-up for 5 [REDACTED] **B6** Cats-DCM & low Taurine
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf.html; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf.html

Good morning Dr. [REDACTED] **B6**

We received your pet food reports for Mr. and Mrs. [REDACTED] **B6** 5 cats. Thank you for submitting the reports. We'd like to request the following:

- Full medical records for each cat-Please email or fax (301-210-4685) a copy to attention: Dr. Jones
- Owner interview-We'd like to speak with the owner about the cats' diet and environment just prior to the illness. The phone interview usually lasts less than 30 minutes. Please let me know if it would be okay to contact the owner.

Attached are a copy of our network procedures. They describe how veterinarians help with our case investigations. An owner friendly version is also attached.

Thank you for reporting your case to FDA.

Please email or call with questions.

Kind regards,

Jennifer

Jennifer L. A. Jones, DVM

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

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 2/27/2018 3:36:45 AM
Subject: blr0004.1.pdf
Attachments: blr0004.1.pdf

Hi Jennifer,

Here is **B4, B5**

The talk of grain free related DCM is exploding on our list serve. One question people have is related to data collection and I thought I would get your input. Should we as a group:

B5

Thanks for your thoughts!
Darcy

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L; Darcy Adin; Joshua A Stern; Fries, Ryan C [REDACTED] **B5, B6**
CC: Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olga
Sent: 4/27/2018 11:26:51 PM
Subject: DCM cases - proposed diet history
Attachments: diet history form 4-27-18 external.doc

Hi everyone

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

Please let me know if you have any comments – I know this is probably more info than you'd like to collect but hopefully, this could help us identify patterns as well as provide information [REDACTED] **B5**

[REDACTED] **B5**

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

Our group also discussed a [REDACTED] **B5**

Thanks
Lisa

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

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]
Sent: Friday, April 20, 2018 3:50 PM
To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B5, B6**
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olga <Olga.Ceric@fda.hhs.gov>
Subject: RE: hold-call with Dr. Adin re: DCM cases
Importance: High

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

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



From: Jones, Jennifer L
Sent: Friday, April 20, 2018 1:19 PM
To: 'Darcy Adin' <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B5, B6**
[REDACTED] **B5, B6**

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: hold-call with Dr. Adin re: DCM cases

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

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

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

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



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

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

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

[redacted] <Jennifer.Jones@fda.hhs.gov>

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

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

Dear Dr. Jones,

[redacted] **B5**

Drs. [redacted] Freeman [redacted] Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

[redacted] **B6**

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

[redacted] **B5, B6**

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

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

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

Sincerely,

Darcy Adin

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

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

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

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

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

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

Join WebEx meeting

Meeting number (access code)

B6

Meeting password

B6

Join by phone

B6

US Toll

US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Can't join the meeting?

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

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

--

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

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 10/26/2018 12:30:01 PM
Subject: DCM cases 10/26/2018 0827
Attachments: Blue Wilderness: [B6] - EON-369415; Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb-Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free-Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato: [B6] - EON-369375; taste of the wild grain free pacific stream-taste of the wild prey trout limited ingredients: [B6] - EON-369346; Taste of the Wild High Prairie: Lisa Freeman - EON-369325; WELLNESS CORE GRAIN FREE: [B6] - EON-369373

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

B6

Dear Doctor, above are the images and measurements.

Thanks for allowing me to consult on this case. Please feel free to contact me regarding this or any other case.

Respectfully, **B4, B6** DVM, MS, DACVIM-CA, DECVIM-**B4, 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: 12/6/2018 3:20:09 AM
Subject: DCM cases 12/5/2018 2200
Attachments: Acana dog food. Varying diet/formulas over the past [B6] years. [B6] EON-372923; Earthborn Meadow Feast dry: Lisa Freeman - EON-372804; Earthborn Meadow Feast dry: Lisa Freeman - EON-372828; Earthborn Meadow Feast dry: Lisa Freeman - EON-372831; Earthborn Meadow Feast dry: Lisa Freeman - EON-372834; Earthborn Meadow Feast dry: Lisa Freeman - EON-372842; Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs: [B6] EON-372864; Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree: [B6] EON-372846; The Honest Kitchen Grain Free Chicken Recipe [B6] [B6] EON-372839; Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish: [B6] [B6] EON-372851

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
[B6] (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: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 12/5/2018 12:16:14 AM
Subject: Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree; EON-372846 B6
Attachments: 2059634-report.pdf

A PFR Report has been received and PFR Event [EON-372846] has been created in the EON System.

A "PDF" report by name "2059634-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-372846

ICSR #: 2059634

EON Title: PFR Event created for Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree; 2059634

AE Date	05/05/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	6 Years		
District Involved			

Product information

Individual Case Safety Report Number: 2059634

Product Group: Pet Food

Product Name: Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree

Description: Sudden collapse witnessed in May 2018. Seen by veterinarian same day. Canine cardiologist diagnosed Dilated Cardiac Myopathy. Cardiologist strongly suspected grain free diet. Dog had been on grain free diet since 1 year of age. Prognosis 2 - 6 months.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree		

Sender information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

Sent: 12/4/2018 11:33:18 PM

Subject: The Honest Kitchen Grain Free Chicken Recipe: EON-372839 B6

Attachments: 2059627-report.pdf

A PFR Report has been received and PFR Event [EON-372839] has been created in the EON System.

A "PDF" report by name "2059627-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-372839

ICSR #: 2059627

EON Title: PFR Event created for The Honest Kitchen Grain Free Chicken Recipe; 2059627

AE Date	06/01/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Other Canine/dog		
Age	8 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2059627

Product Group: Pet Food

Product Name: The Honest Kitchen Grain Free Chicken Recipe

Description: June 2018- Seen by vet (dehydration) Around September 2018 - Seen by vet for rabies and batella shot September 2018 - Seen by Vet multiple times for dehydration, coughing and weekends. This went on for a month. Heart murmur detected. October 2018 - Seen by vet for dehydration, coughing. X-ray taken. Heart murmur confirmed. Placed on two heart medicines. Told she must take for remainder of her life.

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
The Honest Kitchen Grain Free Chicken Recipe		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

Sent: 12/5/2018 12:32:29 AM

Subject: Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish **B6**
B6 EON-372851

Attachments: 2059636-report.pdf

A PFR Report has been received and PFR Event [EON-372851] has been created in the EON System.

A "PDF" report by name "2059636-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-372851

ICSR #: 2059636

EON Title: PFR Event created for Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish Herring & Salmon; 2059636

AE Date	01/01/2016	Number Fed/Exposed	6
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Chihuahua		
Age	15 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2059636

Product Group: Pet Food

Product Name: Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish, Herring & Salmon

Description: 2 years ago my dog was diagnosed with canine dilated cardiomyopathy. All of my pets had been on wellness grain free food because the vet said it was good for their skin.

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish, Herring & Salmon		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: 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: 11/11/2018 1:55:59 AM
Subject: DCM cases- Lisa Freeman and/or Tufts-related- 11/10/18
Attachments: Earthborn grain free weight management dry: Lisa Freeman - EON-370708; Nutro Ultra adult dry dog food the superfood plate (chicken: Lisa Freeman - EON-370712; Pure Balance Salmon and Pea dry: Lisa Freeman - EON-370760; Rachel Ray peak open range recipe (beef: Lisa Freeman - EON-370720; Zignature trout & salmon dry: Lisa Freeman - EON-370715; Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food: B6 EON-370762; Zignature trout and salmon dry: Lisa Freeman - EON-370713

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

B6



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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 11/9/2018 10:08:47 PM
Subject: Earthborn grain free weight management dry: Lisa Freeman - EON-370708
Attachments: 2058678-report.pdf; 2058678-attachments.zip

A PFR Report has been received and PFR Event [EON-370708] has been created in the EON System.

A "PDF" report by name "2058678-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 "2058678-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370708

ICSR #: 2058678

EON Title: PFR Event created for Earthborn grain free weight management dry; 2058678

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	[B6] years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2058678

Product Group: Pet Food

Product Name: Earthborn grain free weight management dry

Description: Diagnosed with DCM, CHF, and atrial fibrillation [B6] Currently hospitalized. Taurine submitted to UC Davis. Unclear if related to diet, given breed but eating boutique, grain-free diet. Only prior history is traumatic injury in 2015.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Earthborn grain free weight management dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 11/9/2018 10:28:41 PM
Subject: Nutro Ultra adult dry dog food the superfood plate (chicken: Lisa Freeman - EON-370712
Attachments: 2058680-report.pdf; 2058680-attachments.zip

A PFR Report has been received and PFR Event [EON-370712] has been created in the EON System.

A "PDF" report by name "2058680-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 "2058680-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370712

ICSR #: 2058680

EON Title: PFR Event created for Nutro Ultra adult dry dog food the superfood plate (chicken lamb salmon); 2058680

AE Date	09/17/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Setter - Irish Red		
Age	11 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2058680

Product Group: Pet Food

Product Name: Nutro Ultra adult dry dog food the superfood plate (chicken, lamb, salmon)

Description: DCM and CHF diagnosed 9/17/18. Unclear if this is a diet-associated DCM because this is not boutique company or grain free but some properties of diet could be suspicious (lamb, rice bran, etc). Owner has fed this same food since dog was a puppy. Has since changed to Pro plan adult sensitive skin and stomach dry plus Science beef/barley canned. Plasma taurine B6 WB B6

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
Nutro Ultra adult dry dog food the superfood plate (chicken, lamb, salmon)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 11/10/2018 8:40:39 PM
Subject: Pure Balance Salmon and Pea dry: Lisa Freeman - EON-370760
Attachments: 2058697-report.pdf; 2058697-attachments.zip

A PFR Report has been received and PFR Event [EON-370760] has been created in the EON System.

A "PDF" report by name "2058697-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 "2058697-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370760

ICSR #: 2058697

EON Title: PFR Event created for Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry; 2058697

AE Date	10/31/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	6.8 Years		
District Involved	PFR; B6 ; DO		

Product information

Individual Case Safety Report Number: 2058697

Product Group: Pet Food

Product Name: Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry

Description: DCM and CHF diagnosed 10/31/18. On BEG diet. Taurine pending

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie dry		
Pure Balance Salmon and Pea dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 11/9/2018 11:12:45 PM
Subject: Rachel Ray peak open range recipe (beef: Lisa Freeman - EON-370720
Attachments: 2058685-report.pdf; 2058685-attachments.zip

A PFR Report has been received and PFR Event [EON-370720] has been created in the EON System.

A "PDF" report by name "2058685-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 "2058685-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370720

ICSR #: 2058685

EON Title: PFR Event created for Rachel Ray peak open range recipe (beef venison lamb); 2058685

AE Date	10/06/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2058685

Product Group: Pet Food

Product Name: Rachel Ray peak open range recipe (beef, venison, lamb)

Description: DCM and arrhythmias diagnosed at time of GDV surgery so unclear if sepsis/post-op or true DCM. Had recheck echo 10/31/18 and still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer

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
Rachel Ray peak open range recipe (beef, venison, lamb)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 11/9/2018 10:52:44 PM
Subject: Zignature trout & salmon dry: Lisa Freeman - EON-370715
Attachments: 2058683-report.pdf; 2058683-attachments.zip

A PFR Report has been received and PFR Event [EON-370715] has been created in the EON System.

A "PDF" report by name "2058683-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 "2058683-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370715
ICSR #: 2058683
EON Title: PFR Event created for Zignature trout & salmon dry; 2058683

AE Date	11/07/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	3 Years		
District Involved	PFR; B6 DO		

Product information

Individual Case Safety Report Number: 2058683

Product Group: Pet Food

Product Name: Zignature trout & salmon dry

Description: Older housemate diagnosed with DCM and CHF. Screening **B6** because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation

Submission Type: Initial

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

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 2

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Carey, Lauren; Rotstein, David; Jones, Jennifer L; Peloquin, Sarah; Reimschuessel, Renate; Hartogensis, Martine; Norris, Anne; Burkholder, William
Sent: 2/19/2019 2:04:57 PM
Subject: DCM paper - Darcy Adin, 2019 Vet Cardiology
Attachments: Adin 2019.pdf

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 3/20/2019 10:26:46 AM
Subject: DCM reports 3/20/19; 0630
Attachments: Fromm's Four Star Grain Free Salmon and Tunalini: **B6** EON-382722; Natural Balance LID High Protein Grain-free Lamb or Beef flavors: Lisa Freeman, EON-382772; Redford Limited Ingredient Grain-Free Lamb and Sweet Potato: **B6** EON-382721

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

B6



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

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 6/10/2019 8:11:44 PM
Subject: DCM Taste of the Wild EON-390065
Attachments: Taste of the Wild (various flavors) since Nov 2013: Lisa Freeman - EON-390087; Taste of the Wild PREY: [B6] EON-390065; Taste of the Wild PREY: [B6] - EON-390066

Everyone,

I know that we aren't forwarding all of these, but since they've added a lot of information, I felt like it's worthwhile to share it with everyone.

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: [B6] Cleary, Michael *; HQ Pet Food Report Notification;
[B6]
Sent: 6/10/2019 6:20:41 PM
Subject: Taste of the Wild PREY; [B6] EON-390066
Attachments: 2068022-report.pdf; 2068022-attachments.zip

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

A "PDF" report by name "2068022-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068022-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390066

ICSR #: 2068022

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

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

Product information

Individual Case Safety Report Number: 2068022

Product Group: Pet Food

Product Name: Taste of the Wild PREY

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

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

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild PREY	9072080 PDR0301-19 MSH 17:27	03/12/2020

This report is linked to:

Initial EON Event Key: EON-390065

Initial ICSR: 2068021

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: 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: 1/28/2019 1:38:48 PM
Subject: DCM-Lisa Freeman
Attachments: 4Health grain=free beef and potato: Lisa Freeman - EON-375111; 4Health whitefish and potato dry: Lisa Freeman - EON-376448; Acana Free Run Poultry dry: Lisa Freeman - EON-374786; Annamaet chicken and rice dry + Honest kitchen beef: Lisa Freeman - EON-376360; Homecooked diet - see diet history in medical record: Lisa Freeman - EON-374789; Orijen Adult Original dry (until Aug 2018): Lisa Freeman - EON-375110; Orijen grain free original dry: Lisa Freeman - EON-375114; Orijen Original dry: Lisa Freeman - EON-374783; Taste of the Wild Sierra Mountain dry: Lisa Freeman - EON-376361; Zignature - various flavors (venison): Lisa Freeman - EON-376446; Zignature kangaroo dry: Lisa Freeman - EON-376363

Here is the Freeman Collection

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

B6

(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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 12/6/2018 3:20:09 AM
Subject: DCM cases 12/5/2018 2200
Attachments: Acana dog food. Varying diet/formulas over the past 3.5 years. [B6] EON-372923; Earthborn Meadow Feast dry: Lisa Freeman - EON-372804; Earthborn Meadow Feast dry: Lisa Freeman - EON-372828; Earthborn Meadow Feast dry: Lisa Freeman - EON-372831; Earthborn Meadow Feast dry: Lisa Freeman - EON-372834; Earthborn Meadow Feast dry: Lisa Freeman - EON-372842; Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs; [B6] EON-372864; Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree; [B6] EON-372846; The Honest Kitchen Grain Free Chicken Recipe; [B6] [B6] EON-372839; Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish; [B6] [B6] EON-372851

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
[B6] (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: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 8/8/2018 8:43:16 PM
Subject: as promised
Attachments: Canine DCM protocol external 7-8-18.docx

Hi Jennifer

Below are the WSAVA guidelines and also my blog that expands on the quality control measures.

<https://www.wsava.org/WSAVA/media/Arpita-and-Emma-editorial/Selecting-the-Best-Food-for-your-Pet.pdf>

<http://vetnutrition.tufts.edu/2016/12/questions-you-should-be-asking-about-your-pets-food/>

Also, I think I sent the attached to you before but resending in case.

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L
Sent: 4/24/2018 4:55:40 PM
Subject: RE: DCM/grain-free - checking in

Jen,

The EON number is 345858

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: Tuesday, April 24, 2018 12:31 PM
To: Norris, Anne <Anne.Norris@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>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@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: DCM/grain-free - checking in

B5

B5

B5

B4, B5

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



From: Norris, Anne
Sent: Friday, April 20, 2018 12:53 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM/grain-free - checking in

Agree wholeheartedly. Thanks for putting that call together, very interesting!

Anne

From: Jones, Jennifer L
Sent: Friday, April 20, 2018 12:42 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM/grain-free - checking in

Anne and Siobhan,

Dave and I were talking after the call.

B5

B5

What do you think?

Jen

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



From: Norris, Anne
Sent: Monday, April 16, 2018 11:07 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM/grain-free - checking in

Following up on our discussion last week, I reached out to [REDACTED] B6 She said we no longer have the arrangement with [REDACTED] B4 we once did [REDACTED] B5 dead end. Exploring alternatives, will keep you posted.

Thanks,
Anne

From: Jones, Jennifer L
Sent: Friday, April 13, 2018 6:37 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM/grain-free - checking in

Thanks, Anne. I'll be in the office until 9am, [REDACTED] B6

[REDACTED] B6

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



From: Norris, Anne
Sent: Thursday, April 12, 2018 6:56 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Re: DCM/grain-free - checking in

Wow. What breeds? I'll send a cal invite for tomorrow AM to try to catch you while you're at Vet-LIRN with Jen.

From: Rotstein, David <David.Rotstein@fda.hhs.gov>
Date: April 12, 2018 at 5:59:56 PM EDT
To: Norris, Anne <Anne.Norris@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: DCM/grain-free - checking in

Anne

I'll be available. I'll be with VetLIRN in the morning.

This sounds great-thanks for moving it forward. We got two new complaints (same submitter) today.

From: Norris, Anne <Anne.Norris@fda.hhs.gov>

Date: April 12, 2018 at 5:36:50 PM EDT

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

Subject: DCM/grain-free - checking in

Hi Jen and Dave,

I know it probably looks like nothing has happened [redacted] **B5**
[redacted] **B5** Most
recently, I just talked with Dan McChesney for a while [redacted] **B5** If you have any availability
tomorrow, [redacted] **B5**

Thanks,
Anne

Anne Norris

Health Communications Specialist

Strategic Communications & Public Engagement Team

Office of Foods and Veterinary Medicine

U.S. Food & Drug Administration

O: 240-402-0132

M: [redacted] **B6**

Anne.Norris@fda.hhs.gov



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Palmer, Lee Anne; Jones, Jennifer L
Sent: 4/28/2018 1:00:09 AM
Subject: Fwd: DCM cases - proposed diet history
Attachments: diet history form 4-27-18 external.doc

Lee Anne,

Thought you would be interested and could provide any comments/suggestions

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Date: April 27, 2018 at 7:27:27 PM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>, Joshua A Stern <jstern@ucdavis.edu>, Fries, Ryan C <rfries@illinois.edu>, [REDACTED] **B6**
[REDACTED] **B6**
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: DCM cases - proposed diet history

Hi everyone

I'm attaching a proposed diet history form

[REDACTED] **B5**

[REDACTED] **B5**

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

[REDACTED] **B5**

Thanks
Lisa

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

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]
Sent: Friday, April 20, 2018 3:50 PM
To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6**

[REDACTED] **B6**

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

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

Importance: High

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

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



From: Jones, Jennifer L

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

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

B6

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

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

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

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

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

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



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

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

To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6** Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>

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

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

Dear Dr. Jones,

We are all able to meet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and

concerns surrounding a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.

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

Just a brief introduction for the FDA group:

B6

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

B6

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

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

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

Sincerely,
Darcy Adin

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

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

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

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

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

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

Join WebEx meeting

Meeting number (access code): **B6**

Meeting password: **B6**

Join by phone

B6

JS Toll

JS Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

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

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

--

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

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'; Darcy Adin; Joshua A Stern; Fries, Ryan C; [REDACTED] B6
CC: Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 4/30/2018 11:25:31 AM
Subject: RE: DCM cases - proposed diet history
Attachments: diet history form 4-27-18 external-jj.doc

Thank you for sharing, Lisa.

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



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Friday, April 27, 2018 7:27 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] B6

CC: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: DCM cases - proposed diet history

Hi everyone

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

B5

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

B5

Thanks
Lisa

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

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]
Sent: Friday, April 20, 2018 3:50 PM
To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] B6

B6

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

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

Importance: High

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

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



From: Jones, Jennifer L

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

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

B6

B6

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

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

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

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

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

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



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

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

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

B6

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

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

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

[B6]

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

[B6]

American College of Veterinary Internal Medicine (Cardiology)

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

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

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

Sincerely,
Darcy Adin

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

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

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

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

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

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

Join WebEx meeting

Meeting number (access code): [B6]

Meeting password: [B6]

Join by phone

[B6]

US Toll

US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

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

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

--

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

From: Darcy Adin <dbadin@ncsu.edu>
To: Freeman, Lisa
CC: Jones, Jennifer L; Joshua A Stern; Fries, Ryan C; [REDACTED] B6; David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 4/30/2018 2:12:38 PM
Subject: Re: DCM cases - proposed diet history

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

Thanks!

Darcy

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

Hi everyone

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

B5

B5

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

B5

Thanks

Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Friedman School of Nutrition Science and Policy

Tufts Clinical and Translational Science Institute

Tufts University

www.petfoodology.org

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

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

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

B6

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

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

Importance: High

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

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

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

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

B6

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

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

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

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

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

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



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

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

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

B6

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

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

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

B6

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

B6

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

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

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

Sincerely,

Darcy Adin

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

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

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

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

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

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

Join WebEx meeting

Meeting number (access code): **B6**

Meeting password: **B6**

Join by phone

B6

US Toll

US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Can't join the meeting?

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

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

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Queen, Jackie L
CC: Ceric, Olgica; Reimschuessel, Renate; Nemser, Sarah
Sent: 5/3/2018 4:26:27 PM
Subject: RE: 800.267-EON-345858-DCM Cluster

Hi Jen,

I think

B5

Thanks,
Lauren

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

B5 I wonder about either

B5

B5

thoughts?

Dave previously sent an email about lentils being deficient in Cystine and Methionine. I found the same information about peas (attached). For Growing labrador dogs, if cystine is limited (~ 0.2%), a Cys:Met cutoff may lie somewhere between 0.32 : 1 and 0.38 : 1. **Above that ratio, the dogs in the study here did poorly**

B4

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

B5

B5

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

B5

B5

Also-This is an older study in beagles, (<https://academic.oup.com/in/article-abstract/111/12/2117/4771254?redirectedFrom=fulltext>)

B5

B5

B5

Jennifer L. A. Jones, DVM

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



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/4/2018 4:00:40 PM
Subject: RE: DCM cases-food-Iodine screening results

B5

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: May 4, 2018 at 10:03:44 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

There is no minimum for dogs...it is apparently a conditionally essential amino acid because dogs can make it from methione and cystine.

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



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:01 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Interesting... so the AAFCO minimum for cats is 0.1% DMB,

B5

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 9:46 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

B5

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



From: Jones, Jennifer L

Sent: Monday, April 23, 2018 10:32 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: DCM cases-food-Iodine screening results

FYI-Iodine < 10ppm for the foods tested.

B5

B5

Jennifer L. A. Jones, DVM

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



From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Rotstein, David; Jones, Jennifer L; Queen, Jackie L; Carey, Lauren
CC: Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/4/2018 4:07:01 PM
Subject: RE: DCM cases-food-Iodine screening results

B5

If you look at the cases we've received

B5

B5

From: Rotstein, David
Sent: Friday, May 4, 2018 11:59 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Lee Anne

This is excellent. Based on what is found moving forward,

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 4, 2018 at 11:15:20 AM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 10:35 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Yes. [redacted] **B5**

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



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:21 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

I know dogs can synthesize taurine [redacted] **B5** [redacted] **B5**

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 10:04 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

There is no minimum for dogs...it is apparently a conditionally essential amino acid because dogs can make it from methione and cystine.

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



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:01 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Interesting... so the AAFCO minimum for cats is 0.1% DMB, [redacted] **B5**

[redacted] **B5**

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 9:46 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

One more nutritional deficiency-Taurine low based on AAFCO's Feline Minimum for Extruded foods. The dog consuming the product had a low whole blood Taurine level.

B5

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



From: Jones, Jennifer L

Sent: Monday, April 23, 2018 10:32 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: DCM cases-food-Iodine screening results

FYI-Iodine < 10ppm for the foods tested.

B5

B5

Jennifer L. A. Jones, DVM

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



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Palmer, Lee Anne; Rotstein, David; Queen, Jackie L; Carey, Lauren
CC: Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/4/2018 4:12:45 PM
Subject: RE: DCM cases-food-Iodine screening results

B5

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



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 12:07 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

If you look at the cases we've received

B5

B5

B5

From: Rotstein, David
Sent: Friday, May 4, 2018 11:59 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Lee Anne

This is excellent. Based on what is found moving forward,

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 4, 2018 at 11:15:20 AM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

B5

From: Jones, Jennifer L

Sent: Friday, May 4, 2018 10:35 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

Yes. I'm going to

B5

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



From: Palmer, Lee Anne

Sent: Friday, May 04, 2018 10:21 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

I know dogs can synthesize taurine.

B5

B5

From: Jones, Jennifer L

Sent: Friday, May 4, 2018 10:04 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

There is no minimum for dogs...it is apparently a conditionally essential amino acid because dogs can make it from methione and cystine.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Palmer, Lee Anne

Sent: Friday, May 04, 2018 10:01 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

Interesting... so the AAFCO minimum for cats is 0.1% DMB.

B5

B5

From: Jones, Jennifer L

Sent: Friday, May 4, 2018 9:46 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

B5

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Monday, April 23, 2018 10:32 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: DCM cases-food-Iodine screening results

FYI-Iodine < 10ppm for the foods tested.

B5

B5

B5

Jennifer L. A. Jones, DVM

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



From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Jones, Jennifer L; Rotstein, David; Queen, Jackie L; Carey, Lauren
CC: Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/4/2018 4:33:54 PM
Subject: RE: DCM cases-food-Iodine screening results
Attachments: Ingredients DCM reports per Jen's table v.2.docx

Just an initial quickie count of Jen's data in JMF

B6

B5

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 12:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

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



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 12:07 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

From: Rotstein, David
Sent: Friday, May 4, 2018 11:59 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Lee Anne

This is excellent. Based on what is found moving forward,

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 4, 2018 at 11:15:20 AM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 10:35 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Yes. [redacted] B5

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



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:21 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

I know dogs can synthesize taurine [redacted] B5

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 10:04 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

There is no minimum for dogs...it is apparently a conditionally essential amino acid because dogs can make it from methione and cystine.

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



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:01 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Interesting... so the AAFCO minimum for cats is 0.1% DMB, [redacted] B5

[redacted] B5

From: Jones, Jennifer L

Sent: Friday, May 4, 2018 9:46 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

B5

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



From: Jones, Jennifer L

Sent: Monday, April 23, 2018 10:32 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: DCM cases-food-Iodine screening results

FYI-Iodine < 10ppm for the foods tested

B5

B5

Jennifer L. A. Jones, DVM

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



From: Andrea Fascetti <ajfascetti@ucdavis.edu>
To: Jones, Jennifer L
Sent: 3/25/2019 8:14:08 PM
Subject: Re: reference ranges for plasma amino acids

Hi Jen - We use the Delaney reference ranges - especially when looking at a complete AA analysis. Remember cysteine will be low unless samples are treated with SSA at the time of collection.

I hope this works.

Andrea

On Mar 25, 2019, at 2:57 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Andrea,
Do you have specific reference ranges for canine plasma amino acids in your lab? I looked at the Delaney et al paper but didn't know if there was a set range you used.
Thank you in advance,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 2/25/2019 11:19:34 AM
Subject: DCM 1 of 2 - Freeman Reports ONLY- 2/25/2019 0615
Attachments: Acana: Lisa Freeman - EON-380708; Earthborn Coastal Catch dry: Lisa Freeman - EON-380720; Fromm Large Breed Adult dry: Lisa Freeman - EON-380709; Poulin Pro Form Lamb and Rice Adult Maintenance Dry: Lisa Freeman - EON-380706; Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-380707; Solid Gold Mighty Mini Beef: Lisa Freeman - EON-380716; Taste of the Wild Sierra Mountain Dry: Lisa Freeman - EON-380714

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

B6

(BB)



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: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification;
Sent: 2/24/2019 10:08:57 PM
Subject: Acana: Lisa Freeman - EON-380708
Attachments: 2063115-report.pdf; 2063115-attachments.zip

B6

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

A "PDF" report by name "2063115-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063115-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380708

ICSR #: 2063115

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

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

Product information

Individual Case Safety Report Number: 2063115

Product Group: Pet Food

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana, Natural Balance, Petcurean (see diet history for additional details)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/24/2019 11:24:38 PM
Subject: Taste of the Wild Sierra Mountain Dry: Lisa Freeman - EON-380714
Attachments: 2063118-report.pdf; 2063118-attachments.zip

A PFR Report has been received and PFR Event [EON-380714] has been created in the EON System.

A "PDF" report by name "2063118-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063118-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380714

ICSR #: 2063118

EON Title: PFR Event created for Taste of the Wild Sierra Mountain Dry; 2063118

AE Date	01/14/2019	Number Fed/Exposed	7
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063118

Product Group: Pet Food

Product Name: Taste of the Wild Sierra Mountain Dry

Description: BEG diet being fed to B6 dogs. We evaluated her other dog B6 who had a murmur and elevated BNP, with reduced contractility and elevated troponin found on exam (see previous report - 2061171). Owner worried about this dog's breathing so we screened her and found reduced contractility, elevated troponin, but normal BNP. Changing diet on both dogs to Pro Plan Sensitive Skin/Stomach Salmon and will recheck in 3 months Other dogs we have not screened: B6 Labrador 5 years old B6 Golden 3 1/2 years old B6 Golden 3 years old B6 Golden 3 years 5 months B6 Golden 3 years 9 months

Submission Type: Initial

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

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

Number of Animals Treated With Product: 7

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Sierra Mountain Dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think

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

Client: **B6**
Patient:

ECG from Cardio

B6

3/8/2019 2:51:01 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

3/8/2019 2:51:01 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 3/21/2019 4:08:56 PM
Subject: Horizons pulsar grain free diet; **B6** EON-382952
Attachments: 2064363-report.pdf; 2064363-attachments.zip

A PFR Report has been received and PFR Event [EON-382952] has been created in the EON System.

A "PDF" report by name "2064363-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2064363-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382952

ICSR #: 2064363

EON Title: PFR Event created for Horizons pulsar grain free diet; 2064363

AE Date	03/08/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Mixed (Dog)		
Age	4 Years		
District Involved	PFR-Baltimore DO		

Product information

Individual Case Safety Report Number: 2064363

Product Group: Pet Food

Product Name: Horizons pulsar grain free diet

Description: [redacted] is presented as a consultation through CVCA Cardiology on 3/18/19 for evaluation of a coughing and marked cardiomegaly with concern for DCM. Arthur initially presented to the pDVM on 3/11 for a few day hx of coughing and was started on cough tabs. His symptoms progressed w/coughing noted mostly at night, decreased energy level and appetite, and he presented to the Emergency Vet Service in [redacted] **B6** CXR showed severe heart enlargement and possible early CHF. He was given a dose of Lasix (with significant improvement in C and appetite per O) and started on Enalapril 15 mg BID with recommendation for referral. He

has been on a grain free diet for the last ~4 years (since he was a puppy) and so DCM was discussed and a diet change recommended. The O's switched **B6** to Purina **B6** and he has had no adverse effects. They also submitted a taurine level (unsure if whole blood vs. plasma) to UC Davis. UTD on HW and F/T preventatives; has also been on salmon oils. PE: HR 180 bpm; grade III/VI holosystolic plateau quality heart murmur - PMI equal over MV and TV; regular tachycardia with s/s femoral pulses; mildly increased RE, RR 40-50 bpm, harsh lung sounds in all fields but no discreet crackles or wheezes. Echo diagnosis: Advanced dilated cardiomyopathy - suspect secondary to nutritional deficiency Moderate to severe mitral valve regurgitation Severely dilated left atrial dimensions Severely dilated left ventricular dimensions with severely decreased heart muscle function Moderate to severe right heart enlargement Left-sided congestive heart failure

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Horizons pulsar grain free diet		

Sender information

B6

USA

Owner information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 4/15/2019 10:48:01 AM
Subject: DCM cases 4/15/2019 0645
Attachments: Nature's Domain - Salmon and Sweet Potato-Nature's Domain - Turkey ad Sweet Potato-Nature's Domain - Beef and Sweet Potato-Nature's Domain - Canned Grain free Dog Food: [B6] - EON-385037; Solid Gold Mighty Mini Beef: Lisa Freeman - EON-380716; Solid Gold Mighty Mini Beef: Lisa Freeman - EON-384905

Related EON-348905 (not sure if following the original)

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



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 </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William
CC: Norris, Anne; Hartogensis, Martine; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica; Nemser, Sarah
Sent: 6/27/2018 5:26:20 PM
Subject: DCM Product [REDACTED] B5
Attachments: [REDACTED]

B5

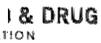
Based on Bill's recommendation, [REDACTED] B5 we've been notified about, including those from Tufts, CVCA, NCSU, and OH (i.e. not necessarily received through the Safety reporting portal). [REDACTED] B5

B5

For the Bottom Line, see the PPT. The ppt notes will walk you through my analysis. Please let me know if you have questions.

Jennifer L. A. Jones, DVM

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



B5

I did not:

B5

B5

B5

Document properties

Author: Jones, Jennifer L
Template: Normal.dotm
Page count: 2
Paragraph count: 132
Line count: 179
Word count: 662
Character count (spaces excluded): 3098
Character count (spaces included): 3654

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 1/1/2019 9:32:34 PM
Subject: 4Health grain=free beef and potato; [REDACTED] B6 EON-375111
Attachments: 2060740-report.pdf; 2060740-attachments.zip

A PFR Report has been received and PFR Event [EON-375111] has been created in the EON System.

A "PDF" report by name "2060740-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060740-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375111

ICSR #: 2060740

EON Title: PFR Event created for 4Health grain=free beef and potato; 2060740

AE Date	12/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	4.5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060740

Product Group: Pet Food

Product Name: 4Health grain=free beef and potato

Description: Weight loss x 3-4 weeks Coughing and dyspnea developed - too to ER in [REDACTED] B6 where they did T-FAST and suspected DCM. Started on [REDACTED] B6 before we saw him Eating BEG diet. Taurine pending. Switched to new food. Will also try to evaluate other dog in their home eating the same diet (15 years old) Owners happy to provide additional info and have saved some of the food they've been feeding (4Health)

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4Health grain=free beef and potato		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

Sent: 1/14/2019 9:56:41 PM

Subject: Annamaet chicken and rice dry + Honest kitchen beef: -
EON-376360

Attachments: 2061170-report.pdf; 2061170-attachments.zip

A PFR Report has been received and PFR Event [EON-376360] has been created in the EON System.

A "PDF" report by name "2061170-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061170-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376360

ICSR #: 2061170

EON Title: PFR Event created for Annamaet chicken and rice dry + Honest kitchen beef chicken or turkey; 2061170

AE Date	12/21/2017	Number Fed/Exposed	3
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061170

Product Group: Pet Food

Product Name: Annamaet chicken and rice dry + Honest kitchen beef, chicken, or turkey

Description: 2 other dogs in household affected previously Eating various BEG diets Early DCM with infrequent ventricular ectopy Have been following - owner agreed to change diet at December 2018 appointment so will follow Taurine normal

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Annamaet chicken and rice dry + Honest kitchen beef, chicken, or turkey		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

Sent: 1/2/2019 5:32:22 PM

Subject: 4Health beef and potato and 4health untamed lamb and Lentil; [REDACTED] B6
EON-375168

Attachments: 2060761-report.pdf

A PFR Report has been received and PFR Event [EON-375168] has been created in the EON System.

A "PDF" report by name "2060761-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375168

ICSR #: 2060761

EON Title: PFR Event created for 4Health beef and potato and 4health untamed lamb and Lentil; 2060761

AE Date	03/01/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Griffon - French Wire-haired Pointing		
Age	5 Years		
District Involved	PFR-Minneapolis DO		

Product information

Individual Case Safety Report Number: 2060761

Product Group: Pet Food

Product Name: 4Health beef and potato and 4health untamed lamb and Lentil

Description: Female spayed dog in excellent health developed DCM and died from it. ([REDACTED] B6 months old) [REDACTED] B6 (2 year Old Spayed female) is now showing early signs of enlarged heart and elevated proBNP. Normal range is 0-900 and her level is [REDACTED] B6. We have an appointment with cardiologist at the [REDACTED] B6 on Feb 7th, 2019.

Submission Type: Initial

Report Type: Both

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
4Health beef and potato and 4health untamed lamb and Lentil		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

A "PDF" report by name "2060599-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060599-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374786

ICSR #: 2060599

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

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

Product information

Individual Case Safety Report Number: 2060599

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 1/12/2019 10:36:20 AM
Subject: ACANA Lamb and Apple Singles Formula; [REDACTED] B6 EON-376195
Attachments: 2061133-report.pdf

A PFR Report has been received and PFR Event [EON-376195] has been created in the EON System.

A "PDF" report by name "2061133-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376195

ICSR #: 2061133

EON Title: PFR Event created for ACANA Lamb and Apple Singles Formula; 2061133

AE Date	10/22/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Unknown
Breed	Pit Bull		
Age	11 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2061133

Product Group: Pet Food

Product Name: ACANA Lamb and Apple Singles Formula

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
ACANA Lamb and Apple Singles Formula		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/2/2019 8:32:33 PM
Subject: Arcana lamb and apple - grain free: B6 - EON-375208
Attachments: 2060775-report.pdf

A PFR Report has been received and PFR Event [EON-375208] has been created in the EON System.

A "PDF" report by name "2060775-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375208

ICSR #: 2060775

EON Title: PFR Event created for Arcana lamb and apple - grain free; 2060775

AE Date	B6	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Weimaraner		
Age	8 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2060775

Product Group: Pet Food

Product Name: Arcana lamb and apple - grain free

Description: Congestive heart failure, hypotension/cardiogenic shock, thrombocytopenia,

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
Arcana lamb and apple - grain free		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

Sent: 1/25/2019 2:12:21 PM

Subject: BLUE BUFFALO GRAIN FREE LAMB AND POTATO: [B6] - EON-377465

Attachments: 2061751-report.pdf; 2061751-attachments.zip

A PFR Report has been received and PFR Event [EON-377465] has been created in the EON System.

A "PDF" report by name "2061751-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 "2061751-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377465

ICSR #: 2061751

EON Title: PFR Event created for BLUE BUFFALO GRAIN FREE LAMB AND POTATO; 2061751

AE Date	[B6]	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Other
Breed	Retriever (unspecified)		
Age	5 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061751

Product Group: Pet Food

Product Name: BLUE BUFFALO GRAIN FREE LAMB AND POTATO

Description: [B6]

[B6] Referring Hospital: [B6]

[B6] TIME: Patient: [B6] 5 year, male, English Lab Re: Client: [B6] Chief

Complaint/Clinical History: [B6] was referred for a suspected tracheal mass. The owner reports that his

appetite has been off for the past week. He is still eating but eating slowly and only wants people food. No vomiting/diarrhea Last night the owner noted increased respiratory noise to his breathing and his cheeks were puffing out. He has been coughing some the past 24hours only. He ate 1 cup of food this morning He is on a limited ingredient, grain free diet(blue buffalo lamb/potato) for the past 2-3 years.

B6

B6

seem weak. He has large thyroid cartilages in his larynx but it is bilaterally symmetrical and is nonpainful. No stridor Diagnostics: RV ran CBC, profile today- all wnl RV sent two upper cervical xrays 3 view chest- marked cardiac enlargement with severe pulmonary infiltrate, no effusion 2 view abdomen- stomach empty no ascites, no masses, no significant findings FAST SCAN US of thorax- dilated chambers with very poor contractility, no pericardial effusion seen abdomen- no ascites noted Laboratory: Treatment: I called owner and advised that B6 is in CHF and likely has DCM. Discussed treatment for CHF. Owner wants to proceed. Gave owner

B6

B6

Continued CPR and advised owner of the situation. Owner elected to stop CPR time of death

B6 Diagnosis: Fulminating Congestive heart failure. Suspect DCM Thank you very much for the referral, if you have any questions regarding B6 or any other case, please do not hesitate to call me. B6

DVM B6 DVM, 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 Other

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
BLUE BUFFALO GRAIN FREE LAMB AND POTATO		

Sender information

B6

USA

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

B6

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

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/19/2018 10:28:21 PM
Subject: BLUE Wilderness with Chicken for Adult Dogs: [B6]
EON-374327
Attachments: 2060407-report.pdf

A PFR Report has been received and PFR Event [EON-374327] has been created in the EON System.

A "PDF" report by name "2060407-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374327

ICSR #: 2060407

EON Title: PFR Event created for BLUE Wilderness with Chicken for Adult Dogs; 2060407

AE Date	11/24/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	American Pit Bull Terrier		
Age	6 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2060407

Product Group: Pet Food

Product Name: BLUE Wilderness with Chicken for Adult Dogs

Description: [B6] began acting strange (lathargic, lack of appetite, breathing hard) since around thanksgiving. His primary vet - chicago pet clinic, ran multiple tests and did an xray- 2 visits from [B6] left him stumped. We were referred to an internal specialist for an ultrasound who determined there is fluid build up, an enlarged right side of the heart, and low function of the heart. [B6] has been in our family since he was a pup and has never had any significant medical issues until this event. He has also exclusively been fed grain free blue buffalo (call of the wild) dog food through out his life. The internal specialist believes [B6] has CDM, and that we need to see a cardiologist immediately. [B6] has already been taken off his grain free diet and now we

anxiously wait to see a cardiologist.

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
BLUE Wilderness with Chicken for Adult Dogs		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/9/2019 2:52:20 AM
Subject: Canidae Grain Free Pure Wild Dry Dog Food with Wild Boar-Grain Free Limited Ingredient Diet: [B6] - EON-375880
Attachments: 2060996-report.pdf; 2060996-attachments.zip

A PFR Report has been received and PFR Event [EON-375880] has been created in the EON System.

A "PDF" report by name "2060996-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 "2060996-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375880

ICSR #: 2060996

EON Title: PFR Event created for Canidae Grain Free Pure Wild Dry Dog Food with Wild Boar Grain Free Limited Ingredient Diet; 2060996

AE Date	06/21/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-San Francisco DO		

Product information

Individual Case Safety Report Number: 2060996

Product Group: Pet Food

Product Name: Canidae Grain Free Pure Wild Dry Dog Food with Wild Boar Grain Free Limited Ingredient Diet

Description: I became aware of a possible link between feeding grain free food and low Taurine levels/DCM. Since my dog had been on Canidae grain free for a year (May 2017 - early June 2018), I tested her whole blood Taurine level on 6/21/18. Her whole blood Taurine level was [B6] which is considered low for Golden Retrievers.

I changed her food to grain inclusive and retested her on 10/1/2018. Her whole blood Taurine level increased to **B6** still slightly below "normal" for Golden Retrievers. She got an echocardiogram on 10/27/2018 and was found to have a "normal" heart.

Submission Type: Initial

Report Type: Both

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Canidae Grain Free Pure Wild Dry Dog Food with Wild Boar Grain Free Limited Ingredient Diet		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/8/2019 2:24:22 PM
Subject: CANIDAE Grain-Free PURE Land with Bison Limited Ingredient Diet Adult Dry Dog Food; [B6] EON-375771
Attachments: 2060959-report.pdf

A PFR Report has been received and PFR Event [EON-375771] has been created in the EON System.

A "PDF" report by name "2060959-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375771

ICSR #: 2060959

EON Title: PFR Event created for CANIDAE Grain-Free PURE Land with Bison Limited Ingredient Diet Adult Dry Dog Food; 2060959

AE Date	11/30/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2060959

Product Group: Pet Food

Product Name: CANIDAE Grain-Free PURE Land with Bison Limited Ingredient Diet Adult Dry Dog Food

Description: For 3.5 years, dog was fed Canidae Pure Land Bison dry dog food. Upon release of FDA warning that heart disease was caused in dogs eating Grain Free food, dog was taken off diet as of July 2018 and switched to Royal Canin Prescription Gastrointestinal. However, at routine physical on November 30, 2018, a grade 1-2 heart murmur was discovered in dog. Upon this finding, an echocardiogram was performed by a licensed veterinary internist, [B6] who concluded that dog has early-stage DCM.

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
CANIDAE Grain-Free PURE Land with Bison Limited Ingredient Diet Adult Dry Dog Food		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/11/2019 2:28:08 AM
Subject: CRAVE Dog Food with Protein from Salmon and Ocean White Fish; [B6]
[B6] EON-376088
Attachments: 2061078-report.pdf

A PFR Report has been received and PFR Event [EON-376088] has been created in the EON System.

A "PDF" report by name "2061078-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376088

ICSR #: 2061078

EON Title: PFR Event created for CRAVE Dog Food with Protein from Salmon and Ocean White Fish;
2061078

AE Date	12/06/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Shih Tzu		
Age			
District Involved			

Product information

Individual Case Safety Report Number: 2061078

Product Group: Pet Food

Product Name: CRAVE Dog Food with Protein from Salmon and Ocean White Fish

Description: [B6] was eating Crave Grain Free Salmon & White Fish kibble as his main diet. After presenting to the veterinarian with a heart murmur, he was evaluated by echocardiogram and found to have severe dilated cardiomyopathy.

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
CRAVE Dog Food with Protein from Salmon and Ocean White Fish		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification [B6]
Sent: 1/10/2019 7:48:20 PM
Subject: Diamond -Naturals-Skin & Coat-All Life Stages Dog-Salmon & Potato Formula: [B6] EON-376046
Attachments: 2061059-report.pdf

A PFR Report has been received and PFR Event [EON-376046] has been created in the EON System.

A "PDF" report by name "2061059-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376046

ICSR #: 2061059

EON Title: PFR Event created for Diamond Naturals Skin & Coat All Life Stages Dog Salmon & Potato Formula; 2061059

AE Date	12/23/2018	Number Fed/Exposed	2
Best By Date	12/17/2019	Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining /Deteriorating
Breed	Basset - Griffon Vendeen (unspecified)		
Age	6 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061059

Product Group: Pet Food

Product Name: Diamond Naturals Skin & Coat All Life Stages Dog Salmon & Potato Formula

Description: After changing foods to a grain-free diet, the dog went into heart failure. His heart failure onset was sudden.

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Diamond Naturals Skin & Coat All Life Stages Dog Salmon & Potato Formula		12/17/2019

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/26/2018 3:16:26 PM
Subject: Fromm Family-From the Heartland-Grain Free-Dog Food; [B6]
EON-374687
Attachments: 2060556-report.pdf

A PFR Report has been received and PFR Event [EON-374687] has been created in the EON System.

A "PDF" report by name "2060556-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374687

ICSR #: 2060556

EON Title: PFR Event created for Fromm Family From the Heartland Grain Free Dog Food; 2060556

AE Date	04/01/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Retriever - Labrador		
Age	8 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2060556

Product Group: Pet Food

Product Name: Fromm Family From the Heartland Grain Free Dog Food

Description: [B6] had [B6] As part of his recovery process, the surgeon put him on Antibiotics. He remained on those for about 3 months. After his recovery period, he was given a clean bill of health from the surgeon and he seemed fine. About a month later, he began coughing one day and the cough gradually worsened over the next few days. We took him to our regular vet. She put him on a different antibiotic stating the one from surgery may have killed off good bacteria and this one should correct that. Within 10 days, he seemed perfectly normal again. About two weeks later, his cough returned and got really bad quickly. We took him to the emergency vet hospital and they diagnosed him with an enlarged heart. We took him back two days

later for an echo cardiogram and it confirmed it. His heart was more than double the normal size. He died three weeks later. Because [B6] had always had some apparent allergies, we at the suggestion of our first veterinarian, we put him on grain free dog food when he was about 3 years old. [B6] had regular check-ups, lived a great life with great care. Even when they did the [B6] surgery, they never detected any abnormalities with his heart. When this occurred, we were stunned, as this condition was usually attributed to a birth defect. Yet at no time did he every exhibit any issues that would have led anyone to believe this was congenital. It was not until this article, that I realized that we had switched [B6] to a different grain free dog food about 12 months before he died.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Fromm Family From the Heartland Grain Free Dog Food		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated

through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/6/2019 12:12:23 AM
Subject: Fromm Surf & Turf dry dog food; [B6] EON-375559
Attachments: 2060907-report.pdf; 2060907-attachments.zip

A PFR Report has been received and PFR Event [EON-375559] has been created in the EON System.

A "PDF" report by name "2060907-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 "2060907-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375559

ICSR #: 2060907

EON Title: PFR Event created for Fromm Surf & Turf dry dog food; 2060907

AE Date	10/30/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Pit Bull		
Age	8 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2060907

Product Group: Pet Food

Product Name: Fromm Surf & Turf dry dog food

Description: [B6] was slightly lethargic and upon veterinary examination, a new heart murmur was discovered. We scheduled an echocardiogram and she was diagnosed with Dilated Cardiomyopathy and a Mitral Valve Regurgitation. We sent her blood into UC Davis for a taurine test and her taurine levels were normal. It is suspected that her food caused this issue.

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
Fromm Surf & Turf dry dog food		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/3/2019 6:40:20 PM
Subject: GO Venison; [B6] EON-375313
Attachments: 2060813-report.pdf

A PFR Report has been received and PFR Event [EON-375313] has been created in the EON System.

A "PDF" report by name "2060813-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375313

ICSR #: 2060813

EON Title: PFR Event created for GO Venison; 2060813

AE Date	12/27/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	5 Years		
District Involved	PFR-Foreign Firms DO		

Product information

Individual Case Safety Report Number: 2060813

Product Group: Pet Food

Product Name: GO Venison

Description: [B6] has been eating grain free GO Venison since September 2014 up until November 2018 when we switched her to Hills Science Diet large breed chicken and barley. Her Taurine level in November 2017 was [B6]. She had an echocardiogram on December 27th and has been diagnosed with Taurine deficient dilated cardiomyopathy. It is recommended that she take Taurine and l-carnitine supplements daily and have another Taurine blood test in 3 months and a recheck cardiology examination and echocardiogram in 6 months.

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
GO Venison		

Sender information

B6

CAN

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 12/27/2018 3:56:41 PM
Subject: Homecooked diet - see diet history in medical record: Lisa Freeman - EON-374789
Attachments: 2060600-report.pdf; 2060600-attachments.zip

A PFR Report has been received and PFR Event [EON-374789] has been created in the EON System.

A "PDF" report by name "2060600-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060600-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374789

ICSR #: 2060600

EON Title: PFR Event created for Homecooked diet - see diet history in medical record; 2060600

AE Date	11/15/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060600

Product Group: Other

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

Description: Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts 12/5/18 and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet. WB taurine B6 plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Homecooked diet - see diet history in medical record		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 1/23/2019 10:32:40 PM
Subject: Honest Kitchen Grain Free Beef Recipe (Love) B6 EON-377314
Attachments: 2061661-report.pdf; 2061661-attachments.zip

A PFR Report has been received and Related PFR Event [EON-377314] has been created in the EON System.

A "PDF" report by name "2061661-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 "2061661-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377314

ICSR #: 2061661

EON Title: Related PFR Event created for Honest Kitchen Grain Free Beef Recipe (Love), Honest Kitchen Grain Free Turkey Recipe (Embark), Honest Kitchen Dehydrated Grain Free Veggie Nut & Seed Base Mix (Kindly), TruDog FEED ME Crunchy Mun.; 2061661

AE Date	07/11/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Recovered Completely
Breed	Pointing Dog - Hungarian Short-haired (Vizsla)		
Age	5 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2061661

Product Group: Pet Food

Product Name: Honest Kitchen Grain Free Beef Recipe (Love), Honest Kitchen Grain Free Turkey Recipe (Embark), Honest Kitchen Dehydrated Grain Free Veggie, Nut & Seed Base Mix (Kindly), TruDog FEED ME Crunchy Munchy Beef Bonanza

Description: Diagnosed with mild dilated cardiomyopathy, sinus bradycardia, first degree AV block; found to have taurine deficiency based on analysis of whole blood: **B6** nmol/mL). Update 10/22/18: Recheck whole blood taurine after diet change and oral supplementation: **B6** mol/nL Update 1/8/19: Unremarkable echocardiogram; DCM resolved

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: Recovered Completely

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Honest Kitchen Grain Free Turkey Recipe (Embark)		
Honest Kitchen Dehydrated Grain Free Veggie, Nut & Seed Base Mix (Kindly)		
TruDog FEED ME Crunchy Munchy Beef Bonanza		
Honest Kitchen Grain Free Beef Recipe (Love)		

This report is linked to:

Initial EON Event Key: EON-362411

Initial ICSR: 2053786

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

Rat

PR

QRSE

QT

QTc

--A

P

QRS

T

B6

B6

118787

1/8/2019

10:48:00 AM

B6

B6

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/3/2019 1:24:36 AM
Subject: Horizon Pulsar Chicken Flavor Dog Kibble: [B6] - EON-375244
Attachments: 2060788-report.pdf; 2060788-attachments.zip

A PFR Report has been received and PFR Event [EON-375244] has been created in the EON System.

A "PDF" report by name "2060788-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 "2060788-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375244

ICSR #: 2060788

EON Title: PFR Event created for Horizon Pulsar Chicken Flavor Dog Kibble; 2060788

AE Date	08/12/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	8 Years		
District Involved	PFR- [B6] DO		

Product information

Individual Case Safety Report Number: 2060788

Product Group: Pet Food

Product Name: Horizon Pulsar Chicken Flavor Dog Kibble

Description: Initially presented to the [B6] for a 4 to 5 day history of lethargy, increased RR and ADR. Had been fed a grain-free diet for an extended period of time. Was evaluated by the Cardiology Service and diagnosed with decreased systolic function and secondary heart enlargement. Chest x-rays from the rDVM raised suspicion for congestive heart failure. However, repeat chest x-rays at [B6] showed no evidence of CHF. During his hospitalization, [B6] experienced a syncopal episode secondary due to a run of ventricular tachycardia. He was started on heart failure therapy (pimobendan, furosemide, spironolcatone, enalapril) as well

as taurine supplementation and an anti-arrhythmic (sotalol). He was initially started on L-carnitine as well, but this medication caused GI side effects and was discontinued.

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
Horizon Pulsar Chicken Flavor Dog Kibble		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/4/2019 3:24:23 PM
Subject: Instinct by Nature's Variety Original Grain-Free Recipe with Real Chicken Dry Dog Food: [B6] - EON-375409
Attachments: 2060866-report.pdf; 2060866-attachments.zip

A PFR Report has been received and PFR Event [EON-375409] has been created in the EON System.

A "PDF" report by name "2060866-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 "2060866-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375409

ICSR #: 2060866

EON Title: PFR Event created for Instinct by Nature's Variety Original Grain-Free Recipe with Real Chicken Dry Dog Food Instinct by Nature's Variety Raw Boost Grain-Free Recipe with Real Chicken Dry Dog Food; 2060866

AE Date	04/14/2016	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Sheepdog - Shetland		
Age	8 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060866

Product Group: Pet Food

Product Name: Instinct by Nature's Variety Original Grain-Free Recipe with Real Chicken Dry Dog Food, Instinct by Nature's Variety Raw Boost Grain-Free Recipe with Real Chicken Dry Dog Food

Description: In April 2016, [B6] developed pancreatitis and her breathing was worsening. We brought her in for an ultrasound when we discovered she had fluid in her chest. The pleural effusion persisted from April 14, 2016

until her death on [B6] On April 23, 2016, we brought her to [B6] in [B6] and implanted pleural ports. Prior to the surgery, a cardiac consult was performed which revealed the start of mitral valve disease. In May 2016, we switched from Natures Variety Grain Free food to Royal Canin Prescription Low Fat Kibble. The pleural effusion persisted with no known cause, we tested for everything. In July 2018, she went into congestive heart failure and had an enlarged heart. Her fluid from the pleural effusion increased exponentially from 100 ml's every 2-3 weeks to 500-600 mls every 1-2 days. She was euthanized on [B6] due to fluid buildup in her lungs not responding to IV Lasix or Torsemide treatment.

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: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Instinct by Nature's Variety Original Grain-Free Recipe with Real Chicken Dry Dog Food, Instinct by Nature's Variety Raw Boost Grain-Free Recipe with Real Chicken Dry Dog Food		

Sender information

[B6]

USA

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

[B6]

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

[B6]

=====
This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade

secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/17/2019 9:00:20 PM
Subject: Merrick Good Earth Grain Free Pork Beef and Lamb Kibble; B6
- EON-376709
Attachments: 2061375-report.pdf

A PFR Report has been received and PFR Event [EON-376709] has been created in the EON System.

A "PDF" report by name "2061375-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376709

ICSR #: 2061375

EON Title: PFR Event created for Merrick Good Earth Grain Free Pork Beef and Lamb Kibble; 2061375

AE Date	12/05/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Shepherd Dog - Australian		
Age	2 Years		
District Involved	PFR-Seattle DO		

Product information

Individual Case Safety Report Number: 2061375

Product Group: Pet Food

Product Name: Merrick Good Earth Grain Free Pork Beef and Lamb Kibble

Description: Diagnosed with dilated cardiomyopathy. Diet: Merrick's Good Earth Grain Free Pork Beef and Lamb kibble

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Merrick Good Earth Grain Free Pork Beef and Lamb Kibble		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/9/2019 2:56:32 PM
Subject: Merrick Grain-Free Chicken and Sweet Potato: [B6] - EON-375900
Attachments: 2061013-report.pdf; 2061013-attachments.zip

A PFR Report has been received and PFR Event [EON-375900] has been created in the EON System.

A "PDF" report by name "2061013-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 "2061013-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375900

ICSR #: 2061013

EON Title: PFR Event created for Merrick Grain-Free Chicken and Sweet Potato; 2061013

AE Date	08/21/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Recovered Completely
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061013

Product Group: Pet Food

Product Name: Merrick Grain-Free Chicken and Sweet Potato

Description: Critically Low Taurine Levels in both dogs [B6] for one and [B6] for the other on this diet, Merrick Grain-Free Chicken and Sweet Potato

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Recovered Completely

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Merrick Grain-Free Chicken and Sweet Potato		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/18/2019 11:48:22 PM
Subject: Merrick Limited Ingredient Diet Grain-Free Real Lamb & Sweet Potatoes Recipe Dry Dog Food [B6] - EON-376853
Attachments: 2061474-report.pdf

A PFR Report has been received and PFR Event [EON-376853] has been created in the EON System.

A "PDF" report by name "2061474-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376853

ICSR #: 2061474

EON Title: PFR Event created for Merrick Limited Ingredient Diet Grain-Free Real Lamb & Sweet Potatoes Recipe Dry Dog Food 22 l, Nature's Variety Instinct Limited Ingredient Diet Lamb Meal & Peas given ~2014 through 03/15/2016; 2061474

AE Date	[B6]	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Mixed (Dog)		
Age	9 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061474

Product Group: Pet Food

Product Name: Merrick Limited Ingredient Diet Grain-Free Real Lamb & Sweet Potatoes Recipe Dry Dog Food, 22 l, Nature's Variety Instinct Limited Ingredient Diet Lamb Meal & Peas given ~2014 through 03/15/2016

Description: [B6] had just turned 9 years old and was fine. She still played with toys, had lots of energy, took long daily walks, and was in good health. She was a happy rambunctious dog. Overnight she became ill with an enlarged heart. She was coughing, had trouble breathing, lost her appetite and had no energy. I took her to her vet and was told she needed to be seen by the cardiologist at [B6] immediately. She had an

enlarged heart, fluid on her lungs, and a leaky valve. Although she was on a heavy regimen of prescription drugs (increased in frequency and strength over time), and had frequent follow up visits with the cardiologists at

B6 she grew weaker over time and her heart eventually gave out after a **B6** month battle with DCM.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Nature's Variety Instinct Limited Ingredient Diet Lamb Meal & Peas given ~2014 through 03/15/2016		
Merrick Limited Ingredient Diet Grain-Free Real Lamb & Sweet Potatoes Recipe Dry Dog Food, 22 l		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be

shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 1/8/2019 6:36:20 PM
Subject: Natural Balance L.I.D. Limited Ingredient Diets- Sweet Potato & Fish Dry Dog Formula [REDACTED] B6 - EON-375818
Attachments: 2060968-report.pdf

A PFR Report has been received and PFR Event [EON-375818] has been created in the EON System.

A "PDF" report by name "2060968-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375818

ICSR #: 2060968

EON Title: PFR Event created for Natural Balance L.I.D. Limited Ingredient Diets® Sweet Potato & Fish Dry Dog Formula; 2060968

AE Date	05/01/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Terrier - Boston		
Age	8 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2060968

Product Group: Pet Food

Product Name: Natural Balance L.I.D. Limited Ingredient Diets® Sweet Potato & Fish Dry Dog Formula

Description: Our dog has been eating a grain-free food (Natural Balance) since she was a puppy. She was recently diagnosed with a heart murmur and enlarged heart. This is unusual in her breed, and has been associated with grain free foods by the FDA. If possible, I would like assistance with testing expenses.

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
Natural Balance L.I.D. Limited Ingredient Diets® Sweet Potato & Fish Dry Dog Formula		

Sender information

B6

USA

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

B6

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

B6

=====
This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/1/2019 9:24:38 PM
Subject: Orijen Adult Original dry (until Aug 2018): Lisa Freeman - EON-375110
Attachments: 2060739-report.pdf; 2060739-attachments.zip

A PFR Report has been received and PFR Event [EON-375110] has been created in the EON System.

A "PDF" report by name "2060739-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 "2060739-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375110

ICSR #: 2060739

EON Title: PFR Event created for Orijen Adult Original dry (until Aug 2018); 2060739

AE Date	12/19/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Terrier - Border		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060739

Product Group: Pet Food

Product Name: Orijen Adult Original dry (until Aug 2018)

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen Adult Original dry (until Aug 2018)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/1/2019 9:48:33 PM
Subject: Orijen grain free original dry: Lisa Freeman - EON-375114
Attachments: 2060741-report.pdf; 2060741-attachments.zip

A PFR Report has been received and PFR Event [EON-375114] has been created in the EON System.

A "PDF" report by name "2060741-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 "2060741-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375114

ICSR #: 2060741

EON Title: PFR Event created for Orijen grain free original dry; 2060741

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	9 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060741

Product Group: Pet Food

Product Name: Orijen grain free original dry

Description: DCM and CHF diagnosed [B6] at emergency clinic. Started on furosemide, diltiazem, digoxin, pimobendan Seen by Tufts cardiology [B6]. Eating Orijen grain free original dry so unclear if just genetically associated DCM or if diet associated.

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
Orijen grain free original dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/27/2018 3:00:35 PM
Subject: Orijen Original dry: Lisa Freeman - EON-374783
Attachments: 2060598-report.pdf; 2060598-attachments.zip

A PFR Report has been received and PFR Event [EON-374783] has been created in the EON System.

A "PDF" report by name "2060598-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 "2060598-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374783

ICSR #: 2060598

EON Title: PFR Event created for Orijen Original dry; 2060598

AE Date	10/05/2017	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mixed (Dog)		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060598

Product Group: Pet Food

Product Name: Orijen Original dry

Description: DCM diagnosed 10/2017. We saw July 2018 Originally feeding Orijen original dry since he was a puppy. Started taurine at time of diagnosis (10/2017). Heart improved significantly between echoes. Changed to Purina Proplan Adult 7+ July 2018. Will be rechecking soon.

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
Orijen Original dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/14/2019 10:08:36 PM
Subject: Taste of the Wild Sierra Mountain dry: Lisa Freeman - EON-376361
Attachments: 2061171-report.pdf; 2061171-attachments.zip

A PFR Report has been received and PFR Event [EON-376361] has been created in the EON System.

A "PDF" report by name "2061171-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 "2061171-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376361

ICSR #: 2061171

EON Title: PFR Event created for Taste of the Wild Sierra Mountain dry; 2061171

AE Date	01/02/2019	Number Fed/Exposed	7
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061171

Product Group: Pet Food

Product Name: Taste of the Wild Sierra Mountain dry

Description: Eating Taste of the Wild Sierra Mountain since June 2018 (Acana Heritage Poultry before that). This diet was fed to multiple dogs - have not screened other dogs yet so unknown whether they are also affected. Echo showed reduced contractility and mild left atrial enlargement. BNP and troponin mildly elevated, troponin =0.547. Taurine WNL (88 and 250) Changing to Pro Plan Sensitive Skin/Stomach dry and will recheck in 3 months

Submission Type: Initial

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

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

Number of Animals Treated With Product: 7

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Sierra Mountain dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/15/2019 8:56:35 PM
Subject: Zignature - various flavors (venison: Lisa Freeman - EON-376446
Attachments: 2061214-report.pdf; 2061214-attachments.zip

A PFR Report has been received and PFR Event [EON-376446] has been created in the EON System.

A "PDF" report by name "2061214-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 "2061214-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376446

ICSR #: 2061214

EON Title: PFR Event created for Zignature - various flavors (venison goat kangaroo lamb turkey pork); 2061214

AE Date	01/09/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061214

Product Group: Pet Food

Product Name: Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)

Description: 2 syncopal episodes in summer got echo in October 2018 and arrhythmia identified Feeding BEG diets all of her life (Zignature) DCM and VPCs identified 1/9/19 Owner changing to Purina EN Fiber and we will recheck in 3 months BNP elevated, troponin and taurine pending

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
Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/14/2019 10:24:45 PM
Subject: Zignature kangaroo dry: Lisa Freeman - EON-376363
Attachments: 2061172-report.pdf; 2061172-attachments.zip

A PFR Report has been received and PFR Event [EON-376363] has been created in the EON System.

A "PDF" report by name "2061172-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 "2061172-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376363

ICSR #: 2061172

EON Title: PFR Event created for Zignature kangaroo dry; 2061172

AE Date	04/11/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061172

Product Group: Pet Food

Product Name: Zignature kangaroo dry

Description: Eating BEG diet; developed DCM and CHF 4/11/18 Owner changed diet to Royal Canin Early Cardiac and dog has improved significantly. Will recheck again in 3 months. Have not gotten approval for you to contact owner but sent an email today

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 dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/4/2019 7:40:21 PM
Subject: 4 Health Untamed: [B6] - EON-375466
Attachments: 2060874-report.pdf

A PFR Report has been received and PFR Event [EON-375466] has been created in the EON System.

A "PDF" report by name "2060874-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375466

ICSR #: 2060874

EON Title: PFR Event created for 4 Health Untamed; 2060874

AE Date	12/08/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Shepherd Dog - German		
Age	6 Years		
District Involved	PFR-Foreign Firms DO		

Product information

Individual Case Safety Report Number: 2060874

Product Group: Pet Food

Product Name: 4 Health Untamed

Description: Since my dog was about a year or so old, he has been eating the Tractor Supply Co. brand of Dog Food, 4Health grain-free and Untamed. Starting in December 2018, my dog developed a cough, stopped eating, and experienced difficulty breathing. He was seen by a veterinarian December 20th. He had blood work done which was unremarkable, his radiograph of his chest showed an enlarged heart with pulmonary edema. He was then started on cardiac medications, and sent to a cardiologist for an echocardiogram. The echo confirmed the diagnosis of Dilated Cardiomyopathy. This is when the topic of grain-free diet associated DCM came up. My Vet recommended supplementing Taurine into his diet, switching to a mainstream brand of dog food that has participated in nutritional research, and limiting his physical activity. We are hoping for the best but he is in

rough shape. We will recheck the echocardiogram in 3 months to see if there have been any improvements. I hope this will help with any research ongoing with this issue. Please let me know if there is any more info I can provide or any additional research that has been done. Thank you. B6

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4 Health Untamed		

Sender information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/23/2019 7:12:35 PM
Subject: Natural Balance Lamb and Brown Rice: [B6] - EON-377272
Attachments: 2061634-report.pdf; 2061634-attachments.zip

A PFR Report has been received and Related PFR Event [EON-377272] has been created in the EON System.

A "PDF" report by name "2061634-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 "2061634-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377272

ICSR #: 2061634

EON Title: Related PFR Event created for Natural Balance Lamb and Brown Rice, Merrick Lamb Peas and Ancient Grains, Zignature Fish; 2061634

AE Date	08/13/2014	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	10 Years		
District Involved	PFR-Baltimore DO		

Product information

Individual Case Safety Report Number: 2061634

Product Group: Pet Food

Product Name: Natural Balance Lamb and Brown Rice, Merrick Lamb, Peas, and Ancient Grains, Zignature Fish

Description: Presented for increased respiratory rate and effort at rest and exercise intolerance; was diagnosed with DCM and ventricular premature complexes of left bundle branch block morphology; was started on Pimobendan, enalapril, furosemide, and Taurine supplementation. 09/17/2018: [B6] was changed to

NutriSource Chicken and Rice - developed diarrhea. 10/6/2018: **B6** was changed to Instinct - developed diarrhea. 11/7 - 11/11/2018: **B6** was transitioned to Royal Canin KP Hydrolyzed Protein.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Natural Balance Lamb and Brown Rice		
Zignature Fish		
Merrick Lamb, Peas, and Ancient Grains		

This report is linked to:

Initial EON Event Key: EON-364756

Initial ICSR: 2054795

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/14/2019 5:08:21 PM
Subject: Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula; [B6]
[B6] - EON-376311
Attachments: 2061163-report.pdf

A PFR Report has been received and PFR Event [EON-376311] has been created in the EON System.

A "PDF" report by name "2061163-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376311

ICSR #: 2061163

EON Title: PFR Event created for Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula;
2061163

AE Date	11/15/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Mixed (Dog)		
Age	7 Years		
District Involved	PFR-Atlanta DO		

Product information

Individual Case Safety Report Number: 2061163

Product Group: Pet Food

Product Name: Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula

Description: After about a year on Balanced Diet Grain Free Dog Food - Salmon and Sweet Potato formula - Dog started having coughing symptoms. Upon evaluation at the vet it was determined she was heart worm free with an enlarged hear upon Xray. Dog was put on two hear medications and referred for ultrasound. Ultrasound determined mitral valve disease and congestive heart failure

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/11/2019 5:12:22 PM
Subject: Now Fresh Grain Free Adult Dog Food-Now Fresh Grain Free Puppy Food: [B6]- EON-376136
Attachments: 2061092-report.pdf

A PFR Report has been received and PFR Event [EON-376136] has been created in the EON System.

A "PDF" report by name "2061092-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376136

ICSR #: 2061092

EON Title: PFR Event created for Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food; 2061092

AE Date	12/03/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061092

Product Group: Pet Food

Product Name: Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food

Description: Patient has been on Now Fresh Grain Free adult dog food/puppy dog food since purchased from breeder at approximately 16 weeks of age. P has developed, and confirmed by echocardiogram by boarded veterinary cardiologist, changes consistent with Nutritional Cardiomyopathy. P is currently on taurine supplementation and food has been changed to non grain-free diet, recheck echo planned for March/April 2019.

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
Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/3/2019 12:52:20 AM
Subject: Nutrisource Small and Medium Breed Puppy Grain Free Dog Food; [B6]
[B6] EON-375242
Attachments: 2060786-report.pdf

A PFR Report has been received and PFR Event [EON-375242] has been created in the EON System.

A "PDF" report by name "2060786-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375242

ICSR #: 2060786

EON Title: PFR Event created for Nutrisource Small and Medium Breed Puppy Grain Free Dog Food; 2060786

AE Date	01/02/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Mixed (Dog)		
Age	9 Months		
District Involved	PFR-Kansas City DO		

Product information

Individual Case Safety Report Number: 2060786

Product Group: Pet Food

Product Name: Nutrisource Small and Medium Breed Puppy Grain Free Dog Food

Description: [B6] 9 month old labradoodle, has been fed Nutrisource grain free small/medium breed puppy food since weaning. For the past 4-5 months it had been noticed that [B6] was often short of breath and had a rapid heart rate. After being taken to the vet, a grade 2 murmur was found leading to the finding of cardiomyopathy. Awaiting echocardiogram. Advised by veterinarian to switch dog food to researched and approved brand because adverse health effects related to foods with lentils, such as the one [B6] was on.

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
Nutrisource Small and Medium Breed Puppy Grain Free Dog Food		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 12/29/2018 9:24:22 AM
Subject: NutriSource Super Premium Pet Foods: [REDACTED] B6 - EON-374952
Attachments: 2060676-report.pdf

A PFR Report has been received and PFR Event [EON-374952] has been created in the EON System.

A "PDF" report by name "2060676-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374952

ICSR #: 2060676

EON Title: PFR Event created for NutriSource Super Premium Pet Foods; 2060676

AE Date	12/17/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	11 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2060676

Product Group: Pet Food

Product Name: NutriSource Super Premium Pet Foods

Description: Dog is a mixed breed: golden retriever and poodle hybrid (goldendoodle). He has developed heart disease (DCM) on the diet. Was told it is most likely related to taurine deficiency. Have put him on heart medication and a taurine supplement. Have already seen marked improvement in his demeanor. EKG to see if taurine supplement has reversed heart disease in 3-6 months.

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
NutriSource Super Premium Pet Foods		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/8/2019 11:00:19 PM
Subject: NWBARBF-Beef Recipe for Dogs-Ground Bone Added-Not for Human Consumption-Made in the USA by Northwest Naturals; B6
EON-375869
Attachments: 2060992-report.pdf

A PFR Report has been received and PFR Event [EON-375869] has been created in the EON System.

A "PDF" report by name "2060992-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375869

ICSR #: 2060992

EON Title: PFR Event created for NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals; 2060992

AE Date	11/14/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Retriever - Golden		
Age	8 Years		
District Involved	PFR-Atlanta DO		

Product information

Individual Case Safety Report Number: 2060992

Product Group: Pet Food

Product Name: NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals

Description: Whole Blood Taurine was 224 Plasma Taurine was 90

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

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

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

Sent: 1/4/2019 12:52:23 PM

Subject: Orijen Regional Red Dry Dog Food-Fromm Beef Frittata A La Veg Dry Dog Food-From Duck & Sweet Potato Dry Dog Food-Purina Fortiflora: B6
B6 - EON-375393

Attachments: 2060845-report.pdf; 2060845-attachments.zip

A PFR Report has been received and Related PFR Event [EON-375393] has been created in the EON System.

A "PDF" report by name "2060845-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 "2060845-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375393

ICSR #: 2060845

EON Title: Related PFR Event created for Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora; 2060845

AE Date	10/25/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR: B6 DO		

Product information

Individual Case Safety Report Number: 2060845

Product Group: Pet Food

Product Name: Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora

Description: This submission is in furtherance of your nutritionally-mediated DCM investigation. My young,

energetic and very healthy Golden Retriever male had his second echocardiogram on Thursday, October 25, 2018. His first was approximately one year ago in September 2017. The 2017 echo was normal. The one from last week was not. It showed a subjective increase in sphericity of his heart, as well as mild systolic dysfunction compared with last year. ACK!!! His whole blood taurine level at U.C. Davis was 226 in September 2018. I had scheduled echocardiograms for [B6] and my other two Golden Retrievers out of an abundance of caution after two ([B6] and his littermate brother) tested below 250 nmol/ml for taurine in whole blood). I'm glad I did. My veterinary cardiologist is [B6] DVM ACVIM (Cardiology) of [B6]. At last week's echocardiogram, he drew blood for CBC, chemistry, a repeat of the taurine test with paired samples, a full tick-borne disease panel, and thyroid tests. All test results are in except for the repeat taurine test from [B6]. [B6] All [B6] results were unremarkable or normal, except for a slightly low globulin level. That test will be repeated this week. I never purposely fed a "grain-free" food or an "exotic protein" food. I'm a physicist and I believe in science and common sense. HOWEVER, after FDA's investigation was announced, I noted that some of the commercial food I was feeding [B6] (which I thought was perfectly conventional) met the FDA's description of "suspect diets". In addition, I had been giving my three Golden Retrievers a probiotic from Purina -- their Fortiflora product -- as a routine part of feeding after a period in which all three dogs had loose stool and diarrhea. I added the Fortiflora to their food for a period of over a year. I think the current thinking on this issue is that it's multifactorial, I wanted to mention first that I had added the Fortiflora and that while I didn't purposely choose a grain-free food (high in legumes), I've also found that the food itself has added "probiotics". I was surprised to see that. Now, I wonder if my accidental food choice for him, plus my "probiotic" supplement, changed something in how his body processed the taurine precursors and dietary taurine. In addition, he's definitely an "easy-keeper", eating nowhere near the amount of food advised on the bag. After his "equivocal" taurine level in mid-September 2018, I stopped feeding Fortiflora to all three Golden Retrievers. Their stool is perfectly fine, perhaps even better. I changed [B6] diet from Fromm to Purina ProPlan Sport 30/20 at the same time. Please do get in touch if there's any further information you require or that you might provide me. Obviously, I hope this is diet-related and can be reversed. FOLLOW UP -- JANUARY 3, 2019 ECHOCARDIOGRAM Hey, good news. After 90 days of diet change, 8 weeks of taurine supplementation, and 6 weeks of l-carnitine supplementation, [B6] echocardiographic findings are either within normal limits or are improving. I will attach his cardiologist's detailed report. I'm delighted, of course.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora		

This report is linked to:

Initial EON Event Key: EON-370539

Initial ICSR: 2058584

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/22/2019 10:12:20 PM
Subject: Rachel Ray's only six - EON-377164
Attachments: 2061580-report.pdf

A PFR Report has been received and PFR Event [EON-377164] has been created in the EON System.

A "PDF" report by name "2061580-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377164

ICSR #: 2061580

EON Title: PFR Event created for Rachel Ray's only six; 2061580

AE Date	09/12/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Chihuahua		
Age	10 Years		
District Involved	PFR- B6 DO		

Product information

Individual Case Safety Report Number: 2061580

Product Group: Pet Food

Product Name: Rachel Ray's only six

Description: dog began coughing at night. very did x-ray and listened; heart murmur which wasn't evident six months earlier, enlarged heart and connection which was also new. began feeding dog grain free food one year ago. dogs heart was healthy at that time at vet visit. have since been prescribed vetmedin and am switching back to mixed diet.

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Rachel Ray's only six		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/8/2019 10:44:21 PM
Subject: Stella & Chewy's -Frozen Raw -Stella's Super Beef -Dinner Patties; B6
B6 -EON-375865
Attachments: 2060990-report.pdf

A PFR Report has been received and PFR Event [EON-375865] has been created in the EON System.

A "PDF" report by name "2060990-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375865

ICSR #: 2060990

EON Title: PFR Event created for Stella & Chewy's Frozen Raw Stella's Super Beef Dinner Patties; 2060990

AE Date	11/14/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Not Applicable
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-Atlanta DO		

Product information

Individual Case Safety Report Number: 2060990

Product Group: Pet Food

Product Name: Stella & Chewy's Frozen Raw Stella's Super Beef Dinner Patties

Description: Whole Blood Taurine Level was 204 Plasma Taurine Level was 79

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Not Applicable

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Stella & Chewy's Frozen Raw Stella's Super Beef Dinner Patties		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/22/2019 11:08:32 PM
Subject: Taste of the Wild High Prairie grain-free with roasted bison and roasted venison: [B6] - EON-377174
Attachments: 2061583-report.pdf

A PFR Report has been received and PFR Event [EON-377174] has been created in the EON System.

A "PDF" report by name "2061583-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377174

ICSR #: 2061583

EON Title: PFR Event created for Taste of the Wild High Prairie grain-free with roasted bison and roasted venison; 2061583

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mixed (Dog)		
Age	11 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061583

Product Group: Pet Food

Product Name: Taste of the Wild High Prairie grain-free with roasted bison and roasted venison

Description: Anorexia, lethargy and abdominal distention noted 6 days before presentation to the ER. He was diagnosed with chronic degenerative valve disease, Dilated cardiomyopathy, myocardial dysfunction, congestive heart failure, both left- and right-sided, atrial fibrillation,

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie grain-free with roasted bison and roasted venison		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/22/2018 10:28:56 PM
Subject: Taste of the Wild Prey [B6] - EON-374547
Attachments: 2060525-report.pdf

A PFR Report has been received and PFR Event [EON-374547] has been created in the EON System.

A "PDF" report by name "2060525-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374547

ICSR #: 2060525

EON Title: PFR Event created for Taste of the Wild Prey; 2060525

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Terrier - Bull - Staffordshire		
Age	2 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2060525

Product Group: Pet Food

Product Name: Taste of the Wild Prey

Description: Patient presented on [B6] with a 10 day history of reduced appetite and an episode of diarrhea 2 weeks prior. Prior to presentation he was found to be very lethargic with a distended abdomen. Patient was found to have changes consistent with dilated cardiomyopathy were severe pump dysfunction and biventricular congestive heart failure. Had been given a grain free diet for over a year (Tate of the Wild Prey). The abdomen was drained of about 2.6 L for comfort. The patient initially responded favorably but died suddenly the next morning with an acute onset of respiratory difficulty. Contacted Jennifer Jones, DVM who recommended a complaint be submitted and obtained tissue samples from the pet even though a full necropsy was unable to be performed.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Prey		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/24/2019 4:28:19 PM
Subject: Taste of the Wild Sierra Mountain: [B6] - EON-377360
Attachments: 2061702-report.pdf

A PFR Report has been received and PFR Event [EON-377360] has been created in the EON System.

A "PDF" report by name "2061702-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377360

ICSR #: 2061702

EON Title: PFR Event created for Taste of the Wild Sierra Mountain; 2061702

AE Date	07/01/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Bulldog		
Age	10 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061702

Product Group: Pet Food

Product Name: Taste of the Wild Sierra Mountain

Description: Diet for entire life consisted of grain free food. Started in July to have labored breathing with an occasional gag. Activity level had decreased. X-rays showed displacement of trachea. Vet treated for pneumonia due to white areas of lung. Finally got an echocardiogram and the diagnosis was Dilated Cardiomyopathy. Tests also showed his liver, spleen, and caudal vena cava were enlarged. The last week of life, he could not lay down but would just stand and pant. When it got so bad, I chose to let him be euthanized.

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: 5

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Sierra Mountain		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/22/2018 3:44:09 PM
Subject: Taste of the Wild Wetlands Canine Formula with roasted Fowl; [B6]
- EON-374534
Attachments: 2060519-report.pdf

A PFR Report has been received and PFR Event [EON-374534] has been created in the EON System.

A "PDF" report by name "2060519-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374534

ICSR #: 2060519

EON Title: PFR Event created for Taste of the Wild Wetlands Canine Formula with roasted Fowl; 2060519

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Retriever - Golden		
Age	6 Years		
District Involved			

Product information

Individual Case Safety Report Number: 2060519

Product Group: Pet Food

Product Name: Taste of the Wild Wetlands Canine Formula with roasted Fowl

Description: On third and final visit to vet due to heavy panting, difficulty breathing, and collapse the vet started an IV to hydrate her and found excessive fluid around the heart in x-ray. Sent us to emergency pet hospital which eventually asked us if we wanted to have them insert breathing tube to aid her struggle to breathe. Eventually, put her down because decided to discontinue breathing assistance.

Submission Type: Initial

Report Type: Both

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Wetlands Canine Formula with roasted Fowl		

Sender information

B6

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/15/2019 11:08:32 PM
Subject: Taste of the Wild.; [B6] - EON-376466
Attachments: 2061221-report.pdf; 2061221-attachments.zip

A PFR Report has been received and PFR Event [EON-376466] has been created in the EON System.

A "PDF" report by name "2061221-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 "2061221-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376466

ICSR #: 2061221

EON Title: PFR Event created for Taste of the Wild.; 2061221

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061221

Product Group: Pet Food

Product Name: Taste of the Wild.

Description: [B6] presented on emergency for lethargy, hyporexia, and tachypnea. Diagnostics testing (echocardiogram) revealed Dilated Cardiomyopathy. It was discovered that [B6] had been on a grain free diet.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild.		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/26/2018 4:36:21 PM
Subject: Taste of the Wild: [B6] - EON-374698
Attachments: 2060561-report.pdf

A PFR Report has been received and PFR Event [EON-374698] has been created in the EON System.

A "PDF" report by name "2060561-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374698

ICSR #: 2060561

EON Title: PFR Event created for Taste of the Wild; 2060561

AE Date	03/01/2016	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Other
Breed	Boxer (German Boxer)		
Age	[B6] Years		
District Involved	PFR- [B6] DO		

Product information

Individual Case Safety Report Number: 2060561

Product Group: Pet Food

Product Name: Taste of the Wild

Description: Started feeding him Taste of the Wild bison formula on 03/2016. On 11/2016 we started to notice a decrease in his activity level and his health in general. After undergoing several test on 05/2018 we were told that he had now an enlarged heart. Something that was not detected previously. We finally determined that it was the food we were feeding him that was causing all the problems. We change the food we were feeding him but the damage had already been done. Sadly he passed away on [B6] while playing in the park.

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
Taste of the Wild		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 1/22/2019 9:08:23 PM
Subject: Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food: [REDACTED] B6
EON-377156
Attachments: 2061571-report.pdf; 2061571-attachments.zip

A PFR Report has been received and PFR Event [EON-377156] has been created in the EON System.

A "PDF" report by name "2061571-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 "2061571-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377156

ICSR #: 2061571

EON Title: PFR Event created for Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food 23.5-lb bag by CANIDAE, Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food 27-lb bag; 2061571

AE Date	12/26/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Shepherd Dog - Australian		
Age	11 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2061571

Product Group: Pet Food

Product Name: Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food, 23.5-lb bag by CANIDAE, Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food, 27-lb bag

Description: [REDACTED] B6 has NEVER had a heart issue and has been fed a grain free diet for several years at least (two different brands, which I purchased from Chewy.com) - and she developed a heart murmur just recently (valve issue), and an irregular heartbeat just recently. This was first noticed in December 2018, at a mostly routine visit;

and then the specialist told me that the grain free diets could be linked. We visited the specialist in January 2019.

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
Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food, 23.5-lb bag by CANIDAE		
Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food, 27-lb bag		

Sender information

B6

USA

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

B6

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

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] **B6**
Sent: 1/24/2019 4:20:22 PM
Subject: Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs; [REDACTED] **B6** EON-377359
Attachments: 2061700-report.pdf; 2061700-attachments.zip

A PFR Report has been received and PFR Event [EON-377359] has been created in the EON System.

A "PDF" report by name "2061700-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 "2061700-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377359

ICSR #: 2061700

EON Title: PFR Event created for Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs; 2061700

AE Date	12/23/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Shepherd Dog - German		
Age	3 Years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2061700

Product Group: Pet Food

Product Name: Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs

Description: [REDACTED] **B6** began vomiting once a day for a few days, then it progressed to a couple of times a day. Her energy seemed to dissipate too...she was lethargic, depressed. I was contacting the vet via email and inquiring on ideas of what was going on. We put her on a bland rice/egg diet for a week, but no change was noted...other than

a new symptom occurred of her panting a lot. When [B6] started to noticeably lose weight, I immediately took her into the vet for a physical exam. She had dropped 9 lbs from the previous visit of two months earlier! The vet kept us there most of the day running blood work, etc. Everything came back fine. When xrays were performed, it was clear what the problem was. [B6] heart was clearly enlarged. Where it normally was supposed to be within 3 ribs, it was over 5 ribs and encroaching on her other organs! The vet immediately suspected it was the grain-free kibble (Wholesomes Food For Dogs Chickmeal and Chickpea formula: Grain-free/Gluten-free that I purchased at Tractor Supply) that I had her on...and she prescribed her heart meds, an antibiotic (going the remedial course as if peritonitis as a secondary diagnosis), and a medication to alleviate the nausea. We purchased Purina dogfood and immediately fed it to her...and she is still on it to this very day. [B6] is still throwing up occasionally, but the vet assured me that if her heart heals this will lessen.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs		

Sender information

[B6]

USA

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

[B6]

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

[B6]

=====
This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

B6

From: Darcy Adin <dbadin@ncsu.edu>
To: Lisa Freeman; [REDACTED] **B6** jstem@ucdavis.edu; rfries@illinois.edu;
[REDACTED] **B6**
CC: Jones, Jennifer L
Sent: 4/18/2018 11:09:14 AM
Subject: Diet DCM Call

Hi All,

We had originally proposed [REDACTED] **B5**
[REDACTED] **B5** would work for you all.

I'm going to pick [REDACTED] **B5** - please let me know if you can talk then or if a different time is better. I'm available throughout the day.

Thanks Everyone!
Darcy

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L; Darcy Adin; Joshua A Stern; Fries, Ryan C; [REDACTED] **B6**
CC: Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 5/24/2018 7:21:01 PM
Subject: diet related DCM - a couple forms
Attachments: diet history form 5-24-18 external.doc; protocol NP 5-17-18.docx

Hi everyone

B5

I'm working on the editorial which will include a writable pdf version of the diet history form (Josh and Darcy – you'll be hearing from me soon)

Thanks
Lisa

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

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]
Sent: Friday, April 20, 2018 3:50 PM
To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6** [REDACTED] **B6** [REDACTED] **B6**
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: hold-call with Dr. Adin re: DCM cases
Importance: High

My apologies for the repeat email. After further internal discussion, [REDACTED] **B5** [REDACTED] you can just email me a spreadsheet with the data.

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



From: Jones, Jennifer L
Sent: Friday, April 20, 2018 1:19 PM
To: 'Darcy Adin' <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6** [REDACTED] **B6** [REDACTED] **B6** [REDACTED] **B6**
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

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

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

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

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

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



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

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

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

B6

B6

B6

Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>

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

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

B6

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

B6

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

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

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

Sincerely,
Darcy Adin

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

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

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

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

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

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

Join WebEx meeting

Meeting number (access code):

Meeting password:

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

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

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

--

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

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

B5

Document properties

Author: Reed Elsevier
Company: Reed Elsevier
Template: Normal.dotm
Page count: 1
Paragraph count: 62
Line count: 112
Word count: 438
Character count (spaces excluded): 3088
Character count (spaces included): 3638

DCM Protocol (canine and feline)

B5

Document properties

Author: Freeman, Lisa
Template: Normal.dotm
Page count: 1
Paragraph count: 29
Line count: 39
Word count: 268
Character count (spaces excluded): 1160
Character count (spaces included): 1406

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
Sent: 5/11/2018 10:05:00 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; [REDACTED] **B6**
Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@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: Dilated Cardiomyopathy
Start: 5/18/2018 5:00:00 PM
End: 5/18/2018 6:00:00 PM
Recurrence: (none)
Meeting Status: Accepted

Required Attendees: Rotstein, David; [REDACTED] **B6** Jones, Jennifer L; Hartogensis, Martine; Carey, Lauren; Burkholder, William; Palmer, Lee Anne; Norris, Anne; DeLancey, Siobhan; Lovell, Randall A
Optional Attendees: Atkinson, Kristina Z

Good Afternoon,

Please join us for a discussion of dilated cardiomyopathy cases and current knowledge.

Agenda:

1. Roll Call and Introduction (CVM)
2. CVCA Case discussion (CVCA)
3. CVM/CVM Vet-LIRN Case Information (Vet-LIRN/DVPS/CERT)
4. Open Discussion

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

Join WebEx meeting

Meeting number (access code) [REDACTED] **B6**
Meeting password: [REDACTED] **B6**

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Can't join the meeting?

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

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

From: [redacted] B6
To: Peloquin, Sarah [redacted] B6
CC: Jones, Jennifer L; jstem@ucdavis.edu
Sent: 3/8/2019 12:37:17 AM
Subject: [redacted] B6
Attachments: [redacted] B6 [redacted] B6 3.7.19.Cardiology Echocardiogram Report
(recheck)sarah.peloquinFDA.hhs.gov.pdf

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
Sent: 10/22/2014 10:16:29 AM
Subject: EON-183693-ICSR-1036446 **B6** Purina Whisker licks
Attachments: 1036446-report.pdf.html

This is an interesting one!!!

11 YO NM

Product Information:

LIVER, WHEAT FLOUR, CORN GLUTEN MEAL, CHICKEN BY-PRODUCT MEAL, WATER, BEEF TALLOW PRESERVED WITH BHA, GLYCERIN, PHOSPHORIC ACID, CALCIUM SULFATE, HYROGENATED STARCH HYDROLYSATE, SALT, SOY PROTEIN ISOLATE, SORBIC ACID (PRESERVATIVE), ADDED COLOR (RED 40 AND OTHER COLOR), POTASSIUM PHOSPHATE, DRIED CHEESE POWDER, CHOLINE CHLORIDE, PROPIONIC ACID (PRESERVATIVE), TAURINE, ZINC SULFATE, FERROUS SULFATE, NIACIN, CALCIUM PANTOTHENATE, ETHOXYQUIN (PRESERVATIVE), VITAMIN SUPPLEMENTS (E, B12, D3), MANGANESE SULFATE, RIBOFLAVIN SUPPLEMENT, BIOTIN, FOLIC ACID, COPPER SULFATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE MONONITRATE, MENADIONE SODIUM BISULFITE COMPLEX (SOURCE OF VITAMIN K ACTIVITY), CALCIUM IODATE, SODIUM SELENITE.

Analysis:

Moisture (maximum)34.00%
Crude Fat (minimum)8.50%
Crude Fiber (maximum)1.00%
Crude Protein (minimum)23.00%<BR< div>



Comment:

Site of manufacture- couldn't find this, but that won't tell us about the ingredients (e.g., glycerin).

Recommend:

MRx

Urine

Exposure history (make sure no other exposures)

Treat collection with lot code evaluation*

*If this case pans out and we have lot information, we may be able to get the district to find out about product manufacture/ingredient sources

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM OSC/DC/ICERT
7519 Standish Place, RM 120

240-276-9213 (Office and Fax)

B6

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

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]

Sent: Tuesday, October 21, 2014 6:20 PM

To: **B6**

Subject: Purina Whisker lickins: **B6**

A PFR Report has been received and PFR Event [EON-183693] has been created in the EON System

A "PDF" report by name "1036446-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report

EON Key: EON-183693

EON Title: PFR Event created for Purina Whisker lickins chicken and cheese flavors soft and delicious; 1036446

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

B6

3

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

B6

Product information

Individual Case Safety Report Number: 1036446

Product Group: Pet Food

Product Name: Purina Whisker lickins, chicken and cheese flavors, soft and delicious

Description: In August I started to give Purina Whisker lickings soft treats on a regular basis (twice a day). After a month I noticed that **B6** had excessive urinations. Urinalysis on 9/9/14 showed 4+ glucose in urine, protein in urine - 30; bloodwork was normal (normal glucose). There have been no other changes in what he eats/takes. I stopped the treats. After a few week, the excessive urination stopped. recheck urinalysis on 10/21/14 showed no glucose.

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Recovered Completely

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Sender information

B6

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: 'Jones, Jennifer L (Jennifer.Jones@fda.hhs.gov)'
CC: Norris, Anne
BCC: ajfascetti@ucdavis.edu; jstern@ucdavis.edu; Freeman, Lisa; ADIN,DARCY BRITTAIN; Steven Rosenthal
Sent: 6/27/2019 3:10:45 PM
Subject: FDA DCM Update Links-Live 6/27/2019

Good morning,
I wanted to let you know that FDA Consumer update about DCM when live this morning. Here are the links:
CVM Update

Web Update – DCM Investigation

Web QA (Updated)

Vet-LIRN Update

DCM Complaint Spreadsheet – 1/1/14 - 4/30/19

If you have any questions about the content, please direct them to: AskCVM@fda.hhs.gov

Thank you and take care,
Jen

Jennifer L. A. Jones, DVM

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



From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogenesis, Martine; Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/5/2018 6:59:03 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: Slides for MH.pptx

B5

Thanks, Lee Anne

From: Palmer, Lee Anne
Sent: Thursday, July 5, 2018 1:50 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hello – [B6] and working my way through emails. To answer these 2 questions:

B5

Martine

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,
Anne

B5

B5

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

Thanks, Lee Anne

From: Hartogensis, Martine
Sent: Thursday, July 5, 2018 10:00 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Awesome! Thank you Jen!!

Martine

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

It's possible we are

B5

B5

I'll put together some slides for AVMA that you can choose from.

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



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

Hi Jen,

B5

Also, would it be possible to get a few high level slides for me to present at AVMA? I will be there July 15th and I

am pretty sure DCM will come up B5 but I defer to the experts J

Thanks again for all the excellent work!

Martine

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

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

B5

B5

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

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



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

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 3, 2018 at 8:19:29 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@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: Redacted complaint file for the DCM webposting

B5

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



From: Carey, Lauren

Sent: Monday, July 02, 2018 5:59 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

I just double checked our database and these are all complaints that came directly to FDA through our reporting portals, not CVCA complaints.

Thanks,
Lauren

From: Hartogensis, Martine

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

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

B5

Martine

From: Norris, Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Subject: FW: Redacted complaint file for the DCM webposting

Importance: High

Hi Jen and Dave,

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

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne

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

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

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

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



From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Palmer, Lee Anne; Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/5/2018 7:28:56 PM
Subject: RE: Redacted complaint file for the DCM webposting

Thank you so very much Lee Anne! Looks like the advisory is going out early next week, so this may be perfect timing J

From: Palmer, Lee Anne
Sent: Thursday, July 05, 2018 2:59 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

B5

Thanks, Lee Anne

From: Palmer, Lee Anne
Sent: Thursday, July 5, 2018 1:50 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

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

B5

B5

Martine

Hi Jen and Dave,

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

B5

Thanks,
Anne

Lauren is correct, the complaint file is ONLY for complaints that came into FDA (all had come via the SRP) as of the end-date they were pulled

B5

B5

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

Thanks, Lee Anne

From: Hartogenesis, Martine

Sent: Thursday, July 5, 2018 10:00 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

Awesome! Thank you Jen!!

Martine

From: Jones, Jennifer L

Sent: Thursday, July 05, 2018 7:02 AM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

It's possible we are

B5

B5

I'll put together some slides for AVMA that you can choose from.

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



From: Hartogenesis, Martine

Sent: Tuesday, July 03, 2018 4:13 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

Hi Jen,

This is excellent work!

B5

B5

Also, would it be possible to get a few high level slides for me to present at AVMA? I will be there July 15th and I am pretty sure DCM will come up. B5 but I defer to the experts J

Thanks again for all the excellent work!

Martine

From: Jones, Jennifer L

Sent: Tuesday, July 03, 2018 2:03 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

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

B5

B5

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

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



From: Rotstein, David

Sent: Tuesday, July 03, 2018 8:26 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

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

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

Date: July 3, 2018 at 8:19:29 AM EDT

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@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: Redacted complaint file for the DCM webposting

B5

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



From: Carey, Lauren

Sent: Monday, July 02, 2018 5:59 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

I just double checked our database and these are all complaints that came directly to FDA through our reporting portals, not CVCA complaints.

Thanks,
Lauren

From: Hartogensis, Martine

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

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

B5

Martine

From: Norris, Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Subject: FW: Redacted complaint file for the DCM webposting

Importance: High

Hi Jen and Dave,

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

B5

Thanks,
Anne

From: Palmer, Lee Anne

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

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

Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Hartogenesis, Martine; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/6/2018 2:27:31 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: 2018-AVMA-VetLIRN DCM.pptx

Hi Martine,

Here are some updated slides you can pick from. I'm fine if you want to
Jen

B5

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



From: Hartogenesis, Martine
Sent: Thursday, July 05, 2018 3:29 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thank you so very much Lee Anne! Looks like the advisory is going out early next week, so this may be perfect timing J

From: Palmer, Lee Anne
Sent: Thursday, July 05, 2018 2:59 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

B5

Thanks, Lee Anne

From: Palmer, Lee Anne
Sent: Thursday, July 5, 2018 1:50 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

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

B5

Martine

Hi Jen and Dave,

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

B5

B5

Thanks,
Anne

B5

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

Thanks, Lee Anne

From: Hartogenesis, Martine

Sent: Thursday, July 5, 2018 10:00 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

Awesome! Thank you Jen!!

Martine

From: Jones, Jennifer L

Sent: Thursday, July 05, 2018 7:02 AM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

It's possible we are

B5

B5

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



From: Hartogensis, Martine

Sent: Tuesday, July 03, 2018 4:13 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

Hi Jen,

This is excellent work!

B5

B5

Thanks again for all the excellent work!

Martine

From: Jones, Jennifer L

Sent: Tuesday, July 03, 2018 2:03 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

B5

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

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



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

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 3, 2018 at 8:19:29 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@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: Redacted complaint file for the DCM webposting

B5

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



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

Hi Martine,

B5

Thanks,
Lauren

From: Hartogensis, Martine
Sent: Monday, July 02, 2018 5:28 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein,

David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

B5

Martine

From: Norris, Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Subject: FW: Redacted complaint file for the DCM webposting

Importance: High

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne

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

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

Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/6/2018 5:14:43 PM
Subject: RE: Redacted complaint file for the DCM webposting

These are excellent! Thank you so much Jen and I think they will work well with Lee Anne's slides very nicely!! Should be an interesting session!

Martine

From: Jones, Jennifer L
Sent: Friday, July 06, 2018 10:28 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@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>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

Here are some updated slides you can pick from. I'm fine if you want to
Jen

B5

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



From: Hartogenesis, Martine
Sent: Thursday, July 05, 2018 3:29 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thank you so very much Lee Anne! Looks like the advisory is going out early next week, so this may be perfect timing J

From: Palmer, Lee Anne
Sent: Thursday, July 05, 2018 2:59 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Martine – if any of these slides are useful for your talk, please use them. They're part of what I put together for

B5

Thanks, Lee Anne

From: Palmer, Lee Anne

Sent: Thursday, July 5, 2018 1:50 PM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

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

B5

Martine

Hi Jen and Dave,

B5

Thanks,
Anne

B5

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

Thanks, Lee Anne

From: Hartogenesis, Martine

Sent: Thursday, July 5, 2018 10:00 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

Awesome! Thank you Jen!!

Martine

From: Jones, Jennifer L

Sent: Thursday, July 05, 2018 7:02 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Redacted complaint file for the DCM webposting

It's possible we are

B5

B5

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



From: Hartogensis, Martine

Sent: Tuesday, July 03, 2018 4:13 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

Hi Jen,

This is excellent work!

B5

B5

Thanks again for all the excellent work!

Martine

From: Jones, Jennifer L

Sent: Tuesday, July 03, 2018 2:03 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

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

B5

B5

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

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



From: Rotstein, David

Sent: Tuesday, July 03, 2018 8:26 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

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

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

Date: July 3, 2018 at 8:19:29 AM EDT

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@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: Redacted complaint file for the DCM webposting

B5

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



From: Carey, Lauren

Sent: Monday, July 02, 2018 5:59 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

B5

Thanks,
Lauren

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

B5

Martine

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

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

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

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 11/18/2018 8:25:14 PM
Subject: FW: JAVMA Manuscript (18-08-0453)
Attachments: 18-08-0453_COM.pdf

Hi Jen

Please see attached. I got permission from B6 to share this with you for internal use only. The planned publication date is Dec 1.

Kind regards,
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: Julie McLearen <JMcLearen@avma.org>
Sent: Friday, November 16, 2018 5:25 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: FW: JAVMA Manuscript (18-08-0453)

Hi Dr. Freeman,

The final PDF is attached.

Kind Regards,
Julie

Julie L. McLearen
Senior Production Coordinator | Publications
American Veterinary Medical Association

www.avma.org



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 11/19/2018 3:39:08 PM
Subject: RE: checking in

Thank you again, Lisa. I hope you have a nice Thanksgiving holiday.

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Friday, November 16, 2018 4:24 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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

B5

Thanks!

Darcy

On Nov 15, 2018, at 7:55 AM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi Jen,

B5

Thanks

Lisa

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

From: Jones, Jennifer L <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

B5

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: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Carey, Lauren; Jones, Jennifer L; DeLancey, Siobhan; Hartogensis, Martine; Burkholder, William; Rotstein, David; Palmer, Lee Anne; Peloquin, Sarah
CC: Ceric, Olgica; Reimschuessel, Renate
Sent: 12/10/2018 7:03:16 PM
Subject: RE: FYI-DCM Article-FW: article

S.T. wrote about the JAVMA paper: <http://truthaboutpetfood.com/diet-associated-heart-disease-in-dogs-what-we-know/>

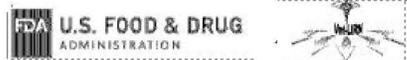
From: Carey, Lauren
Sent: Monday, December 10, 2018 11:38 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: FYI-DCM Article-FW: article

Did they mention any diets? Just curious how much this matches our reported products.

From: Jones, Jennifer L
Sent: Friday, December 07, 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: ADIN,DARCY BRITTAIN <adind@ufl.edu>
To: Jones, Jennifer L
Sent: 12/7/2018 9:53:54 PM
Subject: Re: article

you too!

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Friday, December 7, 2018 8:05 AM
To: ADIN,DARCY BRITTAIN
Subject: RE: article

Thank you, Darcy. I'll share with our team here. I hope you have a happy holiday.
Take care,
Jen

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: McDermott, Patrick </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3D75459A1C2A40B8B73B8B1484C8B850-PMCDERMO>
To: Reimschuessel, Renate
Sent: 7/11/2018 8:13:21 PM
Subject: FW: For CVM Review: CVM Update for Canine DCM & GF Diets

Not for sharing, but FYI.
Pat

From: Norris, Anne
Sent: Wednesday, July 11, 2018 3:54 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; McDermott, Patrick <Patrick.McDermott@fda.hhs.gov>
Subject: RE: For CVM Review: CVM Update for Canine DCM & GF Diets

Hi Martine,

B5

Going to compare notes with Juli in case there are [redacted] **B5** but don't see any reason why we couldn't get these out tomorrow.

Note that in the [redacted] **B5** [redacted] **B5** Please let me know if you have any concerns.

I'll let you know when we have scheduled a time to publish.

Thanks!
Anne

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Solomon, Steven M; Forfa, Tracey; Moxley, Shera; Flynn, William T; Murphy, Jeanette; Hartogensis, Martine; Allen, Mary; Edwards, David; Conway, Charlotte; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Benton, Denise; Goddard, Kristina; Dewitt, Susan J; Alvey, Laura - CVM; Stamper, Carmela; Smith-Collier, Chandra E; DeLancey, Siobhan
Sent: 2/19/2019 3:07:09 PM
Subject: Now live: DCM Investigation Update
Attachments: DCM Plan_Feb2019.docx

Good morning,

The long-awaited investigative update about the potential link between certain diets and canine DCM is now live. Outreach may now begin (plan is attached). Social media and an email to our CVM subscribers will go out around 11:00 am EST.

Links:

CVM Update: <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm630991.htm>

Investigation home page: <http://www.fda.gov/AnimalVeterinary/NewsEvents/ucm630993.htm>

Vet-LIRN page: <https://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm630738.htm>

Web Q&A: <https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm616279.htm>

Thanks so much to everyone for their hard work and patience! And thank you on behalf of the people who will be emailing and calling who might be too preoccupied to express their gratitude.

Anne

Anne Norris

Strategic Initiatives

**Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration**

O: 240-402-0132

M: B6

Anne.Norris@fda.hhs.gov



From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Solomon, Steven M; Flynn, William T; Forfa, Tracey; Schell, Timothy; Jones, Jennifer L; Palmer, Lee Anne; Burkholder, William; Carey, Lauren; DeLancey, Siobhan; Hartogensis, Martine; Murphy, Jeanette; Dewitt, Susan J; Cepeda, Sandra; Steinberg, Nadine; Rotstein, David; Moxley, Shera
Sent: 5/29/2019 8:38:59 PM
Subject: RE: Checkpoint on DCM
Attachments: COMMSPLAN_DCM_Summer_2019.docx

To help facilitate discussion, attached is the draft communications plan for the next DCM public update. Lee Anne, Lauren, and Jen will share some data points/high-level takeaways via WebEx tomorrow.

-----Original Appointment-----

From: Solomon, Steven M
Sent: Monday, May 20, 2019 10:36 AM
To: Solomon, Steven M; Flynn, William T; Forfa, Tracey; Norris, Anne; Schell, Timothy; Jones, Jennifer L; Palmer, Lee Anne; Burkholder, William; Carey, Lauren
Cc: DeLancey, Siobhan; Hartogensis, Martine; Murphy, Jeanette; Dewitt, Susan J; Cepeda, Sandra; Steinberg, Nadine; Rotstein, David
Subject: Checkpoint on DCM
When: Thursday, May 30, 2019 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CVM 7500 Conf E473 and WebEx

Purpose: Discuss currently available DCM data, pending updates, and key messaging in forthcoming communications.

Meeting materials forthcoming.

Apologies for the lunchtime meeting, but schedules were tight.

JOIN WEBEX MEETING

Meeting number (access code):

B6

Meeting password:

B6

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

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

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

From: 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 6:58:31 PM
Subject: RE: DCM write-up for June Web Update

One correction—I double checked and it should be “There are **B5** evaluation.”

FYI, these are the pending necropsy cases:

B5, B6

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

From: Peloquin, Sarah
Sent: Wednesday, June 12, 2019 2:41 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
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

B6



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

From: 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.

I didn't put hard numbers in there given that

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

B6



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

From: 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,

Could you please write-up a summary of the findings we would like to make public for DCM necropsies? This will be part of the technical Vet-LIRN update. The information will build on this paragraph:

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
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
CC: Peloquin, Sarah
Sent: 6/13/2019 1:31:11 PM
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

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



From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all. Thank you and enjoy

B6

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates.
Can I get it to you by COB Thursday?

B6

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM

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

Subject: Vet-LIRN Update on DCM

Hi Jen,

Wanted to circle back after Dr. Solomon's DCM briefing. You did a great job! I think he has a much better appreciation for where things stand now.

I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

[Draft – Vet-LIRN DCM Update for June 2019](#)

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!

Anne

Anne Norris

Strategic Initiatives

Office of the Director

Center for Veterinary Medicine

U.S. Food & Drug Administration

O: 240-402-0132

B6

Anne.Norris@fda.hhs.gov



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Norris, Anne
CC: Peloquin, Sarah
Sent: 6/13/2019 2:03:15 PM
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne.
time.

B5

We don't need to meet unless **B5** In that case, I'm free today until 3.
Otherwise, we can just chat tomorrow with the group.

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



From: Norris, Anne
Sent: Thursday, June 13, 2019 9:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, you're the best! Just one stat I need for the comms that I don't see in there

B5

B5

I'll give this a read through, but I think it's in great shape for tomorrow. If you'd like to talk it through before then, happy to do that.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 9:31 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

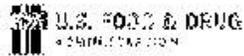
Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

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



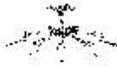
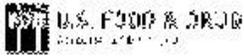
From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all. B6

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates. B6
Can I get it to you by COB Thursday?

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Vet-LIRN Update on DCM

Hi Jen,

Wanted to circle back after Dr. Solomon's DCM briefing. You did a great job! I think he has a much better appreciation for where things stand now.

I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

[Draft - Vet-LIRN DCM Update for June 2019](#)

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132

B6

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
CC: Peloquin, Sarah
Sent: 6/13/2019 2:41:29 PM
Subject: RE: Vet-LIRN Update on DCM

Thanks! Sounds good. Tracey just asked me to reschedule tomorrow's meeting for early next week. I'll still send around the comms docs links for people to start reviewing in the interim.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 10:03 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne
time.

B5

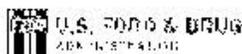
We don't need to meet unless

B5

In that case, I'm free today until 3.

Otherwise, we can just chat tomorrow with the group.

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



From: Norris, Anne
Sent: Thursday, June 13, 2019 9:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks...you're the best! Just one stat I need for the comms that I don't see in there

B5

B5

I'll give this a read through, but I think it's in great shape for tomorrow. If you'd like to talk it through before then, happy to do that.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 9:31 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

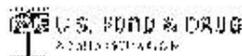
Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Ivorris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all.

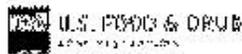
B6

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Ivorris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates.
 Can I get it to you by COB Thursday?

B6

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Vet-LIRN Update on DCM

Hi Jen,

Wanted to circle back after Dr. Solomon's DCM briefing. You did a great job! I think he has a much better appreciation for where things stand now.

I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

[Draft - Vet-LIRN DCM Update for June 2019](#)

Happy to discuss/help however I can. please let me know! If at all possible. I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!

Anne

Anne Norris

Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132

B6



U.S. FOOD & DRUG
ADMINISTRATION



From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Jones, Jennifer L
Sent: 6/13/2019 3:31:42 PM
Subject: RE: DCM write-up for June Web Update

The rest of the numbers shouldn't change, but--

As of April 30, 2019: There is

B5

B5, B6

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

From: Peloquin, Sarah
Sent: Wednesday, June 12, 2019 2:59 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

One correction—I double checked and it should be “There are

B5

evaluation.”

B5, B6

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

From: Peloquin, Sarah
Sent: Wednesday, June 12, 2019 2:41 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Sorry for the delay—I added my changes in blue:

B5

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

B6



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

From: 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 d

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.

I didn't put hard numbers in there given

B5

s. 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

B6



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

From: 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,

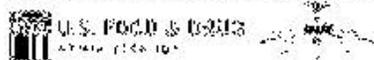
Could you please write-up a summary of the findings we would like to make public for DCM necropsies? This will be part of the technical Vet-LIRN update. The information will build on this paragraph:

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, G7G4
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/ucm247234.htm>



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Norris, Anne
CC: Peloquin, Sarah
Sent: 6/13/2019 2:03:15 PM
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne
time.

B5

We don't need to meet unless **B5** In that case, I'm free today until 3. Otherwise, we can just chat tomorrow with the group.

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



From: Norris, Anne
Sent: Thursday, June 13, 2019 9:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks...you're the best! Just one stat I need for the comms that I don't see in there

B5

B5

I'll give this a read through, but I think it's in great shape for tomorrow. If you'd like to talk it through before then, happy to do that.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 9:31 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

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



From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all B6

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates B6
Can I get it to you by COB Thursday?

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Vet-LIRN Update on DCM

Hi Jen,

Wanted to circle back after Dr. Solomon's DCM briefing. You did a great job! I think he has a much better appreciation for where things stand now.

I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

[Draft – Vet-LIRN DCM Update for June 2019](#)

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration

O: 240-402-0132

B6

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
Sent: 6/13/2019 4:43:51 PM
Subject: RE: Vet-LIRN Update on DCM

TY!

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 12:34 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Yes, correct.

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



From: Norris, Anne
Sent: Thursday, June 13, 2019 12:22 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sorry, and [redacted] **B5**

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 11:37 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Done :)

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



From: Norris, Anne
Sent: Thursday, June 13, 2019 11:17 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Shoot, sorry I spoke too soon [redacted] **B5**

[redacted] **B5**

Sorry about that, I wish I could pull the numbers myself without having to bother you again!

From: Norris, Anne
Sent: Thursday, June 13, 2019 10:41 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks! Sounds good. Tracey just asked me to reschedule tomorrow's meeting for early next week. I'll still send around the comms docs links for people to start reviewing in the interim.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 10:03 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

B5

We don't need to meet unless **B5** In that case, I'm free today until 3.
Otherwise, we can just chat tomorrow with the group.

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



From: Norris, Anne
Sent: Thursday, June 13, 2019 9:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, you're the best! Just one stat I need for the comms that I don't see in there –

B5

B5

I'll give this a read through, but I think it's in great shape for tomorrow. If you'd like to talk it through before then, happy to do that.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 9:31 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

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



From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all.

B6

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates.
Can I get it to you by COB Thursday?

B6

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



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Vet-LIRN Update on DCM

Hi Jen,

Wanted to circle back after Dr. Solomon's DCM briefing. You did a great job! I think he has a much better appreciation for where things stand now.

I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

[Draft – Vet-LIRN DCM Update for June 2019](#)

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!

Anne

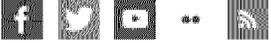
Anne Norris

Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132

B6

Anne.Norris@fda.hhs.gov



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Peloquin, Sarah
Sent: 6/14/2019 12:40:46 PM
Subject: RE: link to VL DCM update for June 2019

Excellent! I changed them :)
Thank you.

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



From: Peloquin, Sarah
Sent: Friday, June 14, 2019 8:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: link to VL DCM update for June 2019

And again, I'm sure this will be caught, but the title says 2018 in the description at the bottom.

Full Title: Vet-LIRN Update on Investigation into Dilated Cardiomyopathy – June 2018
Short Title: Vet-LIRN Update on Investigation into Dilated Cardiomyopathy – June 2018

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

From: Peloquin, Sarah
Sent: Friday, June 14, 2019 8:31 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: link to VL DCM update for June 2019

I know someone will probably catch this, but the last sentence in this paragraph (under "Course of disease") has a grammatical error.

B5

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

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 10:55 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Subject: link to VL DCM update for June 2019

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: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Hartogensis, Martine; Schell, Timothy; Murphy, Jeanette; Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Peloquin, Sarah; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Hodges, April; Nelson, Eric; McCoig, Amber; Conway, Charlotte; Edwards, David; Forfa, Tracey; Steinberg, Nadine
Sent: 6/13/2019 10:22:07 PM
Subject: FOR CLEARANCE: DCM Comms - Review requested by 12pm on Monday, 6/17
Importance: High

Hi all,

Using the SharePoint links below, could you please review the comms for the DCM investigative update by **noon on Monday, 6/17**? Our group call is at 4:00pm on Monday and that'll be an opportunity to discuss any outstanding questions/discrepancies while we have a quorum. This is a big group and not everyone needs to clear these, so if you didn't review the documents the last time we issued an update, you probably don't need to do it this time either. That said, feel free to take a look and weigh in if you have suggestions.

Please note that Lee Anne and Lauren are still slaving over some of the B5
B5 Would be great to discuss that on Monday as well.

B5

Thanks!
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132

B6
Anne.Norris@fda.hhs.gov



From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Hartogenesis, Martine; Schell, Timothy; Murphy, Jeanette; Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Peloquin, Sarah; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Hodges, April; Nelson, Eric; McCoig, Amber; Conway, Charlotte; Edwards, David; Forfa, Tracey; Steinberg, Nadine
Sent: 6/17/2019 1:26:42 PM
Subject: RE: FOR CLEARANCE: DCM Comms - Review requested by 12pm on Monday, 6/17

Friendly reminder to all who plan to review the comms to please: **B5** to do so by this afternoon.

Thanks!

From: Norris, Anne
Sent: Thursday, June 13, 2019 6:22 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Schell, Timothy <Timothy.Schell@fda.hhs.gov>; Jeanette Murphy (Jenny.Murphy@fda.hhs.gov) <Jenny.Murphy@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Siobhan DeLancey - FDA (Siobhan.Delancey@fda.hhs.gov) <Siobhan.Delancey@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>
Subject: FOR CLEARANCE: DCM Comms - Review requested by 12pm on Monday, 6/17
Importance: High

Hi all,

Using the **B5** could you please review the comms for the DCM investigative update by **B5**
B5 This is a big group and not everyone needs to clear these, so if you didn't review the documents the last time we issued an update, you probably don't need to do it this time either. That said, feel free to take a look and weigh in if you have suggestions.

Please note that Lee Anne and Lauren are still **B5**
B5 Would be great to discuss that on Monday as well.

B5

Thanks!
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration

O: 240-402-0132

B6

Anne.Norris@fda.hhs.gov



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Palmer, Lee Anne; Jones, Jennifer L; Hartogensis, Martine; Murphy, Jeanette; Norris, Anne
CC: Forfa, Tracey
Sent: 6/20/2019 3:57:31 PM
Subject: RE: DCM roll-out timing question?

Jenny,

My slides may not be appropriate-they're

B5

Dave

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: June 20, 2019 at 11:54:06 AM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@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>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

Hi – here are the ones I made for Dave Edwards, but they're outdated. I would want to give you updated #'s – and those will be in the public update. Let me know what might be most useful to you.

From: Jones, Jennifer L
Sent: Thursday, June 20, 2019 11:47 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; 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>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

Here are a few slides we shared with Dave Edwards for the AFIA meeting.

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



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>; Hartogenesis, Martine <Martine.Hartogenesis@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

B5

Jenny

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
CC: Norris, Anne
Sent: 6/27/2019 3:19:56 PM
Subject: Re: FDA DCM Update Links-Live 6/27/2019
Attachments: image005.png; image006.png

Hi Jen. I heard rumors of something coming so thanks for letting me know. Did you hear from B6 about our preliminary data presented at ACVIM? Let me know if you'd like to discuss
Thanks. Lisa

Sent from my iPhone

On Jun 27, 2019, at 11:14 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning,
I wanted to let you know that FDA Consumer update about DCM when live this morning. Here are the links:
[CVM Update](#)

[Web Update – DCM Investigation](#)

[Web QA \(Updated\)](#)

[Vet-LIRN Update](#)

[DCM Complaint Spreadsheet – 1/1/14 - 4/30/19](#)

If you have any questions about the content, please direct them to: AskCVM@fda.hhs.gov

Thank you and take care,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>
<[image005.png](#)> <[image006.png](#)>

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 6/13/2018 10:56:39 AM
Subject: RE: Notice

Thank you for the head's up Lisa!

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

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

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Tuesday, June 12, 2018 5:38 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Notice

Hi Jennifer. I heard a rumor that a notice was coming out that [REDACTED] I hope
[REDACTED] Thanks. Lisa

Sent from my iPhone

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 7:56:51 PM
Subject: FW: Redacted complaint file for the DCM webposting
Importance: High
Attachments: DCM Reports to FDA CVM_Redacted.pdf

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

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

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



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 7:58:22 PM
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that [REDACTED] reported.

Dave

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

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

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help [REDACTED]

B5

[REDACTED] B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:01:56 PM
Subject: RE: Redacted complaint file for the DCM webposting

B5

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

B6 (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: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: Redacted complaint file for the DCM webposting
Importance: High

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Rotstein, David; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:04:39 PM
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave

B5

B5

From: Rotstein, David
Sent: Monday, July 02, 2018 3:58 PM
To: Norris, Anne <Anne.Norris@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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that [redacted] reported.

Dave

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

B6

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

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne

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

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

Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:07:12 PM
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

B5

Others may have differing thoughts.

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

B6

(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: Norris, Anne
Sent: Monday, July 02, 2018 4:05 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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave.

B5

B5

From: Rotstein, David
Sent: Monday, July 02, 2018 3:58 PM
To: Norris, Anne <Anne.Norris@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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that [redacted] reported.

B5

Dave

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

B6

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: Norris, Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Subject: FW: Redacted complaint file for the DCM webposting

Importance: High

Hi Jen and Dave,

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

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne

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

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

Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

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

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



From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Rotstein, David; Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:30:55 PM
Subject: RE: Redacted complaint file for the DCM webposting

Hi Anne,

I'm in today, just with intermittent network connectivity at the moment. **B5**
B5 so I'm not any help even though I'm here. Lee Anne will be back on Thursday and should be able to help then, but I'm not sure if that decision was on her end or not.

Thanks,
Lauren

From: Rotstein, David
Sent: Monday, July 02, 2018 4:07 PM
To: Norris, Anne <Anne.Norris@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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

B5

Others may have differing thoughts.

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

B6

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: Norris, Anne
Sent: Monday, July 02, 2018 4:05 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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave

B5

B5

From: Rotstein, David
Sent: Monday, July 02, 2018 3:58 PM
To: Norris, Anne <Anne.Norris@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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that

B5

Dave

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

B6

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

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,

Anne

From: Palmer, Lee Anne

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

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

Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

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: Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Rotstein, David
CC: Norris, Anne; DeLancey, Siobhan; Putnam, Juli
Sent: 10/9/2018 6:59:05 PM
Subject: RE: Media Request - DCM - WUSA9 inquiry

Hi DCM Team!

See the media request below. This is mostly for Lee Anne's group to update numbers (if you have them), but Jen and Dave, please feel free to revise as well. I had one edit in red.

Thanks very much in advance!

Martine

From: Haake, Lindsay
Sent: Tuesday, October 09, 2018 2:48 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: FW: Media Request - DCM - WUSA9 inquiry

Good Afternoon Martine –

B5

When you get a chance, please review and let me know if you have any edits by COB Friday, October 12th.

Thanks!
Lindsay

Media Inquiry

Reporter: Whitney Wild
Media Outlet: WUSA9

Reporter Deadline: Requested an interview for the week of October 15th

Background: I'm reaching out from WUSA9 here in D.C. We are exploring a story about the growing concern about a possible link between grain-free dog food and dilated cardiomyopathy cited in this announcement:

<https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm613305.htm>

Is there anyone from the FDA we could speak with on-camera about the research the agency is doing, any conclusions and the complaints the agency has fielded surrounding this issue?

Questions/Proposed Responses:

B5

B5

Lindsay Haake

Press Officer

**Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration**

Tel: 301-796-3007 / **B6**

Lindsay.Haake@fda.hhs.gov



Appears this Way on Original

From: DeLancey, Siobhan </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A414BA562DCD4C8284B1120074969B9A-SDELANCE>
To: Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Rotstein, David
CC: Norris, Anne; Putnam, Juli
Sent: 10/9/2018 7:01:00 PM
Subject: RE: Media Request - DCM - WUSA9 inquiry

B5

From: Hartogensis, Martine
Sent: Tuesday, October 09, 2018 2:59 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: RE: Media Request - DCM - WUSA9 inquiry

Hi DCM Team!

See the media request below. This is mostly for Lee Anne's group to update numbers (if you have them), but Jen and Dave, please feel free to revise as well. I had one edit in red.

Thanks very much in advance!

Martine

From: Haake, Lindsay
Sent: Tuesday, October 09, 2018 2:48 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: FW: Media Request - DCM - WUSA9 inquiry

Good Afternoon Martine –

B5

When you get a chance, please review and let me know if you have any edits by COB Friday, October 12th.

Thanks!
Lindsay

Media Inquiry

Reporter: Whitney Wild

Media Outlet: WUSA9

Reporter Deadline: Requested an interview for the week of October 15th

Background: I'm reaching out from WUSA9 here in D.C. We are exploring a story about the growing concern about a possible link between grain-free dog food and dilated cardiomyopathy cited in this announcement:

<https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm613305.htm>

Is there anyone from the FDA we could speak with on-camera about the research the agency is doing, any conclusions and the complaints the agency has fielded surrounding this issue?

Questions/Proposed Responses:

B5

Lindsay Haake

Press Officer

**Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration**

Tel: 301-796-3007 / **B6**

Lindsay.Haake@fda.hhs.gov



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Carey, Lauren; Hartogensis, Martine; Norris, Anne; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 7/3/2018 6:02:52 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: 800.267-Product Indexing Results Summary.pptx

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

B5

B5

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

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



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

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 3, 2018 at 8:19:29 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@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: Redacted complaint file for the DCM webposting

B5

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



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

Hi Martine,

B5

Thanks,
Lauren

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

B5

Martine

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

Hi Jen and Dave,

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



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; Queen, Jackie L
CC: Ceric, Olgica; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Nemser, Sarah
Sent: 5/1/2018 1:05:21 PM
Subject: 800.267-EON-345858-DCM Cluster
Attachments: DCM-Case Report Analysis-5.1.2018.xls; Fan-Sauer-Peas Cys-Met Content-1994.pdf; FYI -lentils--deficient in sulfur containing amino acids--methionine, tryptophan, and cysteine; Ko-Fascetti-Beet pulp Tau status-5.1.2018.pdf; Qiao-et al-Met to MetCys ratio-Pigs-2008.pdf; Sarwar-CysMet ratio Rats-1991.pdf

B5 I wonder about either

B5

B5

Thoughts?

Dave previously sent an email about information about peas (attached)

B5

I found the same

B5

B5

(<https://academic.oup.com/jn/article-abstract/112/11/2033/4554028?redirectedFrom=fulltext>).

In chickens (Sarwar article)

B5

B5

B5

B5

B5

Also-This is an older study in beagles

B5

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

B5

B5

Jennifer L. A. Jones, DVM

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



From: 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: 6/4/2018 4:58:23 PM
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy
Attachments: 800.267-DCM-Grainfree analysis.pptx

Everyone,

B5

Thanks,
dave

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

B6



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

From: 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

To address this, CVM is planning the following:

B5

Thank you,

Dave

Brand	flavor	Firm	Location	FEI	Division
B4, B5					

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

B6





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

From: 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 4:05:44 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. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

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

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

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

B6



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

From: 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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied

to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: 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: 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>; 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

B6



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

From: Hartogensis, 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

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>;

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

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

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

CVCA is not a part of Vet-LIRN:

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! One question they part of VET-LIRN?

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

B4, B5

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: 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



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

I do not know about **B5** Once we get a better handle on a specific cause, we can work on that.

From: Hartogenesis, Martine <Martine.Hartogenesis@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

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@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>; Hartogenesis, Martine <Martine.Hartogenesis@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,

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

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

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,

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

B6



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

From: Hartogenesis, 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! The resident I spoke to was **B6**

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

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,

B5

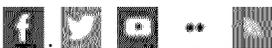
Looping in Jen.

Thanks for the update!

dave

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

B6



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

From: 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

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

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: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Reimschuessel, Renate
CC: Rotstein, David
Sent: 6/11/2018 5:57:09 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought.

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@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>; 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

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. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

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

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

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

B6



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

From: 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

B6



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

From: 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: 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>; 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



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: 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

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

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>; Hartogenesis, Martine <Martine.Hartogenesis@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

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

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

CVCA is not a part of Vet-LIRN!

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

B4, B5

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

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

I do not know about **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>; Hartogenesis, Martine <Martine.Hartogenesis@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>, Hartogenesis, Martine <Martine.Hartogenesis@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

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,

B5, 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

B6



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



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: 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! The resident I spoke to was **B6**

B6

<https://www.cvcavets.com/>

B6

Keep us posted!

Thanks again!

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,

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

B6



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

From: Hartogenesis, 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

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

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: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Hartogensis, Martine; Jones, Jennifer L
CC: Rotstein, David
Sent: 6/11/2018 6:25:07 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

We have done no evaluation of **B5** and like you – I raise my eyebrows a bit when **B5**
B5

I went on Alibaba website and there are many products... same with amazon – not sure how to chose what to test.

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN
Phone 1-240-402-5404 Fax 301-210-4685
Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/tcm247334.htm>

From: Hartogensis, Martine
Sent: Monday, June 11, 2018 1:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought. **B5**
B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@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>; 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

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. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

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

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

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

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

B6



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

From: 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

B6



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

From: 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

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: 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>; 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

B6



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

From: Hartogensis, 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

B5

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>; 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

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: Hartogenesis, Martine <Martine.Hartogenesis@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

CVCA is not a part of Vet-LIRN

B5

B5

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



From: Hartogenesis, 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!
they part of VET-LIRN

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>, 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>, 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

B4, B5

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

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

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



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

I do not know about **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,

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

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

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**. 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

B6



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

From: Hartogenesis, 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! The resident I spoke to was

B6

<https://www.cvcavets.com/doct>

B6

Keep us posted!

Thanks again!

Martine

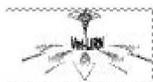
Hi Martine,

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: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

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

B6



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

From: Hartogenesis, 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

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

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: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Reimschuessel, Renate; Jones, Jennifer L
CC: Rotstein, David
Sent: 6/11/2018 6:36:44 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Ok, thank you Renate! Just thought it would be worth discussing ;)

Martine

From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Date: June 11, 2018 at 2:25:11 PM EDT
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN

Phone 1- 240-402-5404 Fax 301-210-4685

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

From: Hartogenesis, Martine
Sent: Monday, June 11, 2018 1:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@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

Good morning everyone.

B5

Documents are attached.

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. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

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

For example, [B4] (not a grain-free diet)

[B5]

B4

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

[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

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]

B5

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

B6



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

From: 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.Delancev@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carev@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.Conwav@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.Delancev@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carev@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.Conwav@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

B6



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

From: 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>; 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>; 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

B5

Thanks,
Dave

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: 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>; 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

B6



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

From: Hartogensis, 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

B5

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>; 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

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

CVCA is not a part of Vet-LIRN

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!
they part of VET-LIRN?

B5

Are

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

B4, B5

B4, B5

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: 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

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

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

I do not know about **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,

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

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

[B6]



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

From: 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]

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

Jen

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



From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

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

B6



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

From: Hartogenesis, 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

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

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Reimschuessel, Renate; Jones, Jennifer L
Sent: 6/11/2018 6:39:51 PM
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

B6



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

From: Hartogensis, Martine
Sent: Monday, June 11, 2018 2:37 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Ok, thank you Renate! Just thought it would be worth discussing ;)

Martine

From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Date: June 11, 2018 at 2:25:11 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN

Phone 1-240-402-5404 Fax 301-210-4685

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

From: Hartogensis, Martine

Sent: Monday, June 11, 2018 1:57 PM

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

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought.

B5

B5

Martine

From: Jones, Jennifer L

Sent: Monday, June 11, 2018 12:06 PM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@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>; 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

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. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

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

For example,

B4

dry (not a grain-free diet)

B5

B5

B4

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,

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

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

B5

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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination,

distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: 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

B5

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

B6



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

From: 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

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: 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>

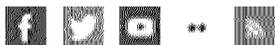
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; 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

B6



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

From: Hartogensis, 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

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

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>; Hartogenesis, Martine <Martine.Hartogenesis@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

B5

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

CVCA is not a part of Vet-LIRN.

B4

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!
Are they part of VET-LIRN?

B5

Are

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

B4, B5

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: 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

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

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: Hartogenesis, Martine <Martine.Hartogenesis@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

I do not know **B5** Once we get a better handle on a specific cause, we can work on that.

From: Hartogenesis, Martine <Martine.Hartogenesis@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>; Hartogenesis, Martine <Martine.Hartogenesis@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,

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>; Hartogenesis, Martine <Martine.Hartogenesis@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: Hartogenesis, Martine <Martine.Hartogenesis@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: Hartogenesis, 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: Hartogenesis, Martine <Martine.Hartogenesis@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

B6



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

From: Hartogenesis, 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

<https://www.cvcavets.com>

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,

B5

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

B6



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

From: Hartogenesis, 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

B5

B5

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

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: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Rotstein, David; Reimschuessel, Renate; Jones, Jennifer L
Sent: 6/11/2018 6:42:48 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Excellent point!

Martine

From: Rotstein, David <David.Rotstein@fda.hhs.gov>
Date: June 11, 2018 at 2:39:55 PM EDT
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@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

B6



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

From: Hartogenesis, Martine
Sent: Monday, June 11, 2018 2:37 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Ok, thank you Renate! Just thought it would be worth discussing ;)

Martine

From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Date: June 11, 2018 at 2:25:11 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN
Phone 1- 240-402-5404 Fax 301-210-4685
Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Hartogensis, Martine
Sent: Monday, June 11, 2018 1:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@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>; 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

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. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

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

For example, **B4** dry (not a grain-free diet) **B4** but they are pretty far down the list:

B4

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

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

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

B5

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

B6



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

From: 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

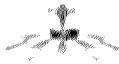
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; 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

B6



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

From: 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>; 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>; 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

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: 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>; 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

B6



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

From: Hartogensis, 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

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>; 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

B5

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

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!
they part of VET-LIRN?

B4, B5

Are

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

B4, B5

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

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

I do not know about **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,

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

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: Hartogenesis, Martine <Martine.Hartogenesis@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
[B6] (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: Hartogenesis, 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]

<https://www.cvcavets.com/>

[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,

B5

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

B6



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

From: 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

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: Hartogensis, Martine <Martine.Hartogensis@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: Burkholder, William
Sent: 6/20/2018 3:50:47 PM
Subject: slides shared with PFI
Attachments: 800.267-DCM-Grainfree analysis-UPDATED.pptx; DCM-Grainfree analysis-UPDATED-PFI-redacted.pptx

The PFI shared slides and our unredacted version.

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: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Jones, Jennifer L; Rotstein, David; Carey, Lauren; Hartogensis, Martine; Palmer, Lee Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/3/2018 6:38:15 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: 800.267-Product Indexing Results Summary.pptx

Thanks, Jen! + Bill.

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

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

B5

B5

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

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



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

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 3, 2018 at 8:19:29 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@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: Redacted complaint file for the DCM webposting

B5

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



From: Carey, Lauren

Sent: Monday, July 02, 2018 5:59 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

B5

Thanks,
Lauren

From: Hartogensis, Martine

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

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

B5

Martine

From: Norris, Anne

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

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Subject: FW: Redacted complaint file for the DCM webposting

Importance: High

Hi Jen and Dave,

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

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

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



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Carey, Lauren; Hartogensis, Martine; Norris, Anne; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 7/3/2018 6:40:06 PM
Subject: RE: Redacted complaint file for the DCM webposting

Jen,

This is very interesting.

B5

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

B6



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

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

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

B5

B5

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

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



From: Rotstein, David

Sent: Tuesday, July 03, 2018 8:26 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

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

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

Date: July 3, 2018 at 8:19:29 AM EDT

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@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: Redacted complaint file for the DCM webposting

B5

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



From: Carey, Lauren

Sent: Monday, July 02, 2018 5:59 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

B5

Thanks,
Lauren

From: Hartogensis, Martine

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

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

Subject: RE: Redacted complaint file for the DCM webposting

B5

Martine

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

Hi Jen and Dave,

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

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

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





Taurine and Carnitine in Canine Cardiomyopathy

Sherry Lynn Sanderson, DVM, PhD

Department of Physiology and Pharmacology, University of Georgia, College of Veterinary
Medicine, 501 DW Brooks Drive, Athens, GA 30602, USA

Dilated cardiomyopathy (DCM) is one of the most common acquired cardiovascular diseases in dogs [1–4]. Although few studies of the prevalence of DCM in the overall population of dogs have been reported, estimates range from 0.5% to 1.1% [5,6]. Only degenerative valvular disease and, in some regions of the world, heartworm infection are more common causes of cardiac morbidity and mortality in dogs. DCM is seen most commonly in large and giant breeds of dogs, although its frequency seems to be increasing in medium-sized breeds, such as the English and American cocker spaniels [4–8]. It has been reported rarely in small and miniature breeds of dogs [9].

DCM is particularly challenging to veterinarians because the cause is often unknown and can vary among dog breeds [10]. Because most cases of DCM in dogs are classified as idiopathic, most therapies can be classified as “Band-Aid therapies” that palliate the effects of this disease for a short duration but do little to address the primary disease process. Therefore, DCM is almost always a progressive disease, and most dogs will eventually succumb to their disease. Survival times in dogs with DCM are variable and can be influenced by several factors, including breed. However, the prognosis for survival of dogs with DCM remains poor, with reported survival rates of 17.5% at 1 year and 7.5% at 2 years [11–13]. Until recently, reported cases of DCM reversal in dogs were very rare.

B4

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

Please review by COB 6/1.

Jennifer L. A. Jones, DVM

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



From: Darcy Adin <dbadin@ncsu.edu>
To: Freeman, Lisa
CC: Jones, Jennifer L; Joshua A Stern; Fries, Ryan C; [REDACTED]; Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olga
Sent: 5/25/2018 9:25:30 PM
Subject: Re: diet related DCM - a couple forms

Thank you Lisa! Those look very helpful.

We have several Great Danes with DCM eating [REDACTED] must be popular with owners of that breed!

Hope you have a good weekend,

Darcy

On Thu, May 24, 2018 at 3:21 PM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi everyone

[REDACTED]

B5

[REDACTED]

B5

Thanks

Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Friedman School of Nutrition Science and Policy

Tufts Clinical and Translational Science Institute

Tufts University

www.petfoodology.org

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

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

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

B6

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

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

Importance: High

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

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

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

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

B6

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

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

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

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

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

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



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

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

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

B6

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

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

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

B6

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

B6

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

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

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

Sincerely,

Darcy Adin

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

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

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

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

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

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

Join WebEx meeting

Meeting number (access code):

Meeting password:

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

Can't join the meeting?

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

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

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: [B6]
CC: Jones, Jennifer L; Darcy Adin; Joshua A Stern; Fries, Ryan C [B6] Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 5/30/2018 10:08:30 AM
Subject: RE: diet related DCM - a couple forms

Hi all
We had another case yesterday on [B4, B5] I'll get that submitted to FDA today.

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

B5

Thanks
Lisa

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

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

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

B5

Thanks,
[B6]

On Thu, May 24, 2018 at 3:21 PM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi everyone

B5

B5

Thanks
Lisa

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

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

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

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

B6

B6

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

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

Importance: High

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

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



From: Jones, Jennifer L

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

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

B6

B6

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

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

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

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

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

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, April 19, 2018 11:00 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] }
Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

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

Drs. [REDACTED] Freeman, [REDACTED], Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

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

[REDACTED]
Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med
Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

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

Sincerely,
Darcy Adin

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: Thu, Apr 19, 2018 at 7:16 AM
Subject: hold-call with Dr. Adin re: DCM cases
To: "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey, Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

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

Join WebEx meeting

Meeting number (access code): **B6**

Meeting password: **B6**

Join by phone

B6 US Toll
US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

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

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

--

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

B6

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

Jen,

This is the second **B4** it used to made by **B4**. If we can get lot info, we can look into that.

B4 manufactures a lot of product and does so according to each firm's specifications, but they do run a lot of different products (brands) on the same line .

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6



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: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]

Sent: Wednesday, May 30, 2018 6:09 AM

To: **B6**

Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; **B6** Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: diet related DCM - a couple forms

Hi all

We had another case yesterday on **B4, B5** I'll get that submitted to FDA today.

Happy to have you share the protocol and diet history. The protocol was designed for internal use so might be good to modify a few things:

B5

Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: [REDACTED] **B6**
Sent: Tuesday, May 29, 2018 10:09 PM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6**; Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: Re: diet related DCM - a couple forms

Thank you so much for all your work Lisa! I just diagnosed a golden today with DCM that eats [REDACTED] **B4** , too. I am having the owners fill out the diet history form and will follow your protocol as above. [REDACTED] **B5**

[REDACTED] **B5**

Thanks,
[REDACTED] **B6**

On Thu, May 24, 2018 at 3:21 PM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:
Hi everyone

[REDACTED] **B5**

[REDACTED] **B5**

Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]

Sent: Friday, April 20, 2018 3:50 PM

To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

B6

B6

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: hold-call with Dr. Adin re: DCM cases

Importance: High

My apologies for the repeat email. After further internal discussion, in lieu of submitting Consumer Complaints, you can just email me a spreadsheet with the data.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Friday, April 20, 2018 1:19 PM

To: 'Darcy Adin' <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

B6

B6

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: hold-call with Dr. Adin re: DCM cases

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, please file an official consumer complaint. Instructions on how to report a pet food report can be found at: <https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>. The complaint can be submitted through the Safety Reporting Portal: <https://www.safetyreporting.hhs.gov>. You can attach documents already created that compile your case data. We will review the data and may contact you for possible follow-up.

In the meantime, if you have a dog with DCM on a grain free diet that dies or is euthanized, please do not dispose of the animal's body or any remaining food. Please submit an individual consumer complaint for that dog, and mention that you have been instructed to submit the report by Vet-LIRN. We will review the complaint for potential follow-up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network procedures that describe how we operate. I also included a version for animal owners.

Please email or call me with any questions. Thank you again for your time and expertise,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Thursday, April 19, 2018 11:00 AM

To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

B6

Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey,

Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

We are all able to meet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and concerns surrounding a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.

Drs. **B6**, Freeman, **B6** Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

B6

Dr. Lisa Freeman is a Professor of Clinical Nutrition at Tufts University, College of Vet Med

B6

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med

Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

Thank you everyone for making time in your schedule! I am looking forward to this.

Sincerely,
Darcy Adin

----- Forwarded message -----

From: **Jones, Jennifer L** <Jennifer.Jones@fda.hhs.gov>

Date: Thu, Apr 19, 2018 at 7:16 AM

Subject: hold-call with Dr. Adin re: DCM cases

To: "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey, Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

-- Do not delete or change any of the following text. --

Join WebEx meeting

Meeting number (access code): **B6**

Meeting password: **B6**

Join by phone

B6

US Toll

US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

If you are a host, [go here](#) to view host information.

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

B6

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
CC: Rotstein, David
Sent: 5/30/2018 11:48:34 AM
Subject: RE: reporting diet/DCM dogs

Thank you, Lisa. Please submit the new case (not deceased) as a Pet Food Report using the online safety reporting portal.

I'll update the case file that the dog has died. Are there any tissues left or the possibility of a necropsy? We could coordinate one and would pay for it.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Wednesday, May 30, 2018 6:01 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: reporting diet/DCM dogs

Hi Jennifer

The dog eating **B4, B5** that I reported last Friday died **B6** How should I report that? Owners are holding food for analysis. We have new one on **B4, B5** that I'll submit today

Also, did you have thoughts **B5** Especially when it's a situation in which **B5**

Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Carey, Lauren; Queen, Jackie L; Rotstein, David; Jones, Jennifer L; Ceric, Olgica; Reimschuessel, Renate; Burkholder, William; Atkinson, Krisztina Z
Sent: 6/5/2018 1:29:50 PM
Subject: FW: Tufts article
Attachments: vetnutrition.tufts.edu-A broken heart Risk of heart disease in boutique or grain-free diets and exotic ingredients.pdf

Hi there – kind of a decent new piece for pet owners from Tufts. Just FYI. And I'll attach a copy as well if that's easier (my highlighting was just for my notes).

<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>

From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Graham, John; Edwards, David; Jones, Jennifer L; Ceric, Olgica; Nemser, Sarah
Sent: 6/6/2018 7:13:45 PM
Subject: RE: dog nutrition

We are on it.

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN
Phone 1-240-402-5404 Fax 301-210-4685
Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Graham, John
Sent: Wednesday, June 6, 2018 1:33 PM
To: Edwards, David <David.Edwards@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: FW: dog nutrition

FYI only, just passing it along.

From: Mendrick, Donna
Sent: Wednesday, June 06, 2018 1:14 PM
To: Graham, John <John.Graham@fda.hhs.gov>
Subject: dog nutrition

This was brought to my attention by a vet friend in AR. Are you aware of this?

<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>

From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:21:12 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi Jen and Dave,

Thanks so much for the update. Can we do a

B5

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 04, 2018 1:01 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@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

I received results from Covance, and I need to update this powerpoint. After further investigation, the lab ran the wrong test, and we'll have new Cys/Met results for the Grain Free foods. Please stay tuned.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, June 04, 2018 12:58 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>; 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

B5

(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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food. B4

B4 Some additional information is attached.

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

CVM is drafting a webposting to indicate that this is under investigation. In addition, B5

B5

Thank you,

Dave

B4

B4

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Rotstein, David; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:23:18 PM
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: Hartogenesis, Martine <Martine.Hartogenesis@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

B6 (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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food.

B5

Some additional information is attached.

B5

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

Thank you,

Dave

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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 </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:24:25 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Ok, I'm updating the values and powerpoint now.

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:24 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: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Martine,

Yes-I think that would work.

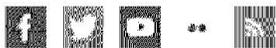
B5

Dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

(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: Hartogensis, Martine
Sent: Tuesday, June 05, 2018 2:21 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi Jen and Dave,

Thanks so much for the update.

B5

B5

B5

Martine

From: Jones, Jennifer L

Sent: Monday, June 04, 2018 1:01 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@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

I received results from Covance, and I need to update this powerpoint. After further investigation, the lab ran the wrong test, and we'll have new Cys/Met results for the Grain Free foods. Please stay tuned.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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

B6 (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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food.

B5

Some additional information is attached.

B5

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

Thank you,

Dave

B4, B5

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:31:13 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Sure. Just let me know when it's ready and we will replace it with the newer version.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6 (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: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@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

Dave, will you hold on the powerpoint? I'd like to give you an updated version.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 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: 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 Tuff'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

B5 (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: 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

B6 (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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food.

B5

Some additional information is attached.

B5

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

Thank you,

Dave

B4, B5

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

(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: 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 6:52:41 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Martine,

I'm available.

Thank you!!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 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: Hartogensis, Martine
Sent: Tuesday, June 05, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi!

B5

We are tentatively going to do a call Monday 9:30-10:30. Does that work for everyone?

They will set up a Go To meeting and I will forward.

Thanks again!

Martine

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@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

Dave B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 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: 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 Tuff'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

B6 (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: 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
B6 (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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food. B5

B5 Some additional information is attached.

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

B5

Thank you,

Dave

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogensis, Martine; Jones, Jennifer L; Rotstein, David; Carey, Lauren
Sent: 6/5/2018 7:19:03 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Looks good to me! Thanks.

From: Hartogensis, Martine
Sent: Tuesday, June 5, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi!

B5 We are tentatively going to do a call Monday 9:30-10:30. Does that work for everyone?

They will set up a Go To meeting and I will forward.

Thanks again!

Martine

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@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

Dave **B5**

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 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: 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 Tuff'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

B6 (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: Hartogenesis, 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: Hartogenesis, Martine <Martine.Hartogenesis@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

B6 (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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food. B5

B5

Some additional information is attached.

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

Thank you,

Dave

B4, B5

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

(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 </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Palmer, Lee Anne; Hartogensis, Martine; Rotstein, David; Carey, Lauren
Sent: 6/6/2018 3:23:28 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy
Attachments: 800.267-DCM-Grainfree analysis-UPDATED.pptx

Here is the updated powerpoint **B4** the grain free diets and non-grain free diets have similar Tau, Cys, and Met content.

B5

is in progress.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Palmer, Lee Anne
Sent: Tuesday, June 05, 2018 3:19 PM
To: Hartogensis, Martine <Martine.Hartogensis@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>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Looks good to me! Thanks.

From: Hartogensis, Martine
Sent: Tuesday, June 5, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi!

B5

Does that work for everyone?

They will set up a Go To meeting and I will forward.

Thanks again!

Martine

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@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

Dave **B5**

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 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: 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 Tuff'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

B6 (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: 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

B5

Thanks,
dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

(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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food.

B5

Some additional information is attached.

B5

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

B5

Thank you,

Dave

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: 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: 6/7/2018 12:17:08 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

I heard back from the Divisions that cover

B5

from B5 is a vet, so I think that she has a professional interest.

thanks

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: Rotstein, David
Sent: Tuesday, June 05, 2018 2:53 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: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

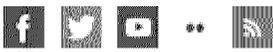
Martine,

I'm available.

Thank you!!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: Hartogensis, Martine
Sent: Tuesday, June 05, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi!

B5

Does that work for

everyone?

They will set up a Go To meeting and I will forward.

Thanks again!

Martine

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@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

Dave,

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 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: 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

B6

(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: 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

B6 (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: 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,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food. B5

B5 Some additional information is attached..

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

Thank you,

Dave

B4, B5

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6 (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: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Burkholder, William; Stamper, Carmela; Rotstein, David; Queen, Jackie L; Jones, Jennifer L; Atkinson, Krisztina Z; Palmer, Lee Anne
CC: Norris, Anne; Glover, Mark; Conway, Charlotte
Sent: 6/7/2018 4:57:15 PM
Subject: RE: Grain-Free Diet Effects
Attachments: Bednar - Starch and fiber fractions in selected food and feed ingredients.pdf; Murray - Evaluation of selected high-starch flours as ingredients in canine diets.pdf; Spears - Resistant starch as related to companion animal nutrition.pdf

I can only find abstracts for two. I have one other paper requested through ILL. I'll forward it once I have it. It was the one I found most interesting in regards to digestibility, etc.

B5

From: Carey, Lauren
Sent: Thursday, June 07, 2018 12:42 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

B5

From: Burkholder, William
Sent: Thursday, June 07, 2018 10:49 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones,

Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: Grain-Free Diet Effects

This is from Charlotte Conway who has contacts within the pet food formulation business:

"In follow-up to Dr. Freeman's article, I got a call from [REDACTED] **B6** this morning - so passing along his thoughts [REDACTED] **B6**
[REDACTED] **B6**
[REDACTED] **B6** Passing along because I said I would."

Some things to think about.

Bill Burkholder

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Jones, Jennifer L; Burkholder, William; Stamper, Carmela; Rotstein, David; Queen, Jackie L; Atkinson, Krisztina Z; Palmer, Lee Anne
CC: Norris, Anne; Glover, Mark; Conway, Charlotte
Sent: 6/7/2018 8:57:01 PM
Subject: RE: Grain-Free Diet Effects
Attachments: de-Oliveira - Fibre analysis and fibre digestibility in pet foods.pdf

I agree. That's important data for us to have.

Attaching the last paper with discussion of some of these grain-free ingredient oddities. This paper has several tables that break down fiber amounts. A lot of these grain free substitutes have a lot of fiber and when you start adding them in multiples...

B5

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 2:09 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I hope so. I thought their data was important for publishing.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren
Sent: Thursday, June 07, 2018 1:55 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

He made it sound like this paper was coming in the future, so maybe a revamp?

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 1:04 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: RE: Grain-Free Diet Effects

Interesting. I reviewed a paper out of cornell that measured metals in pet foods and it wasn't well organized. Maybe they made major revisions. I wasn't concerned about any of the levels they reported.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren

Sent: Thursday, June 07, 2018 12:57 PM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: RE: Grain-Free Diet Effects

I can only find abstracts for two. I have one other paper requested through ILL. I'll forward it once I have it. It was the one I found most interesting in regards to digestibility, etc.

B5

From: Carey, Lauren

Sent: Thursday, June 07, 2018 12:42 PM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: RE: Grain-Free Diet Effects

B5

B5

From: Burkholder, William

Sent: Thursday, June 07, 2018 10:49 AM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: Grain-Free Diet Effects

This is from Charlotte Conway who has contacts within the pet food formulation business:

"In follow-up to Dr. Freeman's article, I got a call from [B6] this morning - so passing along his thoughts: [B6]

B6

B6

Passing along because I said I would."

Some things to think about.

Bill Burkholder

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Norris, Anne; Carey, Lauren; Jones, Jennifer L; Burkholder, William; Stamper, Carmela; Queen, Jackie L; Atkinson, Krisztina Z; Palmer, Lee Anne
CC: Glover, Mark; Conway, Charlotte; DeLancey, Siobhan
Sent: 6/8/2018 6:03:44 PM
Subject: RE: Grain-Free Diet Effects

Thanks!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: Norris, Anne
Sent: Friday, June 08, 2018 1:41 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

Dr. Freeman has been blogging:
<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>

And then this popped up: <https://www.mnn.com/family/pets/stories/dog-food-trends-healthy-for-pets>

From: Carey, Lauren
Sent: Thursday, June 07, 2018 4:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I agree. That's important data for us to have.

Attaching the last paper with discussion of some of these grain-free ingredient oddities. This paper has several

B5

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 2:09 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I hope so. I thought their data was important for publishing.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren
Sent: Thursday, June 07, 2018 1:55 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

He made it sound like this paper was coming in the future, so maybe a revamp?

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 1:04 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

Interesting B5
Maybe they made major revisions. B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren

Sent: Thursday, June 07, 2018 12:57 PM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: RE: Grain-Free Diet Effects

I can only find abstracts for two. I have one other paper requested through ILL. I'll forward it once I have it. It was the one I found most interesting in regards to digestibility, etc.

B5

From: Carey, Lauren

Sent: Thursday, June 07, 2018 12:42 PM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: RE: Grain-Free Diet Effects

B5

From: Burkholder, William

Sent: Thursday, June 07, 2018 10:49 AM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>

Subject: Grain-Free Diet Effects

This is from Charlotte Conway who has contacts within the pet food formulation business:

"In follow-up to Dr. Freeman's article, I got a call from [REDACTED] **B6** this morning - so passing along his thoughts [REDACTED] **B6**

B6

B6

Passing along because I said I would."

Some things to think about.

Bill Burkholder

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Lisa.Freeman@tufts.edu
CC: AskOSC
Sent: 6/11/2018 8:06:59 PM
Subject: question about the FDA Safety Reporting Portal

Dr. Freeman,

Good Afternoon,

Our AskOSC team sent me over your email. It appears that what is being submitted is a RFR which is the FDA Reportable Food Registry. That's for industry to use to report any Class 1 Recalls. That's why you're seeing the fields that don't fit with what you are submitting.

Here are some suggestions:

For the page on the new report-

Select: Start a New Report

Select: A private citizen/business submitting a voluntary report

Select: Pet Food or Pet Treat for the cause of the issue

Select: Pet Food Report (a veterinarian or veterinary staff member) for the next field: Select a Report to begin

From there, it should be pretty straightforward. You can upload any documents.

Please let me know if this helps or if I can provide any other assistance.

Dave Rotstein

Safety Reporting Portal X

https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=b1c84606-0305-4...

New Guest Report

***Required Field**

You have chosen to use this portal as a Guest reporter.

Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

***Select the option that best describes what you want to do:**

- Start a new report
- Follow-up on a report previously submitted as a guest portal user.
- Follow-up on a report previously submitted as a logged in user.
- None of the above

***Who are You?**

- A private citizen/business submitting a voluntary report
- A federal, state or local public health official submitting a reportable food report about human and/or animal food
- A healthcare professional or researcher reporting a tobacco product problem
- A manufacturer reporting a tobacco product problem
- A manufacturer, sponsor or applicant of a drug product
- A manufacturer, packer or distributor of a human dietary supplement
- A food facility or responsible party that manufactures, processes, packs or holds food submitting a reportable food report

***What do you think caused the issue?** Pet Food or Pet Treat

***Select the report to begin** Pet Food Report (a veterinarian or veterinary staff member)

You have selected: Pet Food Report (a veterinarian or veterinary staff member)

David Rotstein, DVM, MPVM, Dipl. ACVP
 CVM Vet-LIRN Liaison
 CVM OSC/DC/CERT
 7519 Standish Place
 B6 } (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 </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Carey, Lauren; Palmer, Lee Anne; Queen, Jackie L
CC: Ceric, Olgica; Reimschuessel, Renate; Nemser, Sarah
Sent: 5/3/2018 4:34:39 PM
Subject: RE: 800.267-EON-345858-DCM Cluster

Thanks, everyone. We will do that!

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Thursday, May 03, 2018 12:34 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-EON-345858-DCM Cluster

Agreed!

From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Date: May 3, 2018 at 12:26:29 PM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-EON-345858-DCM Cluster

Hi Jen,

I think: B5

Thanks,
Lauren

From: Jones, Jennifer L
Sent: Tuesday, May 01, 2018 9:06 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: 800.267-EON-345858-DCM Cluster

B4 I wonder about either B5
B5

B5

Thoughts?

Dave previously sent an email about lentils being deficient in Cystine and Methionine. I found the same information about peas (attached).

B5

B5

In chickens (Sarwar article), a Cys/Met ratio of 0.2 : 1 in low protein diets causes lower 2 wk weight gain, food intake, BUN, and taurine-conjugated bile acids in weanling rats.

B5

B5

In pigs, there is absolute methionine and cystine values but also the met : met+cys ratio is important. For pigs the ratio is between 30-70% but the Qiao says 54.15%. I wonder

B5

B5

B5

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne
Sent: 5/8/2018 3:03:27 PM
Subject: RE: DCM

Thank you Martine!!!!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

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: 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!
Boorstin:

B6

https://www.cvcavets.com/doctor_directory/

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

B5

B5

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,

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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail

the sender immediately at david.rotstein@fda.hhs.gov.

From: Hartogenesis, 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

B5

Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Subject: Re: DCM

Martine

Lee Anne

B6

B6

Vet-LIRN is looking into:

B6

B6

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne
CC: Burkholder, William; Carey, Lauren; Norris, Anne; DeLancey, Siobhan
Sent: 5/9/2018 6:05:49 PM
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with [B4, B5] 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

[B5]



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: 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, Len and Dave! Very interesting and sounds like you all are on it!

[B6]

[B6]

https://www.cvcavets.com/doctor_directory/

[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,

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

B5



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: 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

B5

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

Dave

From: Hartogensis, Martine <Martine.Hartogensis@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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Palmer, Lee Anne; Jones, Jennifer L; Queen, Jackie L; Carey, Lauren
CC: Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/4/2018 3:58:42 PM
Subject: RE: DCM cases-food-Iodine screening results

Lee Anne

This is excellent. Based on what is found moving forward, do you think

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 4, 2018 at 11:15:20 AM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Grain-free does seem to be a problem. I'm going to attach 2 reports from earlier 2017 (illnesses back in 2015) which kind of pre-date this issue a bit. 2 Whippets from the same household seen at B6. You probably recall these, but at the time, they didn't get further f/u. Earthborn Holistic Primitive Naturals is a grain-free food. Iron levels were elevated in this set of 2 cases, same household. DCM cases, young dogs.

I am pulling all the cases (the added ones) into one spreadsheet

B5

B5

B6

I am ready to go with some other analyses – I feel like I work like molasses some days. Have this afternoon, so still working on some stats for these cases.

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 10:35 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Yes. I'm going to test some non grain free foods to see how their met/cys ratios compare to these GF foods.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:21 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 10:04 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

There is no minimum for dogs...it is apparently a conditionally essential amino acid because dogs can make it from methione and cystine.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:01 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Interesting... so the AAFCO minimum for cats is 0.1% DMB, is there a DMB for dogs? (If not, maybe there should be...)

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 9:46 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

One more nutritional deficiency-Taurine low based on AAFCO's Feline Minimum for Extruded foods. The dog consuming the product had a low whole blood Taurine level.

- Taurine = 45.5 mg/100g = 0.0455g/100g = 0.046% As Is Basis
If we assume a max of 10% moisture per the label (= 90% DMB),
then $0.0455 / 0.90 = 0.05\%$ DMB, which is less than the AAFCO minimum for cats eating extruded foods (0.1% DMB.)
- Cystine = 293 mg/100g = 0.293 g/100g = 0.29% As Is Basis
If we assume a max of 10% moisture per the label (= 90% DMB), then $0.293 / 0.90 = 0.33\%$ DMB
- Methionine = 358mg/100g = 0.358 g/100g = 0.36% As Is Basis

If we assume

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Monday, April 23, 2018 10:32 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: DCM cases-food-Iodine screening results

FYI-

B5

B5

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica
CC: Norris, Anne; DeLancey, Siobhan
Sent: 4/13/2018 1:06:07 PM
Subject: FYI-FW: Call to discuss DCM cases

I'll keep everyone posted about a time for the meeting.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Friday, April 13, 2018 9:05 AM
To: 'Darcy Adin' <dbadin@ncsu.edu>
Subject: Call to discuss DCM cases

Good morning Darcy,
I hope you're well. Are you able to chat more about the DCM cases from dogs eating grain free food that the cardiology community is seeing? I'd like to schedule a call with you and some of your colleagues who are also following the issue. I'd like to gather more information about the clinical findings and your ideas on what could be the cause. Do you have any contacts with Dr. Joshua Stern or other clinical research cardiologists that could provide additional information following this issue? I can include them on the call.

Thank you in advance for your time, and have a great weekend.
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
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: 'Darcy Adin'
CC: Rotstein, David; Norris, Anne; DeLancey, Siobhan
Sent: 4/16/2018 1:48:17 PM
Subject: RE: Call to discuss DCM cases

Yes, I can do 2 pm.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, April 16, 2018 9:43 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Re: Call to discuss DCM cases

Thank you Jennifer. I will reach out to them to ask them to see if they are interested. Would it be possible to meet a bit earlier on thursday (say 2pm?)

Thanks!

Darcy

On Mon, Apr 16, 2018 at 8:20 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy.

Would you be available Thursday at 3pm eastern? If Dr. Freeman or any of the other cardiologists you mentioned below are interested, they can join the call as well.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Friday, April 13, 2018 12:31 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Call to discuss DCM cases

Hi Jennifer,

Definitely! I'd love to chat more. I have not talked with Dr. Stern in a while but I can certainly reach out to him.

B5, B6

B6

Dr. Lisa Freeman (nutritionist at Tufts) and indirectly Dr. Ryan Fries at Illinois (he has

B5

I am free next week to chat wed-fri. Let me know how you would like to proceed - thank you!

Darcy

On Fri, Apr 13, 2018 at 9:05 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Darcy,

I hope you're well. Are you able to chat more about the DCM cases from dogs eating grain free food that the cardiology community is seeing? I'd like to schedule a call with you and some of your colleagues who are also following the issue. I'd like to gather more information about the clinical findings and your ideas on what could be the cause. Do you have any contacts with Dr. Joshua Stern or other clinical research cardiologists that could provide additional information following this issue? I can include them on the call.

Thank you in advance for your time, and have a great weekend.

Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 4/18/2018 10:58:16 AM
Subject: Re: hold-call with Dr. Adin re: DCM cases

Great! I will poll the group and got back to you

On Apr 18, 2018, at 6:46 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Darcy,
If Friday works best for the group, we can be available between 11 to 3pm eastern.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<[image001.png](#)> <[image002.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, April 17, 2018 5:18 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: hold-call with Dr. Adin re: DCM cases

B6 is free friday as well. If this works for you then I'll poll the others!

On Tue, Apr 17, 2018 at 5:16 PM, Darcy Adin <dbadin@ncsu.edu> wrote:
I will!

I haven't heard from her but Drs. Freeman and **B6** can't easily do thursday afternoon. I'm sure there is not going to be a time that is good for everyone but I would love for her to participate. She would be available earlier on thursday (before 11) but not sure if that will work for Dr. Stern on the west coast (I can ask if this is good for you) or friday except over lunch.

Would either of these options work for your team?
Take care
Darcy

On Tue, Apr 17, 2018 at 8:47 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Thank you, Darcy.
I hope **B6** can join. I haven't talked with her in many years. **B6**

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<[image001.png](#)> <[image005.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, April 17, 2018 8:38 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: hold-call with Dr. Adin re: DCM cases

Thank you Jennifer. I will forward this on to Drs. Freeman (nutritionist at Tufts), Fries (cardiologist at Illinois) and [redacted] B5, B6 I am still waiting to hear back from [redacted] B5, B6 and [redacted] B5, B6
Take care
Darcy

On Apr 17, 2018, at 7:53 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

-- Do not delete or change any of the following text. --

Join WebEx meeting

Meeting number (access code): [redacted] B6
Meeting password: [redacted] B6

Join by phone

[redacted] B6 US Toll
[redacted] B6 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

If you are a host, [go here](#) to view host information.

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

<mime-attachment.ics>

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Freeman, Lisa; Joshua A Stern <[REDACTED] B6 [REDACTED]>; Rotstein, David
Sent: 8/16/2018 12:49:22 PM
Subject: Re: a few NCSU cases

Thanks Jennifer!

On Thu, Aug 16, 2018 at 8:13 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning everyone,

Here's our Vet-LIRN rapid necropsy document.

Take care,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Wednesday, August 15, 2018 2:49 PM
To: 'Freeman, Lisa' <Lisa.Freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>

Cc: Joshua A Stern <jstern@ucdavis.edu> <[REDACTED] B6 [REDACTED]>

Subject: RE: a few NCSU cases

Thank you, Darcy! We'll be on the lookout for the cases.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]

Sent: Wednesday, August 15, 2018 8:50 AM

To: Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Joshua A Stern <jstern@ucdavis.edu>

B6

Subject: RE: a few NCSU cases

That's really interesting, Darcy!

I wonder

B5

Thanks for sharing

Lisa

From: Darcy Adin <dbadin@ncsu.edu>

Sent: Tuesday, August 14, 2018 8:00 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>

B6

B6

Subject: a few NCSU cases

Hi Jennifer,

I wanted to follow up on the case where NCSU sent you necropsy samples (B6 3 yr Fs Great Dane). I've attached her whole blood and plasma taurine concentrations for your records, which were normal.

One of my residents saw a littermate pair of Dobermans back for their 3 month recheck after being diagnosed with DCM while eating Acana. Taurines were normal on these dogs back in April and I honestly didn't have a ton of hope for these dogs (B6) because they were dobermans and their genetic tests were abnormal (the female is homozygous positive for one mutation and negative for a 2nd, the male was heterozygous positive for one mutation and negative for a 2nd). But, 3 months after a diet change to Purina grain-based (and no taurine supplementation), they both have shown significant improvement (the less severely affected female has near normalized and the severely affected male (who was in heart failure) has also significantly improved.

I have asked our resident to report these dogs to the FDA using the portal (B6) so hopefully you will see these soon. She will also be submitting a taurine deficient Golden eating Acana (B6 maybe the lowest I've ever seen).

Thank you!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

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: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L; Darcy Adin
CC: Joshua A Stern; [REDACTED] Rotstein, David
Sent: 8/16/2018 6:17:49 PM
Subject: RE: a few NCSU cases

Hi Jen
[REDACTED] B5 Just want to be sure we get what you're
looking for.
We appreciate your putting this together. This will be helpful
Thanks
Lisa

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, August 16, 2018 8:13 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>
Cc: Joshua A Stern <jstern@ucdavis.edu>; [REDACTED] B6 Rotstein, David
<David.Rotstein@fda.hhs.gov>
Subject: RE: a few NCSU cases

Good morning everyone,
Here's our Vet-LIRN rapid necropsy document.
Take care,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Wednesday, August 15, 2018 2:49 PM
To: 'Freeman, Lisa' <Lisa.Freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>
Cc: Joshua A Stern <jstern@ucdavis.edu>; [REDACTED] B6
Subject: RE: a few NCSU cases

Thank you, Darcy! We'll be on the lookout for the cases.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Wednesday, August 15, 2018 8:50 AM
To: Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Joshua A Stern <jstern@ucdavis.edu>; [REDACTED] B6
Subject: RE: a few NCSU cases

That's really interesting, Darcy!
I wonder [REDACTED] B5
Thanks for sharing
Lisa

From: Darcy Adin <dbadin@ncsu.edu>

Sent: Tuesday, August 14, 2018 8:00 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <istern@ucdavis.edu>; [REDACTED] B6

[REDACTED] B6

Subject: a few NCSU cases

Hi Jennifer,

I wanted to follow up on the case where NCSU sent you necropsy samples [REDACTED] B6 3 yr Fs Great Dane). I've attached her whole blood and plasma taurine concentrations for your records, which were normal.

One of my residents saw a littermate pair of Dobermans back for their 3 month recheck after being diagnosed with DCM while eating Acana. Taurines were normal on these dogs back in April and I honestly didn't have a ton of hope for these dogs [REDACTED] B6 because they were dobermans and their genetic tests were abnormal (the female is homozygous positive for one mutation and negative for a 2nd, the male was heterozygous positive for one mutation and negative for a 2nd). But, 3 months after a diet change to Purina grain-based (and no taurine supplementation), they both have shown significant improvement (the less severely affected female has near normalized and the severely affected male (who was in heart failure) has also significantly improved.

I have asked our resident to report these dogs to the FDA using the portal [REDACTED] B6 hopefully you will see these soon. She will also be submitting a taurine deficient Golden eating Acana [REDACTED] B6 maybe the lowest I've ever seen).

Thank you!
Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 8/23/2018 3:56:57 PM
Subject: RE: updates

Hi Lisa,
Do we have permission to contact [B6] about the 2 dobermans?
Thank you,
Jen

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 [B6] 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: 'Freeman, Lisa'
Sent: 8/24/2018 11:29:51 AM
Subject: RE: updates

Thank you, Lisa. I'll contact them.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Thursday, August 23, 2018 12:26 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: updates

Hi Jen. They gave permission to report so i think it would be fine til contact but I can specifically check if you'd prefer
Lisa

Sent from my iPhone

On Aug 23, 2018, at 11:57 A Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Lisa,
Do we have permission to contact [B6] about the 2 dobermans?
Thank you,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<image001.png> <image002.png>

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 [B6] 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: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 2/24/2019 11:05:45 PM
Subject: ps - **B6**

Hi Jen

I forgot to mention that I have diet samples for the Natural Balance and Acana for

Lisa

B6

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

Client: **B6**
Patient:

ECG from Cardio

B6

3/14/2019 3:34:06 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

3/14/2019 3:34:06 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from Cardio

B6

3/14/2019 3:34:20 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

3/14/2019 3:34:20 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

3/14/2019 3:34:39 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

3/14/2019 3:34:39 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 10/11/2018 9:32:04 PM
Subject: B6 Taurine result
Attachments: T_22910.jpg

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: Tufts Veterinary Cardiology Service
Sent: Thursday, October 11, 2018 4:57 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Cc: B6
Subject: FW: Taurine result

Veterinary Cardiology Service
Tufts University Cummings School of Veterinary Medicine

Please note: This account is not monitored on weekends, holidays, or evenings (after 5pm). Please allow 24 - 48 business hours for a reply. For immediate service during business hours, please call the liaison office at 508-887-4696. If you need to speak with the Emergency Service, please call 508-839-5395.

Foster Hospital for Small Animals
200 Westboro Road
North Grafton, MA 01536
<http://www.tufts.edu/vet/>
508.887.4696 phone
508.887.4363 fax

From: Amino Acid Lab <ucd.aminoacid.lab@ucdavis.edu>
Sent: Thursday, October 11, 2018 4:55 PM
To: Clinical Pathology Lab <clinpath@tufts.edu>; Tufts Veterinary Cardiology Service <cardiovet@tufts.edu>
Subject: Taurine result

Hello -

Thank you for using the Amino Acid Laboratory at UC Davis, School of Veterinary Medicine.

Please find attached the results for your patient. You will note that we are now using a new submission form. The new form requests some additional information that may be useful in interpreting your results. Please note, with the recent increase in the number of dogs screened for taurine deficiency, we are seeing some dogs with values within the lower reference ranges (or above the “no known risk for deficiency range”) yet are still exhibiting changes in cardiac function.

In addition to our new submission form, we have also attached 2 handouts developed by our cardiology service at UC Davis for your information. The first is a general handout on dilated cardiomyopathy in dogs. The second is a handout specifically focused on Golden Retrievers, a breed that has been over-represented in the association between grain-free diet consumption and dilated cardiomyopathy.

We hope your clinic finds this information helpful. Veterinarians are always welcome to contact our laboratory for assistance in evaluating your patient’s results.

Thank you -

The Amino Acid Laboratory
Department of Molecular Biosciences
School of Veterinary Medicine
University of California, Davis

Phone: 530-752-5058

Email: ucd.aminoacid.lab@ucdavis.edu

B6

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'; Freeman, Lisa; Joshua A Stern; Fries, Ryan C; [REDACTED] **B6**
CC: Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 4/20/2018 5:18:50 PM
Subject: RE: hold-call with Dr. Adin re: DCM cases
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, please file an official consumer complaint. Instructions on how to report a pet food report can be found at: <https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>. The complaint can be submitted through the Safety Reporting Portal: <https://www.safetyreporting.hhs.gov>. You can attach documents already created that compile your case data. We will review the data and may contact you for possible follow-up.

In the meantime, if you have a dog with DCM on a grain free diet that dies or is euthanized, please do not dispose of the animal's body or any remaining food. Please submit an individual consumer complaint for that dog, and mention that you have been instructed to submit the report by Vet-LIRN. We will review the complaint for potential follow-up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network procedures that describe how we operate. I also included a version for animal owners.

Please email or call me with any questions. Thank you again for your time and expertise,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, April 19, 2018 11:00 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6**; [REDACTED] **B6**
Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

We are all able to meet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and concerns surrounding a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.

Drs. [REDACTED] **B6** Freeman, [REDACTED] **B6** Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

[REDACTED] **B6**

Dr. Lisa Freeman is a Professor of Clinical Nutrition at Tufts University, College of Vet Med

[REDACTED] **B6**

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med
Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

Thank you everyone for making time in your schedule! I am looking forward to this.

Sincerely,
Darcy Adin

----- Forwarded message -----

From: **Jones, Jennifer L** <Jennifer.Jones@fda.hhs.gov>

Date: Thu, Apr 19, 2018 at 7:16 AM

Subject: hold-call with Dr. Adin re: DCM cases

To: "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey, Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

-- Do not delete or change any of the following text. --

[Join WebEx meeting](#)

Meeting number (access code):

B6

Meeting password:

B6

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

If you are a host, [go here](#) to view host information.

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

--

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: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Rotstein, David; Jones, Jennifer L
Sent: 5/1/2018 1:38:39 PM
Subject: RE: DCM cases - proposed diet history

Thanks – this is a great dietary history. My only comments:

B5

Thanks for the opportunity to comment!

Lee Anne

From: Rotstein, David
Sent: Friday, April 27, 2018 9:00 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Fwd: DCM cases - proposed diet history

Lee Anne,

Thought you would be interested and could provide any comments/suggestions

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Date: April 27, 2018 at 7:27:27 PM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>, Joshua A Stern <jstern@ucdavis.edu>, Fries, Ryan C <rfries@illinois.edu> **B6**
B6
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: DCM cases - proposed diet history

Hi everyone

I'm attaching a proposed diet history form. I met with our cardiology group yesterday **B5**

B5

Please let me know if you have any comments –

B5

B5

Our group also discussed

B5

B5

Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L [<mailto:Jennifer.Jones@fda.hhs.gov>]

Sent: Friday, April 20, 2018 3:50 PM

To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>;

B6

B6

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: hold-call with Dr. Adin re: DCM cases

Importance: High

My apologies for the repeat email. After further internal discussion, in lieu of submitting Consumer Complaints, you can just email me a spreadsheet with the data.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Friday, April 20, 2018 1:19 PM

To: 'Darcy Adin' <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>;

B6

B6

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: hold-call with Dr. Adin re: DCM cases

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, please file an official consumer complaint. Instructions on how to report a pet food report can be found at: <https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>. The complaint can be submitted through the Safety Reporting Portal: <https://www.safetyreporting.hhs.gov>. You can attach documents already created that compile your case data. We will review the data and may contact you for possible follow-up.

In the meantime, if you have a dog with DCM on a grain free diet that dies or is euthanized, please do not

dispose of the animal's body or any remaining food. Please submit an individual consumer complaint for that dog, and mention that you have been instructed to submit the report by Vet-LIRN. We will review the complaint for potential follow-up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network procedures that describe how we operate. I also included a version for animal owners.

Please email or call me with any questions. Thank you again for your time and expertise,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, April 19, 2018 11:00 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jsstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu> [B6]
Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

We are all able to meet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and concerns surrounding a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.

Drs. [B6] Freeman, [B6] Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

[B6]

Dr. Lisa Freeman is a Professor of Clinical Nutrition at Tufts University, College of Vet Med

[B6]

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med

Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

Thank you everyone for making time in your schedule! I am looking forward to this.

Sincerely,
Darcy Adin

----- Forwarded message -----

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Date: Thu, Apr 19, 2018 at 7:16 AM

Subject: hold-call with Dr. Adin re: DCM cases

To: "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey, Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

-- Do not delete or change any of the following text. --

Join WebEx meeting

Meeting number (access code)

B6

Meeting password

B6

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

[Can't join the meeting?](#)

If you are a host, [go here](#) to view host information.

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

--

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: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Jones, Jennifer L; Rotstein, David; Carey, Lauren
Sent: 5/7/2018 6:07:39 PM
Subject: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx
Attachments: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Jones, Jennifer L; Palmer, Lee Anne; Hartogensis, Martine; DeLancey, Siobhan
CC: Burkholder, William; Norris, Anne; Lovell, Randall A; Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/21/2018 11:41:45 AM
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: Carey, Lauren
Sent: Monday, May 21, 2018 7:39 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@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>; 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 an FYI, this formulation type is so popular Amazon jumped on board.

<https://www.petfoodindustry.com/articles/7209-amazon-wag-dog-foods-nutrient-content-analyzed-rated?eid=418335734&bid=2101343>

<https://www.amazon.com/WAG-Added-Grain-Lentil-Recipe/dp/B078VV67DT>

INGREDIENTS: BEEF, BEEF MEAL, LENTILS, PEA PROTEIN, PEAS, EGG PRODUCT, CHICKEN FAT (PRESERVED WITH MIXED TOCOPHEROLS), BREWERS YEAST, WILD BOAR, POTATO PROTEIN, DRIED PLAIN BEET PULP, FLAXSEED, NATURAL FLAVOR, SALT, CHOLINE CHLORIDE, DRIED CHICORY ROOT, YUCCA SCHIDIGERA EXTRACT, DRIED LACTOBACILLUS PLANTARUM FERMENTATION PRODUCT, DRIED BACILLUS SUBTILIS FERMENTATION PRODUCT, DRIED LACTOBACILLUS ACIDOPHILUS FERMENTATION PRODUCT, DRIED ENTEROCOCCUS FAECIUM FERMENTATION PRODUCT, DRIED BIFIDOBACTERIUM ANIMALIS FERMENTATION PRODUCT, VITAMIN E SUPPLEMENT, IRON PROTEINATE, ZINC PROTEINATE, COPPER PROTEINATE, FERROUS SULFATE, ZINC SULFATE, COPPER

SULFATE, POTASSIUM IODIDE, THIAMINE MONONITRATE (SOURCE OF VITAMIN B1), MANGANESE PROTEINATE, MANGANOUS OXIDE, ASCORBIC ACID (PRESERVATIVE), VITAMIN A SUPPLEMENT, BIOTIN, NIACIN, CALCIUM PANTOTHENATE, MANGANESE SULFATE, SODIUM SELENITE, PYRIDOXINE HYDROCHLORIDE (SOURCE OF VITAMIN B6), VITAMIN B12 SUPPLEMENT, RIBOFLAVIN (VITAMIN B2), VITAMIN D3 SUPPLEMENT, FOLIC ACID.

B4, B5

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 3:31 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@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

Yes, you're correct Lee Anne.

B4

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Palmer, Lee Anne
Sent: Friday, May 18, 2018 3:29 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

B4, B5

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 3:24 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@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

I just got a call from Dr. Fascetti with UC Davis-She runs the amino acid laboratory and B5

B5

B5

B5

B5

B5

B5

B5

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Palmer, Lee Anne
Sent: Friday, May 18, 2018 3:10 PM
To: Hartogensis, Martine <Martine.Hartogensis@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: 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

In terms of # reported to us - I would look at (in terms of reports directly to FDA CVM) the top 2 primarily. Dave could do much better with contact info.

B5

There are a variety of others – among those reported to us, several have 1 report per brand, but all grain-free.

B4, B5

From: Hartogensis, Martine
Sent: Friday, May 18, 2018 2:53 PM
To: 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: 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, thank you to everyone on the call.

Anne and I are working on the advisory. In meantime, I think we **B5**
B5 Dave, do you have that or any suggestions on how to find contact names/numbers?

Martie

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,
suppose

B5

B5

I also cleaned up and did
this one out!

B5

hanks – hope we can figure

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

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! One question though...do we see

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

B5

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

Hi there – is the slide set for tomorrow's meeting? Great work!

B5

B5

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!!

Just a few questions
DCM?

B5

One other quest
issue?

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

We

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

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

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

From what I've read, it can be a

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

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

Hi there -

B5

B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

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 I want to confirm it, then will send it along – could be Friday before I get this in shape to send... not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!

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
B5



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: 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: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

B5

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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: 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

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

Lee Anne will likely discuss at

B5

B5

Vet-LIRN is looking into

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: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Palmer, Lee Anne; Jones, Jennifer L; DeLancey, Siobhan; Rotstein, David
CC: Burkholder, William; Carey, Lauren; Norris, Anne; Lovell, Randall A; Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/18/2018 7:13:53 PM
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 18, 2018 3:10 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@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: 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

In terms of # reported to us - I would look at (in terms of reports directly to FDA CVM) the top 2 primarily. Dave could do much better with contact info.

B4, B5

From: Hartogenesis, Martine
Sent: Friday, May 18, 2018 2:53 PM
To: 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: 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, thank you to everyone on the call.

B5

Martie

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

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: Hartogenesis, Martine <Martine.Hartogenesis@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

CVCA is not a part of Vet-LIRN.

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogenesis, 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! One question though...do we see

B5

with CVCA? Are they part of VET-LIRN?

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>; 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>; 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

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

Hi there – is the slide set for tomorrow's meeting? Great work!

B5

B5

B5

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!!

Just a few questions. On slide 6 (or the spreadsheet);

B5

DCM?

One other question –
issue?

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



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

I do not know

B5

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. [REDACTED] Dave, do you have any idea about [REDACTED]

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

From what I've read, it can be

B

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. [REDACTED]

B5

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

Hi there –

B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

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 I want to confirm it, I will send it on Friday before this is a tape to send... not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!

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 wet 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



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: Hartogenesis, 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: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: Hartogenesis, 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

B5

Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Subject: Re: DCM

Martine

Lee Anne will likely discuss at [REDACTED] **B5** But it does look like there is a relationship between the increased DCM reports and grain free diets.

Vet-LIRN is looking into [REDACTED] **B5**
[REDACTED] **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: Burkholder, William
Sent: 6/18/2018 12:01:06 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Excellent! Thanks, Bill.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Burkholder, William
Sent: Sunday, June 17, 2018 8:49 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen,

First, thanks for compiling my literature reading list for the next few weeks (I am being serious in my thanks). Attached are the two documents you requested comment on with edits and comments in track changes. Keep or reject as you see fit. As always, thank you for the opportunity to comment.

Bill

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@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>; 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

Good morning everyone,
Vet-LIRN created a procedure document that outlines a prospective case investigation for new complaints about DCM and consuming grain free products. We plan to: B5

B5 However, we will be: B5 to 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

B4, 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;

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,

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.

Part of this outreach is for us to directly contact firms.

B5

B5

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

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: 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

B5

We could update the advisory further as more information comes in.

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

B6 (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: 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

I agree with a careful approach to this investigation.

B5

B5

B5

B5

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

B5

Not meaning to restart any prior conversations about these sub

B5

Thanks,
Dave

From: Rotstein, David
Sent: Monday, May 21, 2018 7:49 AM
To: 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>; 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

Yes, if I can get the complete list of products so that I don't miss any, we will reach out to the Divisions and provide a general summary of what is going on and then work with the Divisions on setting up calls.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: 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

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>; 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

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

B5

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>

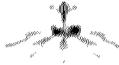
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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

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! One question though...

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

B5

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

B5

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!!

Just a few questions.

B5

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

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** ..Dave, do you have any idea

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

I think

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

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

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

Hi – the deeper I dia through this data, the more interesting it is becoming.

B5

B6

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
[B6] (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: 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: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

B5

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
B6 **(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: 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

B5

B5

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

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Andrea Fascetti'
Sent: 8/17/2018 2:48:55 PM
Subject: [REDACTED] **B5**

Hi Andrea,

I had a quick question. I'm trying to order the [REDACTED] **B5** but does it matter [REDACTED] **B5**? I referenced the [REDACTED] **B5** paper you sent but couldn't find any specifics of the chemical formula.

I hope you and your family are doing well, including your dog after the quarantine period J

Thanks again and take care,

Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: [REDACTED] B6
Sent: 7/18/2019 11:11:54 AM
Subject: RE: [REDACTED] B6 FDA-CVCA Study for Dilated Cardiomyopathy
Importance: High

Good morning Mr. [REDACTED] B6

Are you interested in speaking with me about [REDACTED] B6 case? Please see my previous email below.

If so, please send me your availability for a 30-minute phone call on the following days:

- Tuesday July 23: 10 am to 12 noon eastern, or 1 to 3 pm
- Wednesday July 24: 6:30 am to 11 am eastern
- Thursday July 25: 6:30 am to 3 pm eastern
- Friday July 26: 6:30 am to 11:30 am eastern.

If you are unwilling to perform the interview, please let me know. I can then remove you from the interview list.

Thank you,

Dr. Jones

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Friday, July 05, 2019 12:52 PM
To: [REDACTED] B6
Subject: [REDACTED] B6 FDA-CVCA Study for Dilated Cardiomyopathy
Importance: High

Good afternoon [REDACTED] B6

We have been working with CVCA to better understand Dilated Cardiomyopathy in dogs that ate pet foods labelled "grain free" and contain higher amounts of legumes and/or potato products. As part of that investigation, we would like to ask you some questions about [REDACTED] B6's past and current diet and environmental exposures.

The phone interview lasts approximately 30 minutes. Please send me 3 times when you would be available to speak between 6:30 am and 3 pm eastern time the following days:

- 7/11
- 7/12
- 7/15
- 7/16
- 7/17
- 7/18

I attached a copy of our network procedures. They describe how owners help with our case investigations.

Thank you kindly,

Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708

new tel: 240-402-5421

fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6 Andrea Fascetti
CC: Guag, Jake
Sent: 4/2/2019 11:19:19 AM
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Received. Thank you, [REDACTED] B6

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: [REDACTED] B6
Sent: Monday, April 01, 2019 8:06 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Andrea Fascetti <ajfascetti@ucdavis.edu>
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi Dr. Jones,

Attached please find the corrected data file.

Kind Regards,

[REDACTED] B6

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Monday, April 1, 2019 4:30 AM
To: Andrea Fascetti; [REDACTED] B6
Cc: Guag, Jake
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Good morning Andrea and [REDACTED] B6

I was reviewing the results and needed some clarification of the results for 2 cases. The results you sent show plasma amino acid values for cv-09 but not cv-14. However, I did not send any plasma for cv-09. I did send plasma for cv-14 (attached inventory sheet). Can you please clarify which set of plasma values belong to cv-14? Thank you in advance and have a wonderful week,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Andrea Fascetti <ajfascetti@ucdavis.edu>
Sent: Saturday, March 23, 2019 1:30 PM
To: [REDACTED] B6
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hello Jen and Jake- Please see attached file with your results. Thanks for the heads-up on the species. We have to know in case someone in the lab comes in contact with the blood (especially through a cut). Our occupational health and safety folks then have us file a report and follow up on those cases to ensure vaccination status etc.

We will bill according to your comments below.

Have a nice weekend.

Andrea

On Mar 21, 2019, at 10:51 AM, [REDACTED] B6 [REDACTED]@ucdavis.edu> wrote:

Hi Jake,

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks,

[REDACTED] B6 [REDACTED]

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, March 12, 2019 8:53 AM
To: [REDACTED] B6 [REDACTED]
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi [REDACTED] B6 [REDACTED]

Hope you are well. We shipped 800.267 samples on dry ice to you.

Box#1 has urine samples its tracking number is 1ZA4420T0194520315 with UPS.

Box#2 has whole blood and serum samples and its tracking number is 1ZA4420T0192121929 with UPS. Both boxes are expected to arrive your location tomorrow (Mar. 13th, 2019)

Please charge the urine sample analysis under AA contract.

Please provide invoice for the blood and serum analysis.

Thank you
Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6
CC: 'Guag, Jake * (Jake.Guag@fda.hhs.gov)'
Sent: 3/22/2019 10:35:43 AM
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi [REDACTED] B6
They are all dogs.
Thank you,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Guag, Jake
Sent: Thursday, March 21, 2019 2:09 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Jen, could you please provide me info or where I can find the info?

Thanks
Jake

From: [REDACTED] B6
Sent: Thursday, March 21, 2019 1:52 PM
To: Andrea Fascetti <ajfascetti@ucdavis.edu>
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Fw: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi Jake,

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks,

[REDACTED] B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, March 12, 2019 8:53 AM
To: [REDACTED] B6
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi [REDACTED] B6
Hope you are well. We shipped 800.267 samples on dry ice to you.
Box#1 has urine samples its tracking number is 1ZA4420T0194520315 with UPS.
Box#2 has whole blood and serum samples and its tracking number is 1ZA4420T0192121929 with UPS. Both boxes are expected to arrive your location tomorrow (Mar. 13th, 2019)

Please charge the urine sample analysis under AA contract.

Please provide invoice for the blood and serum analysis.

Thank you
Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: [REDACTED] B6
CC: Andrea Fascetti
Sent: 8/20/2019 11:44:03 AM
Subject: Question about results

Good morning [REDACTED] B6 and Andrea,
I had two quick general questions about the plasma and urine amino acid results.

[REDACTED] B5

Thank you in advance,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
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>

 **U.S. FOOD & DRUG**
ADMINISTRATION



From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: [REDACTED] B6
Sent: 6/27/2019 4:48:27 PM
Subject: RE: Fw: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi [REDACTED] B6

Thanks. You are correct. I forgot to update the CV-10 samples.

[REDACTED] B6

Could you please provide me when we can expect to get results?

Thanks

From: [REDACTED] B6 <[REDACTED]@ucdavis.edu>
Sent: Thursday, June 27, 2019 12:41 PM
To: [REDACTED] B6 <Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Fw: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hello Jake-

Attached please find the completed inventory form. The only thing of note is there were 2 vials of cv-10 plasma, otherwise everything was in order.

Kind regards-

[REDACTED] B6

On Thu, Jun 27, 2019 at 9:26 AM [REDACTED] B6 <[REDACTED]@ucdavis.edu> wrote:

Hi [REDACTED] B6

Could you fill their sample inventory forms and email a PDF to Jake?

Thanks,

[REDACTED] B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Thursday, June 27, 2019 9:21 AM
To: [REDACTED] B6
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi [REDACTED] B6

Could you please provide me filled out sample inventory forms?

Thanks
Jake

From: [B6]@ucdavis.edu
Sent: Tuesday, June 25, 2019 1:16 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>; [B6]@ucdavis.edu
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi Jake,

Thanks for the notice. I will Let Dr. Fascetti know your plan. I am not in charge of the billing issues.

Kind Regards,

[B6]

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, June 25, 2019 9:17 AM
To: [B6]
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi [B6]

I shipped 800.267 R3 samples on dry ice to your place this morning. R3 Urine samples are in Box#1, and R3 whole blood and plasma samples are in Box #2.

Both boxes will be arrive tomorrow (Jun 26, 2019), and their tracking numbers are [B6] (Box#1) and [B6] (Box#2) with UPS.

Inside you will find sample an inventory sheet in each box. Please fill out and provide to me (Scan or Fax).

[B5]

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

From: Andrea Fascetti <ajfascetti@ucdavis.edu>
To: Jones, Jennifer L
Sent: 9/18/2018 12:16:47 PM
Subject: Re: control dog Taurine-urine

Hi Jen - Here is [B6] email address:

[B6]

And Josh:

jstern@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: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Peloquin, Sarah
Sent: 9/18/2018 1:54:55 PM
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:

jstern@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: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Peloquin, Sarah
Sent: 9/18/2018 2:12:18 PM
Subject: RE: control dog Taurine-urine

No-this is different. We can chat tomorrow.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Peloquin, Sarah
Sent: Tuesday, September 18, 2018 10:08 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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 [@ucdavis.edu](mailto:>@ucdavis.edu)

And Josh:

jstern@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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 10/9/2018 1:48:13 PM
Subject: house mate of EON-366516 (attached) FW: Taste of the Wild (various flavors) since Nov 2013: Lisa Freeman - EON-367899
Attachments: 2055822-report.pdf; Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor-Before that: Lisa Freeman - EON-366516; 2055822-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: PFR Event <pfpreventcreation@fda.hhs.gov>
Sent: Tuesday, October 09, 2018 9:45 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6
Subject: Taste of the Wild (various flavors) since Nov 2013: Lisa Freeman - EON-367899

A PFR Report has been received and PFR Event [EON-367899] has been created in the EON System.

A "PDF" report by name "2055822-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 "2055822-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367899
ICSR #: 2055822
EON Title: PFR Event created for Taste of the Wild (various flavors) since Nov 2013; 2055822

AE Date	10/02/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2

Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055822

Product Group: Pet Food

Product Name: Taste of the Wild (various flavors) since Nov 2013

Description: Asymptomatic but is housemate of **B6** who was diagnosed with DCM recently (FDA ICSR ID 2055229). Eating same diet until mid-September when switched to Pro Plan Weight Management dry. Note **B6** does not have clear DCM but has reduced contractility. Will recheck in 6 months. Taurine pending - will submit when available.

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Taste of the Wild (various flavors) since Nov 2013		

Sender information

Lisa Freeman
 200 Westboro Rd
 North Grafton, MA 01536
 USA

Owner information

B6

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

=====

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this

information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/11/2019 6:36:57 PM
Subject: Pure Balance Salmon and Pea dry: Lisa Freeman - EON-390200
Attachments: 2068093-report.pdf; 2068093-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390200] has been created in the EON System.

A "PDF" report by name "2068093-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 "2068093-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390200

ICSR #: 2068093

EON Title: Related PFR Event created for Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry; 2068093

AE Date	10/31/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068093

Product Group: Pet Food

Product Name: Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry

Description: DCM and CHF diagnosed 10/31/18. On BEG diet. Normal taurine levels

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie dry		
Pure Balance Salmon and Pea dry		

This report is linked to:

Initial EON Event Key: EON-370760

Initial ICSR: 2058697

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

To view this Related PFR Event, please click the link below:

B6

To view the Related PFR Event Report, please click the link below:

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

Client:
Patient:

B6

ECG from Cardio

B6

2/14/2019 4:16:11 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

2/14/2019 4:16:11 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from Cardio

B6

2/14/2019 4:16:12 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

2/14/2019 4:16:25 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from Cardio

B6

2/14/2019 4:16:25 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from Cardio

B6

2/14/2019 4:19:51 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient: **B6**

ECG from Cardio

B6

2/14/2019 4:20:16 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient: **B6**

ECG from Cardio

B6

2/14/2019 4:21:38 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient: **B6**

ECG from Cardio

B6

2/14/2019 4:22:05 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from Cardio

B6

2/14/2019 4:22:05 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: 4/11/2019 9:16:05 PM
Subject: Tuff's cases-FW: ACANA - Heritage Red Meat Formula Dog Food (Grain-free) [B6] EON-384833
Attachments: 2065712-report.pdf; 2065712-attachments.zip

Echo is likely, but the dog collapsed and died [B6] Not sure if necropsy done.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

[B6]



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Thursday, April 11, 2019 4:53 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; usha.gulati@doveltech.com
Subject: ACANA - Heritage Red Meat Formula Dog Food (Grain-free) [B6] EON-384833

A PFR Report has been received and Related PFR Event [EON-384833] has been created in the EON System.

A "PDF" report by name "2065712-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 "2065712-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-384833
ICSR #: 2065712
EON Title: Related PFR Event created for ACANA - Heritage Red Meat Formula Dog Food (Grain-free); 2065712

AE Date	03/15/2019	Number Fed/Exposed	2
Best By Date		Number Reacted	1

Animal Species	Dog	Outcome to Date	Died Other
Breed	Shepherd Dog - German		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2065712

Product Group: Pet Food

Product Name: ACANA - Heritage Red Meat Formula Dog Food (Grain-free)

Description: 3/15/2019 - Acute onset of difficulty breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF **B6** Patient suddenly collapsed, within seconds of collapse patient died.

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Died Other

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
ACANA - Heritage Red Meat Formula Dog Food (Grain-free)		

This report is linked to:

Initial EON Event Key: EON-383914

Initial ICSR: 2065085

Sender information

B6

USA

Owner information

B6

USA

To view this Related PFR Event, please click the link below:

B6

To view the Related PFR Event Report, please click the link below:

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

Client:
Patient:

B6

ECG from cardio

B6

4/30/2019 11:53:50 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from cardio

B6

4/30/2019 11:54:19 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from cardio

B6

4/30/2019 11:54:41 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12-Lead: Standard Placement

B6

Client:
Patient:

B6

ECG from cardio

B6

4/30/2019 11:55:39 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12-Lead Standard Placement

B6

Client: **B6**
Patient:

ECG from cardio

B6

4/30/2019 11:58:37 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from cardio

B6

4/30/2019 12:00:51 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

B6

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
CC: Peloquin, Sarah; Guag, Jake
Sent: 7/2/2019 1:45:01 PM
Subject: RE: [REDACTED] euthanized

Hi Jen
Thanks for letting me know. I'll update her primary care vet
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, July 02, 2019 9:41 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: RE: [REDACTED] euthanized

Good morning Lisa,
Thank you for the update about [REDACTED] I'm sorry to hear that she passed away.
Currently, we are not collecting more tissues for DCM histopathology except on a case-by-case basis. We will not request histopathology or tissue for [REDACTED] case.
Thank you again,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Monday, July 01, 2019 11:32 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: [REDACTED] euthanized

Hi Jen and all

[REDACTED] one of the dogs in our study (Cocker Spaniel with heart failure, mitral valve disease but reduced contractility) and that we reported to you, was euthanized on [REDACTED]. The RDVM is holding the body in case you'd like the heart but I wasn't sure if it would be too autolyzed at this point. Can you let me know either way asap so that I can update the vet?

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: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 8/24/2018 10:17:06 PM
Subject: FW: 800.267-FDA Case Investigation for [REDACTED] (EON-308715)

Hi Jen,
[REDACTED] will send records on [REDACTED] since I wasn't involve in that case but since she and I have worked together on [REDACTED] she asked me to submit that one. I just submitted a report along with his records. I indicated in the report that I had more records but on more careful inspection, I think I've sent you everything I have. [REDACTED] would be very happy to provide more info. She found a small amount of the original diet which she sent to me and I am including that in the food box that I'm submitting to you on Monday.

Thanks for all your work on this!
Lisa

From: Jones, Jennifer L [<mailto:Jennifer.Jones@fda.hhs.gov>]
Sent: Thursday, August 23, 2018 11:51 AM
To: [REDACTED]
Subject: 800.267-FDA Case Investigation for [REDACTED] and [REDACTED] (EON-308715)

Good morning [REDACTED]
Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about [REDACTED] illness. As part of our investigation, we'd like to request:

- **Full Medical Records**
 - Please email (preferred) or fax (301-210-4685) a copy of [REDACTED] **entire** medical history (not just this event), including any referral diagnostics.
- **Have you submitted a report for [REDACTED]** I was forwarded the medical records and told from Dr. Lisa Freeman that you may have submitted a complaint. I cannot seem to locate it within our system.

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.

Please respond to this email so that we can initiate our investigation.

Thank you kindly,
Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 9/10/2018 7:44:25 PM
Subject: FW: Earthborn Naturals Lamb Grain Free for 1 year-Zignature Kangaroo Grain Free for 2 years: **B6** - EON-364808 plus first dog's PFR EON-362973
Attachments: 2054800-report.pdf; Zignature Kangaroo Grain Free Formula; **B6** EON-362973; 2054800-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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: PFR Event <pfpreventcreation@fda.hhs.gov>
Sent: Monday, September 10, 2018 3:36 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; usha.gulati@doveltech.com
Subject: Earthborn Naturals Lamb Grain Free for 1 year-Zignature Kangaroo Grain Free for 2 years **B6**
B6 EON-364808

A PFR Report has been received and PFR Event [EON-364808] has been created in the EON System.

A "PDF" report by name "2054800-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 "2054800-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-364808
ICSR #: 2054800
EON Title: PFR Event created for Earthborn Naturals Lamb Grain Free for 1 year Zignature Kangaroo Grain Free for 2 years; 2054800

AE Date	05/23/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2

Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mastiff		
Age	6 Years		
District Involved	PFR-Atlanta DO		

Product information

Individual Case Safety Report Number: 2054800

Product Group: Pet Food

Product Name: Earthborn Naturals Lamb Grain Free for 1 year Zignature Kangaroo Grain Free for 2 years

Description: Other mastiff in the house **B6** was presented in congestive heart failure, possibly due to a grain free diet. **B6** was presented on 5/23/18 for occult DCM screening. **B6** has been doing well at home and not showing any signs of heart disease. He had been eating the same grain free diet as **B6** and was transitioned to a diet containing grains 3 weeks prior to this visit. Whole blood taurine basically normal. Echo revealed moderate to severe left ventricular enlargement, mild MR, mildly decreased LV ejection fraction. No arrhythmias detected. **B6** was placed on taurine supplementation. **B6** returned for a 3 month recheck 8/31/18. His echo showed considerable improvement in size, although still enlarged.

Submission Type: Initial

Report Type: Both

Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Earthborn Naturals Lamb Grain Free for 1 year Zignature Kangaroo Grain Free for 2 years		

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-364808>

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&issueld=381567>

=====

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 8/27/2018 1:23:54 PM
Subject: FW: Taurine result for patients [B6]
Attachments: T_20484.pdf; T_20485.pdf

Taurine results on [B6]
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: 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 6:54:31 PM
Subject: RE: DCM - More from L Freeman 2/25/2019 0915

EON-380745 is part of that household as well. 3 with DCM so far.

From: Rotstein, David
Sent: Monday, February 25, 2019 9:19 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 - More from L Freeman 2/25/2019 0915

Note: 380742 & 380743 are from the same household. Other dogs in household – 2 not tested yet & 1 normal BNP

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (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 </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 3/4/2019 12:13:14 PM
Subject: RE: taurine results for [REDACTED] **B6**

Thanks, Lisa!

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Friday, March 01, 2019 4:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FW: taurine results for [REDACTED] **B6**

FYI

[REDACTED] 3 bulldogs from same household and on same diet
B6 DCM and CHF had [REDACTED] **B6**
– with ARVC and arrhythmias had [REDACTED] **B6**
this most recent one (likely ARVC) was [REDACTED] **B6**

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: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6

Sent: 6/11/2019 7:00:42 PM

Subject: Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-390205

Attachments: 2068096-report.pdf

A PFR Report has been received and Related PFR Event [EON-390205] has been created in the EON System.

A "PDF" report by name "2068096-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-390205

ICSR #: 2068096

EON Title: Related PFR Event created for Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey chicken liver and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe; 2068096

AE Date	02/01/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Died Other
Breed	Bulldog		
Age	8 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068096

Product Group: Pet Food

Product Name: Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: Housemate (half sister; [REDACTED] - (ICSR) OF 2063133) diagnosed with DCM and CHF SO screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet

sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated) Patient DOA when owners arrived home on (B6) Suspected sudden death. Heart muscle samples were collected by rDVM and submitted to FDA for further evaluation.

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Died Other

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe		

This report is linked to:

Initial EON Event Key: EON-380743

Initial ICSR: 2063134

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

To view this Related PFR Event, please click the link below:

<https://eon.fda.gov/eon//browse/EON-390205>

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=407477&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.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/11/2019 6:52:47 PM
Subject: Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-390203
Attachments: 2068095-report.pdf; 2068095-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390203] has been created in the EON System.

A "PDF" report by name "2068095-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 "2068095-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390203

ICSR #: 2068095

EON Title: Related PFR Event created for Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey chicken liver and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe; 2068095

AE Date	02/20/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Bulldog		
Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068095

Product Group: Pet Food

Product Name: Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: Eating BEG diet - 2 other dogs in household diagnosed with DCM

B6

already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts 2/20/19 Probable ARVC/diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Low plasma and whole blood taurine levels - started taurine supplement 3/1/2019 Troponin - B6

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: 6

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe		

This report is linked to:

Initial EON Event Key: EON-380745

Initial ICSR: 2063135

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

To view this Related PFR Event, please click the link below:

<https://eon.fda.gov/eon//browse/EON-390203>

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&issueId=407475&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.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Palmer, Lee Anne; Jones, Jennifer L
Sent: 11/8/2018 12:07:21 PM
Subject: **B6** FW: Merrick LID Grain Free dry (salmon: Lisa Freeman - EON-369322
Attachments: 2057941-report.pdf; 2057941-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6 (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: PFR Event <ppreventcreation@fda.hhs.gov>
Sent: Thursday, October 25, 2018 7:29 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> **B6**
Subject: Merrick LID Grain Free dry (salmon: Lisa Freeman - EON-369322

A PFR Report has been received and PFR Event [EON-369322] has been created in the EON System.

A "PDF" report by name "2057941-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 "2057941-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-369322
ICSR #: 2057941
EON Title: PFR Event created for Merrick LID Grain Free dry (salmon duck or chicken); 2057941

AE Date	02/09/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Retriever - Labrador		

Age	9 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2057941

Product Group: Pet Food

Product Name: Merrick LID Grain Free dry (salmon, duck, or chicken)

Description: DCM and CHF Euthanized for worsening heart failure and arrhythmia in September

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
Merrick LID Grain Free dry (salmon, duck, or chicken)		

Sender information

Lisa Freeman
 200 Westboro Rd
 North Grafton, MA 01536
 USA

Owner information

B6

To view this PFR Event, please click the link below:

<https://eon.fda.gov/eon//browse/EON-369322>

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&issuelid=386244>

=====

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade

secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: 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: 11/11/2018 1:15:58 PM
Subject: DCM case-Tufts-- repeat submission EON-370776 and 370708
Attachments: Earthborn grain free weight management dry: Lisa Freeman - EON-370708; Earthborn Holistic Weight Control (Grain Free); B6 - EON-370776

Please note that these are for the same dog

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 11/9/2018 10:08:47 PM
Subject: Earthborn grain free weight management dry: Lisa Freeman - EON-370708
Attachments: 2058678-report.pdf; 2058678-attachments.zip

A PFR Report has been received and PFR Event [EON-370708] has been created in the EON System.

A "PDF" report by name "2058678-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 "2058678-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370708

ICSR #: 2058678

EON Title: PFR Event created for Earthborn grain free weight management dry; 2058678

AE Date	11/05/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2058678

Product Group: Pet Food

Product Name: Earthborn grain free weight management dry

Description: Diagnosed with DCM, CHF, and atrial fibrillation 11/5/18. Currently hospitalized. Taurine submitted to UC Davis. Unclear if related to diet, given breed but eating boutique, grain-free diet. Only prior history is traumatic injury in 2015.

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Earthborn grain free weight management 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-370708>

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=387677>

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 11/11/2018 2:32:25 AM
Subject: Earthborn Holistic Weight Control (Grain Free); **B6** - EON-370776
Attachments: 2058702-report.pdf

A PFR Report has been received and PFR Event [EON-370776] has been created in the EON System.

A "PDF" report by name "2058702-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-370776

ICSR #: 2058702

EON Title: PFR Event created for Earthborn Holistic Weight Control (Grain Free); 2058702

AE Date	B6	Number Fed/Exposed	1
Best By Date	11/09/2019	Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	9 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2058702

Product Group: Pet Food

Product Name: Earthborn Holistic Weight Control (Grain Free)

Description: Diagnosed and treated for DCM at Cummings Medical Center at Tufts. Have fed Earthborn Holistic Weight Management Grain Free diet for about 5 years. Read FDA Study Report and decided to report experience. I wrote a comprehensive description of what happened twice and got timed out both times. Call if I can be of further help.

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Earthborn Holistic Weight Control (Grain Free)		11/09/2019

Sender information

B6

USA

To view this PFR Event, please click the link below:

<https://eon.fda.gov/eon//browse/EON-370776>

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=387745>

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 11/9/2018 10:52:44 PM
Subject: Zignature trout & salmon dry: Lisa Freeman - EON-370715
Attachments: 2058683-report.pdf; 2058683-attachments.zip

A PFR Report has been received and PFR Event [EON-370715] has been created in the EON System.

A "PDF" report by name "2058683-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 "2058683-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370715
ICSR #: 2058683
EON Title: PFR Event created for Zignature trout & salmon dry; 2058683

AE Date	11/07/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	3 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2058683

Product Group: Pet Food

Product Name: Zignature trout & salmon dry

Description: Older housemate diagnosed with DCM and CHF. Screening B6 because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Zignature trout & salmon dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
B6 USA

To view this PFR Event, please click the link below:

<https://eon.fda.gov/eon/browse/EON-370715>

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=387684>

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification [B6]
Sent: 1/1/2019 9:48:33 PM
Subject: Orijen grain free original dry: Lisa Freeman - EON-375114
Attachments: 2060741-report.pdf; 2060741-attachments.zip

A PFR Report has been received and PFR Event [EON-375114] has been created in the EON System.

A "PDF" report by name "2060741-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 "2060741-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375114
ICSR #: 2060741
EON Title: PFR Event created for Orijen grain free original dry; 2060741

AE Date	12/28/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	9 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2060741

Product Group: Pet Food

Product Name: Orijen grain free original dry

Description: DCM and CHF diagnosed 12/28/18 at emergency clinic. Started on [B6]

[B6] Seen by Tufts cardiology 12/31/18. Eating Orijen grain free original dry so unclear if just genetically associated DCM or if diet associated.

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
Orijen grain free original 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-375114>

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=392123>

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: B6
To: Darcy Adin
CC: Jones, Jennifer L; Reimschuessel, Renate
Sent: 7/10/2017 2:49:30 PM
Subject: Pet food concern

Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

B6

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: [REDACTED] B6
Sent: 7/11/2017 1:57:59 PM
Subject: Re: Pet food concern

Great! I will give you a call during one of those times depending on our clinic cases - thank you!

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I can chat today from 11-1pm or or 2-3pm.

Jen

Jennifer Jones, DVM

Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, July 10, 2017 6:47 PM
To: Jones, Jennifer L
Cc: Reimschuessel, Renate; [REDACTED] B6

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or later this week). My number is [REDACTED] B6 or I can be paged from [REDACTED] B6

Thank you!

Darcy

On Jul 10, 2017, at 1:05 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hello Dr. Adin,

Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.

Thank you,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<image001.png> <image004.png>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Monday, July 10, 2017 11:31 AM

To: **B6**

Cc: Jones, Jennifer L; Reimschuessel, Renate

Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, **B6** wrote:

Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

B6

B6

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 7/11/2017 9:44:00 PM
Subject: Re: Pet food concern
Attachments:

B6

Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:

2023230 (I) for B6
2023228 (I) for B6

I've also attached the visit summaries for B6 and B6 as well as B6 necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!

Take care

Darcy

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I can chat today from 11-1pm or or 2-3pm.

Jen

Jennifer Jones, DVM

Veterinary Medical Officer



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Monday, July 10, 2017 6:47 PM
To: Jones, Jennifer L
Cc: Reimschuessel, Renate; B6

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or

later this week). My number is [B6] or I can be paged from [B6]

Thank you!

Darcy

On Jul 10, 2017, at 1:05 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hello Dr. Adin,

Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.

Thank you,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image004.png](#)>

From: Darcy Adiu [<mailto:dbadin@ncsu.edu>]

Sent: Monday, July 10, 2017 11:31 AM

To: [B6]

Cc: Jones, Jennifer L; Reimschuessel, Renate

Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, [B6] wrote:

Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

B6

B6

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Jones, Jennifer L </o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>
To: 'Darcy Adin'
CC: Ceric, Olgica
Sent: 8/22/2017 11:54:03 AM
Subject: RE: Pet food concern (800.218)

My apologies for the second email.
Which dry food (Kangaroo or Venison) was sent to us for the testing?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 7:37 AM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

Good morning Dr. Adin,
We received results of the product testing for [B5] those were negative. Please see the attached. The results for the [B5] and taurine are in progress. I'll forward along as soon as possible.
Thank you for your patience,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Friday, August 18, 2017 10:38 AM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

I'm not sure what timeline to expect so forgive me if this premature, but I wanted to check in to see if you have any information about the cases yet?

Thanks!
Darcy Adin

On Jul 28, 2017, at 9:18 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

This is great information to add to the case. Thank you, Darcy.

Jennifer Jones, DVM

Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, July 26, 2017 9:39 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Jennifer,

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.

Thank you!
Darcy

On Jul 26, 2017, at 8:08 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. One way I've seen veterinarians handle the reimbursement for other cases is posting the amount to the patient's chart, leaving a balance of the shipping charges. In those cases, our accountant then called and paid the shipping charge balance on the account.

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image002.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, July 26, 2017 7:42 AM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones

We included the invoice in the package. There was a fair bit of discussion here because I don't think there will be an easy way to reimburse - so probably don't worry about it!
Thank you!
Darcy

On Jul 26, 2017, at 6:32 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Excellent. Thank you, Darcy. Please email or fax an invoice so we can reimburse you for the shipping.

Jennifer Jones, DVM
Veterinary Medical Officer

<image001.png> <image003.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, July 25, 2017 10:36 PM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Thank you Dr. Jones!
It went out tonight by FedEx tonight. I'll look forward to hearing from you soon.
Take care
Darcy

On Tue, Jul 25, 2017 at 10:48 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,
I spoke with my colleague. If you can, please return ship the box using FedEx or your preferred carrier. You'll ship the box for overnight delivery on a Monday-Wednesday. Please ship to:

Attention: Jennifer Jones
8401 Muirkirk Rd
Laurel, MD 20708

After you return ship the box, please email or fax (301-210-4685) an invoice for the shipping charges. We can then call NCSU and reimburse with our VISA information.

Please let me know if you have questions.
Thank you again for your patience,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image005.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, July 25, 2017 10:30 AM

To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

thanks!

On Tue, Jul 25, 2017 at 8:45 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,
I'm sorry for the trouble getting the label. I'm going to reach out to my colleague to get one made for you. I'll send it via email. If that doesn't work, then we can go with FedEx.
Thank you for the update, and sorry for the trouble with the label,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image008.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, July 24, 2017 3:31 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Jen,

The shipping box arrived this afternoon, however, we don't see a return shipping label. Our shipping and receiving staff suggested that FedEx might be better since with UPS pick up, we can't control how much time the package may be sitting in the heat. I'm happy to send however you would recommend though!

Thank you!

Darcy

On Fri, Jul 21, 2017 at 12:47 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

The package will ship today and arrive Monday. UPS said they will give you a return shipping label. For some reason, we were unable to put it in the shipping box we sent to you. UPS, however, has assured us they will give you the label Monday. Please let me know if you do not get that label, because I'll need to get you one.

Thank you,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image009.png](#)>

From: Jones, Jennifer L

Sent: Wednesday, July 19, 2017 1:04 PM

To: 'Darcy Adin'

Cc: Ceric, Olgica

Subject: RE: Pet food concern (800.218)

Excellent. Thank you, Darcy. We'll ship the kit to your office to collect the food. It will contain the return shipping label for use with the box.

The box should arrive for you by close of business Tuesday (7/25).

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image008.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Tuesday, July 18, 2017 9:59 PM

To: Jones, Jennifer L

Cc: Ceric, Olgica

Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

The owner confirmed that neither dog B5 in February or chronically.

Thank you!

Darcy

On Jul 18, 2017, at 8:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Dr. Adin,

After reviewing the complaint and medical records, we'd like to request the following:

· Please check with the owner/confirm B5 either in February 2017 or consistently) B5 injury.

Collect open bag of California Naturals food to test for **B5**

- Please email me the size/weight of the food.
- We will send you an empty box with a prepaid shipping label to send the product back to our lab.
- After we test the product, we'll send you the results to share with the owner.

After I get the size/weight of the food, I'll send the box.
Thank you for helping with the case,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image003.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, July 11, 2017 5:44 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern

Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:
2023230 (I) for **B6**
2023228 (I) for **B6**

I've also attached the visit summaries for **B6** (2) and **B6** (1) as well as **B6** necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!
Take care
Darcy

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Hi Darcy,
I can chat today from 11-1pm or or 2-3pm.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image010.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, July 10, 2017 6:47 PM
To: Jones, Jennifer L
Cc: Reimschuessel, Renate; **B6**

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or

later this week). My number is [B6] or I can be paged from [B6]

Thank you!

Darcy

On Jul 10, 2017, at 1:05 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hello Dr. Adin,

Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.

Thank you,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image004.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Monday, July 10, 2017 11:31 AM

To: [B6]

Cc: Jones, Jennifer L; Reimschuessel, Renate

Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, [B6] wrote:

Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

[B6]

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

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=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica
Sent: 8/22/2017 12:39:27 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **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.

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.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine [B5] still pending, but [B5] negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for [B5]. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?

[B5]

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check with the vet if seafood fed and will plan to test open product fo

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question

B5

B5

This would highly unlikely, but wanted to put it out there.

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 <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@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>

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for [B5] in food, what does the group think? Any additional testing? Is it worth testing the [B5]

Medical Record Review:

[B6]

Presenting complaint [B6]

B6

PE [B6]

[B6]

[B6]

[B6]

B6

B6

Rads 1/31

B6

B6 cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudo-dorsally, hepatomegaly, dec abdominal serosal contrast

B6 severe generalized cardiomegaly with biventricular heart failure, improved vs rDVM rads

B6 worsening cardiogenic pulmonary edema, cannot exclude lung induced injury +/- pneumonia

B6 post ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar

B6 improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia

B6 markedly progressive alveolar pattern with significantly worse cardiogenic edema

tFAST **B6** severe cardiomegaly with ventricular hypocontractility

Echo **B6** dcm 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

B6

B6

B6

B6 Rads: left sided congestive heart failure

B6 moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

B6 Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

, so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
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: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to MARS who said there was no corn in this food...but that doesn't rule out treats.

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for

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: Jones, Jennifer L

Sent: Tuesday, July 11, 2017 11:38 AM

To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Cc: Ceric, Olgica; Reimschuessel, Renate

Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHFà severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigsà plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodesà 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM

Veterinary Medical Officer

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704

Laurel, Maryland 20708

new tel: 240-402-5421

fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 8/22/2017 2:11:22 PM
Subject: Re: Pet food concern (800.218)

Thank you for all your help!

On Tue, Aug 22, 2017 at 8:45 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

B5

The cause of the two dogs' DCM is unclear.

B5

B5

B5

At this time we will not request any further testing. Thank you very much for all your help with the case. Please let me know if you have any additional questions or any future animal food related illness concerns.

Jen

Jennifer Jones, DVM

Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 8:20 AM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

Thank you for the quick response.

B5

Jennifer Jones, DVM

Veterinary Medical Officer



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, August 22, 2017 8:17 AM

To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Jennifer

It was kangaroo. That's great about the **B5** We'll wait for the taurine and **B5** however I guess I'd be surprised if this was the answer since blood amino acid levels were adequate. Is there any other testing that can be done (e.g. **B5**)

Thanks so much!

Darcy

On Aug 22, 2017, at 7:54 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

My apologies for the second email.

Which dry food (Kangaroo or Venison) was sent to us for the testing?

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image002.png](#)>

From: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 7:37 AM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

Good morning Dr. Adin,

We received results of the product testing for **B5** those were negative. Please see the attached. The results for the **B5** and taurine are in progress. I'll forward along as soon as possible.

Thank you for your patience,
Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<image001.png> <image003.png>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Friday, August 18, 2017 10:38 AM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

I'm not sure what timeline to expect so forgive me if this premature, but I wanted to check in to see if you have any information about the cases yet?

Thanks!

Darcy Adin

On Jul 28, 2017, at 9:18 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

This is great information to add to the case. Thank you, Darcy.

Jennifer Jones, DVM

Veterinary Medical Officer

<image001.png> <image004.png>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, July 26, 2017 9:39 PM
To: Jones, Jennifer L

Subject: Re: Pet food concern (800.218)

Hi Jennifer,

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.

Thank you!

Darcy

On Jul 26, 2017, at 8:08 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. One way I've seen veterinarians handle the reimbursement for other cases is posting the amount to the patient's chart, leaving a balance of the shipping charges. In those cases, our accountant then called and paid the shipping charge balance on the account.

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image002.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, July 26, 2017 7:42 AM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones

We included the invoice in the package. There was a fair bit of discussion here because I don't think there will be an easy way to reimburse - so probably don't worry about it!

Thank you!

Darcy

On Jul 26, 2017, at 6:32 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Excellent. Thank you, Darcy. Please email or fax an invoice so we can reimburse you for the shipping.

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Tuesday, July 25, 2017 10:36 PM

To: Jones, Jennifer L

Cc: Ceric, Olgica

Subject: Re: Pet food concern (800.218)

Thank you Dr. Jones!

It went out tonight by FedEx tonight. I'll look forward to hearing from you soon.

Take care

Darcy

On Tue, Jul 25, 2017 at 10:48 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I spoke with my colleague. If you can, please return ship the box using FedEx or your preferred carrier. You'll ship the box for overnight delivery on a Monday-Wednesday. Please ship to:

Attention: Jennifer Jones

8401 Muirkirk Rd

Laurel, MD 20708

After you return ship the box, please email or fax ([301-210-4685](tel:301-210-4685)) an invoice for the shipping charges. We can then call NCSU and reimburse with our VISA information.

Please let me know if you have questions.

Thank you again for your patience,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image005.png](#)>

From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Tuesday, July 25, 2017 10:30 AM

To: Jones, Jennifer L

Cc: Ceric, Olgica

Subject: Re: Pet food concern (800.218)

thanks!

On Tue, Jul 25, 2017 at 8:45 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I'm sorry for the trouble getting the label. I'm going to reach out to my colleague to get one made for you. I'll send it via email. If that doesn't work, then we can go with FedEx.

Thank you for the update, and sorry for the trouble with the label,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image008.png](#)>

From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Monday, July 24, 2017 3:31 PM

To: Jones, Jennifer L

Subject: Re: Pet food concern (800.218)

Hi Jen,

The shipping box arrived this afternoon, however, we don't see a return shipping label. Our shipping and

receiving staff suggested that FedEx might be better since with UPS pick up, we can't control how much time the package may be sitting in the heat. I'm happy to send however you would recommend though!

Thank you!

Darcy

On Fri, Jul 21, 2017 at 12:47 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

The package will ship today and arrive Monday. UPS said they will give you a return shipping label. For some reason, we were unable to put it in the shipping box we sent to you. UPS, however, has assured us they will give you the label Monday. Please let me know if you do not get that label, because I'll need to get you one.

Thank you,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image009.png](#)>

From: Jones, Jennifer L
Sent: Wednesday, July 19, 2017 1:04 PM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

Excellent. Thank you, Darcy. We'll ship the kit to your office to collect the food. It will contain the return shipping label for use with the box.

The box should arrive for you by close of business Tuesday (7/25).

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image008.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, July 18, 2017 9:59 PM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

The owner confirmed that neither do [REDACTED] B5 February or chronically.

Thank you!

Darcy

On Jul 18, 2017, at 8:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Dr. Adin,

After reviewing the complaint and medical records, we'd like to request the following:

- Please check with the owner/confirm if [REDACTED] B5 (either in February 2017 or consistently) [REDACTED] B5
- Collect open bag of California Naturals food to test for [REDACTED] B5
 - o Please email me the size/weight of the food.
 - o We will send you an empty box with a prepaid shipping label to send the product back to our lab.
 - o After we test the product, we'll send you the results to share with the owner.

After I get the size/weight of the food, I'll send the box.

Thank you for helping with the case,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, July 11, 2017 5:44 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern

Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:

2023230 (I) for [B6]
2023228 (I) for [B6]

I've also attached the visit summaries for [B6] (2) and [B6] (1) as well as [B6] necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!

Take care

Darcy

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I can chat today from 11-1pm or or 2-3pm.

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image010.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Monday, July 10, 2017 6:47 PM

To: Jones, Jennifer L

Cc: Reimschuessel, Renate; [B6]

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or later this week). My number is [B6] or I can be paged from [B6]

Thank you!

Darcy

On Jul 10, 2017, at 1:05 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hello Dr. Adin,

Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.

Thank you,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image004.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Monday, July 10, 2017 11:31 AM
To: B6
Cc: Jones, Jennifer L; Reinschuessel, Renate
Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, B6 wrote:

Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in

the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

B6

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 1/3/2018 7:59:43 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519
Attachments: cardiomyopathy.pdf

Please see the attached article.

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: Wednesday, January 03, 2018 2:32 PM
To: Rotstein, David <David.Rotstein@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for [B5] based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for [B5]

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, August 22, 2017 8:39 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@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>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **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.

B5

B5

B5

Interpretation: No [B5] minimum for dogs or cats. Unclear whether or not this is low, normal, or high.

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.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/[B5] still pending, but [B5] negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for [B5] The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?

B5

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check with: [REDACTED] **B5**

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question, [REDACTED] **B5**

I was thinking of the [REDACTED] **B5** and was thinking of [REDACTED] **B5**

This would highly unlikely, but wanted to put it out there.

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 <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@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>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for **B5** in food, what does the group think? Any additional testing? Is it worth testing the **B6** /other analytes or trending?

Medical Record Review:

B6

Presenting complaint

B6

B6

PE

B6

B6

Labwork:

B6

B6

B6

Rads

B6

B6 cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudo-dorsally, hepatomegaly, dec abdominal serosal contrast

B6

severe generalized cardiomegaly with biventricular heart failure, improved vs rDVM rads
worsening cardiogenic pulmonary edema, cannot exclude lung induced injury
+/- pneumonia

B6

post ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar

B6

improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia
markedly progressive alveolar pattern with significantly worse cardiogenic edema

tFAST

B6

severe cardiomegaly with ventricular hypocontractility

Echo

B6

dcm 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

Prior MHx

B6

B6

B6

Presented

B6

B6

B6

ECG: left ventricular enlargement suggested

B6

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

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5 can be present in **B5** so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
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: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to MARS who said there was no corn in this food... but that doesn't rule out treats.

I'm not sure with normal **B5** and taurine levels if we should suspect issues with those as well.

B5 **B5**

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for **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: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHF à severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigs à plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodes à 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Ceric, Olgica; Nemser, Sarah
Sent: 1/4/2018 7:46:50 PM
Subject: Re: dog food concern

I also have a food sample for our current inpatient (same food - California Naturals kangaroo and lentil)

B5

B5

On Thu, Jan 4, 2018 at 2:39 PM, Darcy Adin <dbadin@ncsu.edu> wrote:

The myocardium is from **B6** Maybe we will wait to see what the blood levels show.

B5

Thanks!
Darcy

On Thu, Jan 4, 2018 at 2:14 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you for the update. I'll let you know the **B5** concentration from **B6** food after the results are back.

The frozen myocardium, is it from the **B6** case?

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Wednesday, January 03, 2018 3:10 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: Re: dog food concern

Hi Jennifer,

Thank you! We have not tested for [B5] 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?

Thank you!

Darcy

On Wed, Jan 3, 2018 at 2:30 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

Happy New Year! Thank you for the additional information. I discussed the information you provided below and from the previous case ([B6] Miniature Schnauzers-800.218) with my colleagues.

Based on our discussions, I will test some leftover food from the 800.218 case, for [B5] content. Have any of the dogs with DCM had blood or tissue [B5] levels tested?

Thank you kindly,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, January 03, 2018 11:31 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: dog food concern

Hi Dr. Jones,

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.

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.

Have you had any other reports of such an association? If you have any other thoughts or testing suggestions, I would be all ears!

Thank you!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

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=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 1/11/2018 2:45:57 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen.

B5

d.

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: Thursday, January 11, 2018 9:36 AM
To: Rotstein, David <David.Rotstein@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

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.”

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Wednesday, January 03, 2018 2:32 PM

To: Rotstein, David <David.Rotstein@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)' <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for **B5** based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for **B5**

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, August 22, 2017 8:39 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@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>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Tuesday, August 22, 2017 8:37 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **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.

B5

6

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.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine [B5] still pending, but [B5] negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for [B5]. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?

[B5]

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check with [B5]

[B5]

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question, [B5]

[B5]

I was thinking of the [B5] and was thinking of [B5]

[B5]

[B5]

This would highly unlikely, but wanted to put it out there.

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 <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@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>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for **B5** in food, what does the group think? Any additional testing? Is it worth testing the **B5**

Medical Record Review:

B6

Presenting complaint

B6

B6

PE

B6

B6

Labwork:

B6

B6

ECG: suspected atrial tachycardia

Rads **B6**: concern for aspiration pneumonia

B6 cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudo-dorsally, hepatomegaly, dec abdominal serosal contrast

B6 severe generalized cardiomegaly with biventricular heart failure, improved vs rDVM rads
B6 worsening cardiogenic pulmonary edema, cannot exclude lung induced injury
+/- pneumonia

B6: post ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar

B6 improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia
B6 markedly progressive alveolar pattern with significantly worse cardiogenic edema

tFAST **B6**: severe cardiomegaly with ventricular hypocontractility

Echo **B6** dcm 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

Prior MHx: [redacted] B6

[redacted] B6

Presented [redacted] B6

[redacted] B6

[redacted] B6

ECG: left ventricular enlargement suggested

[redacted] B6

[redacted] B6 Rads: left sided congestive heart failure

[redacted] B6 moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

[redacted] B6 Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

B5
B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
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: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to MARS who said there was no corn in this food...but that doesn't rule out

treats.

I'm not sure with normal B5 and taurine levels if we should suspect issues with those as well.

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for 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: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHF à severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigs à plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodes à 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

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; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 1/11/2018 2:50:57 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks, Dave. If you have info readily available that's great. If no, I can look/prompt NCSU to look too.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Thursday, January 11, 2018 9:46 AM
To: Jones, Jennifer L <Jennifer.Jones@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen.

B5

d.

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: Thursday, January 11, 2018 9:36 AM

To: Rotstein, David <David.Rotstein@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

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.”

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Wednesday, January 03, 2018 2:32 PM

To: Rotstein, David <David.Rotstein@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>)' <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for [B5] based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for [B5]

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, August 22, 2017 8:39 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@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>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **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.

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.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine **B5** still pending, but **B5** negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for **B5**. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?

B5

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check with t

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question:

B5

I was thinking of the **B5** and was thinking of **B5**

This would highly unlikely, but wanted to put it out there.

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 <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@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>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for **B5** in food, what does the group think? Any additional testing? Is it worth testing the **B5**

Medical Record Review:

B6

B6

Rads

B6

B6 : 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

B6 worsening cardiogenic pulmonary edema, cannot exclude lung induced injury +/- pneumonia

B6 post ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar

B6 improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia
markedly progressive alveolar pattern with significantly worse cardiogenic edema

tFAST **B6** severe cardiomegaly with ventricular hypocontractility

Echo **B6** dcm 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

Prior MHx **B6**

B6

B6

ECG: left ventricular enlargement suggested

B6

B6

B6 Rads: left sided congestive heart failure

B6 moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

B6 Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
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: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to MARS who said there was no corn in this food... but that doesn't rule out treats.

I'm not sure with normal **B5** and taurine levels if we should suspect issues with those as well.

B5

B5

Jennifer Jones, DVM
 Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for **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: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
 2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHFà severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigsà plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodesà 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

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: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 1/11/2018 3:05:21 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519
Attachments: 1925740_1662_Bossart_Cardiomyopathy.pdf; Kogia [B5] 1-s2.0-S0045653512006728-main.pdf; Kogia [B5] -s2.0-S0946672X16302577-main.pdf

Here you go!

I couldn't get the original article:

J Am Vet Med Assoc. 1985 Dec 1;187(11):1137-40.

Cardiomyopathy in stranded pygmy and dwarf sperm whales.

Bossart GD, Odell DK, Altman NH.

Abstract

Necropsy and histologic examinations were performed in 23 pygmy sperm whales (*Kogia breviceps*) and 6 dwarf sperm whales (*Kogia simus*) that had been stranded singly or in cow-calf pairs along the southeastern coastline of the United States. At necropsy, the gross findings in the adult whales included pale, flabby right ventricles. Microscopically, lesions in the hearts of the whales were characterized by moderate to extensive myocellular degeneration, atrophy, and fibrosis. Similar changes were not seen in 5 of 6 sexually immature whales or in the whale calves. Hepatic changes were consistent with heart failure. The cause of the myocardial lesions was not determined. The systemic effects of failing myocardium probably were a major reason for the stranding of the adult whales.

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: Thursday, January 11, 2018 9:51 AM
To: Rotstein, David <David.Rotstein@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks, Dave. If you have info readily available that's great. If no, I can look/prompt NCSU to look too.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Thursday, January 11, 2018 9:46 AM
To: Jones, Jennifer L <Jennifer.Jones@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen.

B5

d.

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: Thursday, January 11, 2018 9:36 AM
To: Rotstein, David <David.Rotstein@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

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.”

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Wednesday, January 03, 2018 2:32 PM

To: Rotstein, David <David.Rotstein@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)' <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for B5 based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, August 22, 2017 8:39 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@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>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Tuesday, August 22, 2017 8:37 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **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.

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.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine [B5] still pending, but [B5] negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for [B5]. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?

[B5]

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check [B5]

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question

B5

I was thinking of the

B6

and was thinking of

B6

This would highly unlikely, but wanted to put it out there.

David Rotstein, DVM, MPVM, Dipl.ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Date: July 13, 2017 at 2:44:24 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@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>

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for **B5** in food, what does the group think? Any additional testing? Is it worth testing the **B5**

Medical Record Review:

B6

Presenting complaint

B6

B6

PE

B6

B6

Labwork:

B6

B6

ECG: suspected atrial tachycardia

Rads **B6** concern for aspiration pneumonia

B6 cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudo-dorsally, hepatomegaly, dec abdominal serosal contrast

B6 severe generalized cardiomegaly with biventricular heart failure, improved vs rDVM rads
B6 worsening cardiogenic pulmonary edema, cannot exclude lung induced injury
+/- pneumonia

B6 post ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar

B6 improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia

B6 markedly progressive alveolar pattern with significantly worse cardiogenic edema

tFAST **B6** severe cardiomegaly with ventricular hypocontractility

Echo **B6** dcm 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

Prior MHx: B6 B6

B6

Presented B6

B6

B6

Labs: **B6**

ECG: left ventricular enlargement suggested

B6

B6 Rads: left sided congestive heart failure

B6 moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

B6 Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
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: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to MARS who said there was no corn in this food...but that doesn't rule out treats.

I'm not sure with normal **B5** and taurine levels if we should suspect issues with those as well.

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for **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: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHFà severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigsà plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodesà 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet

has samples of food and treats

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: Darcy Adin
CC: Ceric, Olgica; Nemser, Sarah
Sent: 1/12/2018 1:01:50 PM
Subject: RE: dog food concern
Attachments: 1925740_1662_Bossart_Cardiomyopathy.pdf; Kogia selenium 2 1-s2.0-S0045653512006728-main.pdf; Kogia selenium-1-s2.0-S0946672X16302577-main.pdf

Thank you, Darcy,

B5

B5

I'll forward the feed results when they are back.

Have a nice weekend,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, January 10, 2018 6:13 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

Thank you Jennifer - we will be on the lookout for it.

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.

Take care
Darcy

On Jan 10, 2018, at 8:05 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. We're sending the kit this week. It should arrive by close of business Friday.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<image001.png> <image006.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, January 09, 2018 11:27 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

Hi Jennifer,

That is great! I've attached a picture of the food sample - the weight is 0.36 kg. We sent blood samples off from 2 dogs to test for **B5** one was in the reference range and the other a bit high.

Thank you!
Take care
Darcy

On Tue, Jan 9, 2018 at 10:07 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Good morning Darcy,

We'd like to collect some of the food from your current case (California Naturals Kangaroo). I'm going to send it with the archived sample of food from the **B6** case. **B5**

B5

Please let me know the size/weight of the sample you have, and I'll send a box to collect it.

Thank you,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: [240-402-5421](tel:240-402-5421)
<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Thursday, January 04, 2018 2:47 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

I also have a food sample for our current inpatient (same food - California Naturals kangaroo and lentil). **B5**

B5

On Thu, Jan 4, 2018 at 2:39 PM, Darcy Adin <dbadin@ncsu.edu> wrote:
The myocardium is from **B6** Maybe we will wait to see what the blood levels show.

B5

Thanks!
Darcy

On Thu, Jan 4, 2018 at 2:14 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you for the update. I'll let you know the [B5] concentration from [B6] food after the results are back.

The frozen myocardium, is it from the [B6] case?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<image001.png> <image004.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, January 03, 2018 3:10 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

Hi Jennifer,

Thank you! We have not tested for [B5] 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?

Thank you!
Darcy

On Wed, Jan 3, 2018 at 2:30 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,
Happy New Year! Thank you for the additional information. I discussed the information you provided below and from the previous case [B6] (Miniature Schnauzers-800.218) with my colleagues.

Based on our discussions, I will test some leftover food from the 800.218 case, for [B5] content. Have any of the dogs with DCM had blood or tissue [B5] levels tested?

Thank you kindly,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<image001.png> <image005.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, January 03, 2018 11:31 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: dog food concern

Hi Dr. Jones,

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.

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.

Have you had any other reports of such an association? If you have any other thoughts or testing suggestions, I would be all ears!

Thank you!
Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: dbadin@ncsu.edu
CC: Jones, Jennifer L
Sent: 1/17/2018 2:12:36 PM
Subject: FDA (Vet-LIRN) shipped sample collection kit

Dear Dr. Adin,

We shipped a food sample collection kit to your place this morning. Its tracking number is 1ZA4420T0194648732 with UPS. It is expected to arrive on tomorrow (Jan 18, 2018).

Thank you
Jake Guag

Jake Guag, MPH , CPH
Biologist
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Vet-LIRN
8401 Muirkirk Road.
Laurel, Maryland 20708
tel: 1-240-402-0917
email: Jake.Guag@fda.hhs.gov

From: Darcy Adin <dbadin@ncsu.edu>
To: Guag, Jake
CC: Jones, Jennifer L; B6
Sent: 1/17/2018 4:12:39 PM
Subject: Re: FDA (Vet-LIRN) shipped sample collection kit

Thank you! We will be on the lookout for it.

Take care

Darcy

On Wed, Jan 17, 2018 at 9:12 AM, Guag, Jake <Jake.Guag@fda.hhs.gov> wrote:

Dear Dr. Adin,

We shipped a food sample collection kit to your place this morning. Its tracking number is 1ZA4420T0194648732 with UPS. It is expected to arrive on tomorrow (Jan 18, 2018).

Thank you

Jake Guag

Jake Guag, MPH , CPH

Biologist

U.S. Food & Drug Administration

Center for Veterinary Medicine

Office of Research

Vet-LIRN

8401 Muirkirk Road.

Laurel, Maryland 20708

tel: 1-240-402-0917

email: Jake.Guag@fda.hhs.gov

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L; B6
Sent: 1/22/2018 4:24:22 PM
Subject: Re: dog food concern

Hi Jennifer,

The boxes have both arrived today. Apparently, the other one was delivered to a different location. Since they are prepaid boxes, I am going to send some other grain free food that an owner gave us as well. These will go out later today.

So, one box will have California Naturals Kangaroo and Lentil and the other box will have Fromm Large Breed Adult Grain free - they are labeled.

Thank you so much!
Darcy

On Wed, Jan 17, 2018 at 7:00 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Yes, we can resend the kit. I'll forward the tracking information.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, January 16, 2018 3:09 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: Re: dog food concern

Hi Jennifer,

Unfortunately it looks like it was delivered on thursday but we are not able to find it. Would it be possible to send another box? I am so sorry....

Thanks

Darcy

On Tue, Jan 16, 2018 at 11:27 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. Here is the tracking info:

UPS NEXT DAY AIR

TRACKING #: 1Z A44 20T 01 9190 2873

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, January 16, 2018 11:18 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: dog food concern

Thank you Jennifer! Very interesting...

We have not received the box - do you have a tracking number that we can look into? We have had some FedEx delays both friday and today.

Thank you!

Darcy

On Fri, Jan 12, 2018 at 8:01 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy!

B5

B5

I'll forward the feed results when they are back.

Have a nice weekend,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, January 10, 2018 6:13 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

Thank you Jennifer - we will be on the lookout for it.

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.

Take care

Darcy

On Jan 10, 2018, at 8:05 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. We're sending the kit this week. It should arrive by close of business Friday.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image006.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, January 09, 2018 11:27 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

Hi Jennifer,

That is great! I've attached a picture of the food sample - the weight is 0.36 kg. We sent blood samples off from 2 dogs to test for **B5** one was in the reference range and the other a bit high.

Thank you!

Take care

Darcy

On Tue, Jan 9, 2018 at 10:07 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Darcy,

We'd like to collect some of the food from your current case (California Naturals Kangaroo). I'm going to send it with the archived sample of food from the **B6** case **B5**

B5

Please let me know the size/weight of the sample you have, and I'll send a box to collect it.

Thank you,
Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Thursday, January 04, 2018 2:47 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: Re: dog food concern

I also have a food sample for our current inpatient (same food - California Naturals kangaroo and lentil). **B5**

B5

On Thu, Jan 4, 2018 at 2:39 PM, Darcy Adin <dbadin@ncsu.edu> wrote:

The myocardium is from **B6** Maybe we will wait to see what the blood levels show.

B5

Thanks!

Darcy

On Thu, Jan 4, 2018 at 2:14 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you for the update. I'll let you know the **B5** concentration from **B6** is food after the results are back.

The frozen myocardium, is it from the **B6** case?

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image004.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Wednesday, January 03, 2018 3:10 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: Re: dog food concern

Hi Jennifer,

Thank you! We have not tested for [B5] 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?

Thank you!

Darcy

On Wed, Jan 3, 2018 at 2:30 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

Happy New Year! Thank you for the additional information. I discussed the information you provided below and from the previous case [B6] Miniature Schnauzers-800.218) with my colleagues.

Based on our discussions, I will test some leftover food from the 800.218 case, for [B5] content. Have any of the dogs with DCM had blood or tissue [B5] levels tested?

Thank you kindly,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image005.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, January 03, 2018 11:31 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: dog food concern

Hi Dr. Jones,

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.

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.

Have you had any other reports of such an association? If you have any other thoughts or testing suggestions, I would be all ears!

Thank you!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Ceric, Olgica; Nemser, Sarah
Sent: 1/23/2018 6:53:11 PM
Subject: Re: dog food concern

Thanks for chatting today Jennifer!

B5

B5

Do you have access to sales estimates for Grain free diets and California natural diets in particular? I am not able to find this on the web. All I can say is that CN does not come up as one of the "top" diets on websites that discuss Grain free benefits.

Thank you!
Darcy

On Tue, Jan 23, 2018 at 8:49 AM, Darcy Adin <dbadin@ncsu.edu> wrote:
Hi Jennifer,

I wondered if I could speak with you sometime today about the diets and some data we have compiled? My office is 919-513-6032 and my cell is **B6** Alternatively, we could email - just let me know!

Take care
Darcy

On Fri, Jan 12, 2018 at 8:01 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy.

B5

B5

I'll forward the feed results when they are back.

Have a nice weekend,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Wednesday, January 10, 2018 6:13 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: Re: dog food concern

Thank you Jennifer - we will be on the lookout for it.

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.

Take care

Darcy

On Jan 10, 2018, at 8:05 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. We're sending the kit this week. It should arrive by close of business Friday.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image006.png](#)>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, January 09, 2018 11:27 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

Hi Jennifer,

That is great! I've attached a picture of the food sample - the weight is 0.36 kg. We sent blood samples off from 2 dogs to test for B5 one was in the reference range and the other a bit high.

Thank you!

Take care

Darcy

On Tue, Jan 9, 2018 at 10:07 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Darcy,

We'd like to collect some of the food from your current case (California Naturals Kangaroo). I'm going to send it with the archived sample of food from the B6 case. B5

B5

Please let me know the size/weight of the sample you have, and I'll send a box to collect it.

Thank you,
Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Thursday, January 04, 2018 2:47 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: Re: dog food concern

I also have a food sample for our current inpatient (same food - California Naturals kangaroo and lentil)

B5

B5

On Thu, Jan 4, 2018 at 2:39 PM, Darcy Adin <dbadin@ncsu.edu> wrote:

The myocardium is from **B6** Maybe we will wait to see what the blood levels show.

B5

Thanks!

Darcy

On Thu, Jan 4, 2018 at 2:14 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you for the update. I'll let you know the **B5** concentration from **B6** food after the results are back.

The frozen myocardium, is it from the **B6** case?

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image004.png](#)>

From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Wednesday, January 03, 2018 3:10 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: Re: dog food concern

Hi Jennifer,

Thank you! We have not tested for **B5** 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?

Thank you!

Darcy

On Wed, Jan 3, 2018 at 2:30 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

Happy New Year! Thank you for the additional information. I discussed the information you provided below and from the previous case (**B6** Miniature Schnauzers-800.218) with my colleagues.

Based on our discussions, I will test some leftover food from the 800.218 case, for **B5** content. Have any of the dogs with DCM had blood or tissue **B5** levels tested?

Thank you kindly,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)

<[image001.png](#)> <[image005.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]

Sent: Wednesday, January 03, 2018 11:31 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: dog food concern

Hi Dr. Jones,

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.

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.

Have you had any other reports of such an association? If you have any other thoughts or testing suggestions, I would be all ears!

Thank you!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607
919-513-6032

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 1/23/2018 6:59:39 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519
Attachments: Re: dog food concern

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Thursday, January 11, 2018 9:36 AM
To: Rotstein, David <David.Rotstein@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: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

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.”

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Wednesday, January 03, 2018 2:32 PM
To: Rotstein, David <David.Rotstein@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)' <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for [B5] based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for [B5]

Jennifer Jones, DVM
Veterinary Medical Officer

Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, August 22, 2017 8:39 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@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>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Tuesday, August 22, 2017 8:37 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **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.

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.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/[B5] still pending, but [B5] negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for [B5]. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.

a. We can consider taurine and other types of testing?

B5

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check with the vet if:

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question, but

B5

I was thinking of the

B5

and was thinking of

B5

This would highly unlikely, but wanted to put it out there.

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 <Jennifer.Jones@fda.hhs.gov>

Date: July 13, 2017 at 2:44:24 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@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>

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for **B5** in food, what does the group think? Any additional testing? Is it worth testing the **B5**?

Medical Record Review:

B6

Presenting complaint

B6

B6

PE

B6

B6

Labwork:

B6

B6

B6

Rads B6 concern for aspiration pneumonia

B6 cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudo-dorsally, hepatomegaly, dec abdominal serosal contrast

B6 severe generalized cardiomegaly with biventricular heart failure, improved vs rDVM rads
worsening cardiogenic pulmonary edema, cannot exclude lung induced injury +/- pneumonia

B6 post ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar

B6 improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia
markedly progressive alveolar pattern with significantly worse cardiogenic edema

tFAST B6 severe cardiomegaly with ventricular hypocontractility

Echo B6 dcm 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

Prior MHx B6
B6

B6

Presented B6

B6

B6

Labs:

B6

ECG: left ventricular enlargement suggested

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

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David

Sent: Tuesday, July 11, 2017 12:44 PM

To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP

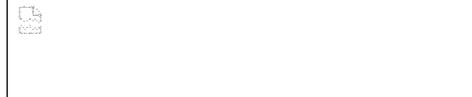
CVM Vet-LIRN Liaison

CVM OSC/DC/CERT

7519 Standish Place, RM 120

240-402-5613 (Office) (NEW NUMBER)

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: Tuesday, July 11, 2017 12:41 PM

To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to MARS who said there was no corn in this food... but that doesn't rule out treats.

I'm not sure with normal: **B5** and taurine levels if we should suspect issues with those as well.

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate

Sent: Tuesday, July 11, 2017 11:51 AM

To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen fo: 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: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHFà severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigsà plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodesà 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

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: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 12/3/2018 2:36:39 PM
Subject: Acana Lamb and Apple singles: Lisa Freeman - EON-372606
Attachments: 2059540-report.pdf; 2059540-attachments.zip

A PFR Report has been received and PFR Event [EON-372606] has been created in the EON System.

A "PDF" report by name "2059540-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2059540-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-372606

ICSR #: 2059540

EON Title: PFR Event created for Acana Lamb and Apple singles; 2059540

AE Date	11/08/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Irish Wolfhound		
Age	3 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2059540

Product Group: Pet Food

Product Name: Acana Lamb and Apple singles

Description: Littermate diagnosed with DCM. Initial taurine level (plasma only) was [B6]. WB taurine submitted = [B6]. Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = [B6] troponin mildly elevated at [B6] (istat) and [B6] at Texas A&M Will recheck in 3-4 months

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Lamb and Apple singles		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

To view this PFR Event, please click the link below:

<https://eon.fda.gov/eon//browse/EON-372606>

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=389575>

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

Client:
Patient:

B6

ECG from Cardio

B6

3/8/2019 2:51:01 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12-Lead, Standard Placement

B6

Client:
Patient:

B6

ECG from Cardio

B6

3/8/2019 2:51:01 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: B6 HQ Pet Food Report Notification;
Sent: 3/26/2019 6:25:57 PM
Subject: 4Health whitefish and potato dry: Lisa Freeman - EON-383414
Attachments: 2064645-report.pdf; 2064645-attachments.zip

A PFR Report has been received and Related PFR Event [EON-383414] has been created in the EON System.

A "PDF" report by name "2064645-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 "2064645-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383414

ICSR #: 2064645

EON Title: Related PFR Event created for 4Health whitefish and potato dry, 4Health salmon and potato adult dog food; 2064645

AE Date	01/03/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Pit Bull		
Age	7.5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2064645

Product Group: Pet Food

Product Name: 4Health whitefish and potato dry, 4Health salmon and potato adult dog food

Description: Eating BEG diet Syncopal episodes - identified arrhythmia recently Owner changing diet and will recheck in 3 months Elevated BNP (B6) taurine and troponin pending 2 other dogs in household eating same diet - they have not been screened yet

Submission Type: Followup

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Died Euthanized

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4Health salmon and potato adult dog food		
4Health whitefish and potato dry		

This report is linked to:

Initial EON Event Key: EON-376448

Initial ICSR: 2061217

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

To view this Related PFR Event, please click the link below:

<https://eon.fda.gov/eon//browse/EON-383414>

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&issueId=400512&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.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be

shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: PFR Event <pfpreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification **B6**

Sent: 3/26/2019 7:48:30 PM

Subject: Acana Singles Duck and Pear Formula Dry dog food EON-383424 **B6**

Attachments: 2064656-report.pdf

A PFR Report has been received and PFR Event [EON-383424] has been created in the EON System.

A "PDF" report by name "2064656-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-383424

ICSR #: 2064656

EON Title: PFR Event created for Acana Singles Duck and Pear Formula Dry dog food, Wet Noses Grain Free pea and carrot dog treats Wet Noses Grain Free berry Blast dog treats, Now Fresh Grain Free Large Breed Adult Recipe Dry Dog f.; 2064656

AE Date	03/16/2019	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Retriever - Labrador		
Age	8 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2064656

Product Group: Pet Food

Product Name: Acana Singles Duck and Pear Formula Dry dog food, Wet Noses Grain Free pea and carrot dog treats Wet Noses Grain Free berry Blast dog treats, Now Fresh Grain Free Large Breed Adult Recipe Dry Dog food

Description: Both my dogs **B6** 3 years Labrador, and **B6** 5 year Labrador) lived on grain free food and treats for years. Lots of peas and legumes. Brands like Acana Lamb and Pear, Wet Noses grain free peas and carrots treats and later on NOW grain free large breed adult food. I thought **B6** was doing great. She looked

so healthy, but she developed enlarged heart and died at only 8 years old.. My sweet girl is now gone. About 6 months ago?, I learned of the FDA warning and added in grain inclusive food along with her grain free as well as cooked meat, thinking this would help. So she was still on grain free 2/3rds with 1/3rd grain inclusive and cooked meat like chicken/beef. But at the emergency room, her heart enzymes were at **B6** (should be under 900) and her diagnosis was Dilated Cardiomyopathy. **B6** dog (Labrador), age 5, was then tested as he ate the same food and shows high enzymes test for heart issues (**B6**) so I know this was not a genetic defect for my other dog. No Vet detected any murmur when listening to her heart, and she loved to run. Those were all of my reasoning I did not fully believe the warning. This disease can stay hidden. Her heart compensated right up until the weekend of her death, when she did have tachycardia the weekend of her death. So terrible that this food is still on the market. I have now heard that Labrador and Golden Retrievers may be more at risk with this food.

B6 vet was **B6** at https: **B6** Her Emergency Vet was http:// **B6**

Submission type: Injured

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Died Naturally

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Now Fresh Grain Free Large Breed Adult Recipe Dry Dog food		
Wet Noses Grain Free pea and carrot dog treats Wet Noses Grain Free berry Blast dog treats		
Acana Singles Duck and Pear Formula Dry dog food		

Sender information

B6

USA

To view this PFR Event, please click the link below:

<https://eon.fda.gov/eon//browse/EON-383424>

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=400522>

This email and attached document are being provided to you in your capacity as a Commissioned Official with

the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: EON Admin <eoncvmlabsamples@fda.hhs.gov>
To: Queen, Jackie L; Carey, Lauren; Rotstein, David; Palmer, Lee Anne
Sent: 3/27/2019 3:00:26 AM
Subject: Consumer Complaint Record Created in EON IMS (EON-383456)
Attachments: EON-383456-ConsumerComplaint-Report.pdf

B6

The ORA Reporting Database was polled and the following Consumer Complaint record was inserted into the Emergency Operations Network Incident Management System (EON IMS).

EON Key: EON-383456

Complaint Number: 156879

Brand Name: Zignature

Product Name: Turkey Blend Grain Free

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 3/26/2019 2:44:44 PM
Subject: Rachel Ray's Chicken and Veggies: [B6] EON-383378
Attachments: 2064635-report.pdf; 2064635-attachments.zip

A PFR Report has been received and PFR Event [EON-383378] has been created in the EON System.

A "PDF" report by name "2064635-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 "2064635-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383378

ICSR #: 2064635

EON Title: PFR Event created for Rachel Ray's Chicken and Veggies; 2064635

AE Date	11/14/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	2 Years		
District Involved	PFR-Baltimore DO		

Product information

Individual Case Safety Report Number: 2064635

Product Group: Pet Food

Product Name: Rachel Ray's Chicken and Veggies

Description: On 11/14/2018, presented to pcDVM for on/off limping with unknown trauma and cardiomegaly was identified on the subsequent radiographs, as well as muffled heart sounds on auscultation; a cardiac consultation was recommended. At consult, a Grade V/VI heart murmur was ausculted with significantly muffled heart sounds on the left. She was diagnosed with severe tricuspid valve dysplasia, severe tricuspid insufficiency, severe right heart volume load, severe enlargement of the caudal vena cava and hepatic veins, and dilated, thin-walled, hypocontractile left ventricle consistent with left-sided DCM. An ECG showed sinus rhythm

conducted with first-degree AV block, and a Holter monitor was performed (normal). She was started on **B6** (following a Taurine level being drawn).

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
Rachel Ray's Chicken and Veggies		

Sender information

B6

USA

Owner information

B6

To view this PFR Event, please click the link below:

<https://eon.fda.gov/eon/browse/EON-383378>

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=400476>

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: [REDACTED] **B5, B6**
To: Jones, Jennifer L
Sent: 7/6/2018 4:54:55 PM
Subject: Suspected diet related DCM case logs
Attachments: Dilated cardiomyopathy cases 2017.xlsx

Dr. Jones,

Please find attached the current case log for suspected diet related DCM cases. Let me know if you have any questions.

B5, B6

**DOCUMENT
PRODUCED IN NATIVE**

From: B5, B6
To: Jones, Jennifer L
Sent: 5/18/2018 5:25:41 PM
Subject: DCM and Diet spreadsheet
Attachments: Diet Breakdown by Brand.xlsx

**DOCUMENT
PRODUCED IN NATIVE**

**DOCUMENT
PRODUCED IN NATIVE**

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/24/2019 4:28:19 PM
Subject: Taste of the Wild Sierra Mountain: [B6] - EON-377360
Attachments: 2061702-report.pdf

A PFR Report has been received and PFR Event [EON-377360] has been created in the EON System.

A "PDF" report by name "2061702-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377360

ICSR #: 2061702

EON Title: PFR Event created for Taste of the Wild Sierra Mountain; 2061702

AE Date	07/01/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Bulldog		
Age	10 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2061702

Product Group: Pet Food

Product Name: Taste of the Wild Sierra Mountain

Description: Diet for entire life consisted of grain free food. Started in July to have labored breathing with an occasional gag. Activity level had decreased. X-rays showed displacement of trachea. Vet treated for pneumonia due to white areas of lung. Finally got an echocardiogram and the diagnosis was Dilated Cardiomyopathy. Tests also showed his liver, spleen, and caudal vena cava were enlarged. The last week of life, he could not lay down but would just stand and pant. When it got so bad, I chose to let him be euthanized.

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: 5

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Sierra Mountain		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.

From: 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 6:58:31 PM
Subject: RE: DCM write-up for June Web Update

One correction—I double checked and it should be “There are **B5** evaluation.”

FYI, these are the pending necropsy cases:

B5, B6

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Peloquin, Sarah
Sent: Wednesday, June 12, 2019 2:41 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: 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.

I didn't put hard numbers in there given that

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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: 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,

Could you please write-up a summary of the findings we would like to make public for DCM necropsies? This will be part of the technical Vet-LIRN update. The information will build on this paragraph:

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
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
CC: Peloquin, Sarah
Sent: 6/13/2019 1:31:11 PM
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all. Thank you and enjoy

B6

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates.
Can I get it to you by COB Thursday?

B6

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: Vet-LIRN Update on DCM

Hi Jen,

Wanted to circle back after Dr. Solomon's DCM briefing. You did a great job! I think he has a much better appreciation for where things stand now.

I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

[Draft – Vet-LIRN DCM Update for June 2019](#)

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!

Anne

Anne Norris

Strategic Initiatives

Office of the Director

Center for Veterinary Medicine

U.S. Food & Drug Administration

O: 240-402-0132

B6

Anne.Norris@fda.hhs.gov

