From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS> To: Jones, Jennifer L; Carey, Lauren; Rotstein, David; Palmer, Lee Anne CC: DeLancey, Siobhan Sent: 8/6/2018 2:56:52 PM RE: DCM-Follow up call? Subject: Sure! ----Original Message----From: Jones, Jennifer L Sent: Monday, August 06, 2018 10:46 AM To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: DCM-Follow up call? Would Wed from 4-5 work? Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 ----Original Message-----From: Norris, Anne Sent: Monday, August 06, 2018 8:34 AM To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov> Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov> Subject: RE: DCM-Follow up call? I'm interested. Best times would be this morning or Tuesday afternoon. My calendar should be up to date. Thanks! ----Original Message-----From: Carey, Lauren Sent: Monday, August 06, 2018 7:10 AM 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: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov> Subject: RE: DCM-Follow up call? I'm interested. I'm free every afternoon except today and all day Friday. Lee Anne's **B6** but I'll take notes for her.

----Original Message-----From: Rotstein, David

Sent: Monday, August 06, 2018 6:48 AM

To: 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>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: DCM-Follow up call?

I'm interested. Vet-LIRN grants Tues and Thursday; I can do today, Wednesday, and possibly Friday.

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.

----Original Message-----From: Jones, Jennifer L

Sent: Monday, August 06, 2018 6:42 AM

To: 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>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: FW: DCM-Follow up call?

Are you folks interested in attending? Let me know your availability this week (except Thursday).

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

----Original Message-----

From: Darcy Adin [mailto:dbadin@ncsu.edu] Sent: Friday, August 03, 2018 11:29 PM

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

Cc: Lisa Freeman < lisa.freeman@tufts.edu>

Subject: Follow up call?

Hi Dr. Jones.

Dr. Freeman and I are wondering if your group would be willing to have another conference call as a follow-up to discuss the nutritionally based DCM cases? As you know, since the release of the FDA statement, there has been much discussion among the public and the veterinary community, and we thought it could be useful to reconvene.

Thank you for your thoughts!

Darcy

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To:

Jones, Jennifer L; Norris, Anne; Carey, Lauren; Palmer, Lee Anne

CC: Sent: DeLancey, Siobhan 8/6/2018 2:57:12 PM

Subject:

RE: DCM-Follow up call?

That will work

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.

----Original Message----

From: Jones, Jennifer L

Sent: Monday, August 06, 2018 10:46 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: DCM-Follow up call?

Would Wed from 4-5 work?

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

----Original Message----

From: Norris, Anne

Sent: Monday, August 06, 2018 8:34 AM

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

<Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

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Thanks!

----Original Message-----

From: Carey, Lauren

Sent: Monday, August 06, 2018 7:10 AM

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

Subject: RE: DCM-Follow up call?

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B6

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----Original Message-----From: Rotstein, David

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To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne < Lee Anne.Palmer@fda.hhs.gov>; Carey, Lauren

<Lauren.Carey@fda.hhs.gov>

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

Subject: RE: DCM-Follow up call?

I'm interested. Vet-LIRN grants Tues and Thursday; I can do today, Wednesday, and possibly Friday.

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

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<Lauren.Carey@fda.hhs.gov>

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

Subject: FW: DCM-Follow up call?

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Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

----Original Message-----

From: Darcy Adin [mailto:dbadin@ncsu.edu] Sent: Friday, August 03, 2018 11:29 PM

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

Cc: Lisa Freeman < lisa.freeman@tufts.edu>

Subject: Follow up call?

Hi Dr. Jones,

Dr. Freeman and I are wondering if your group would be willing to have another conference call as a follow-up to discuss the nutritionally based DCM cases? As you know, since the release of the FDA statement, there has been much discussion among the public and the veterinary community, and we thought it could be useful to reconvene.

Thank you for your thoughts! Darcy

From:

Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

To:

Ask CVM; Carey, Lauren; Jones, Jennifer L

Sent:

7/3/2019 6:02:32 PM

Subject:

RE: Dog food link to DCM in dogs

Would AskCVM be willing to give B6 the link to our Safety Reporting Portal? https://www.safetyreporting.hhs.gov. We'd be happy to receive B6 report. If it is possible to do that from an AskCVM email address (or AskOSC, but I know Laura is out), it might be better. If I do it, my email would be out there...yikes. Thanks!

I would recommend saying,

B5

В5

----Original Message-----

From: Ask CVM

Sent: Wednesday, July 3, 2019 1:54 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>

Subject: FW: Dog food link to DCM in dogs

----Original Message---

B6

Sent: Friday, June 28, 2019 9:22 PM
To: Ask CVM <AskCVM@fda.hhs.gov>
Subject: Dog food link to DCM in dogs

Dear Sirs,

I just wanted to touch base with your organization regarding the dog food like to canine heart disease. My beloved little guy passed away in January 2019 after a battle with CHF. I cannot say it was DCM but definitely he had really bad CHF. I started feeding him Blue buffalo food sometime ago. This was before there was a problem and then when I changed to the Blue Buffalo Wilderness Rocky Mountain Recipe with Red Meat, Small Breed Grain free dry dog food. He was seen by a Cardiologist and there are Echocardiograms of his heart. I have pictures also. Let me know if your investigators might want copies of these.

Sincerely,

B6

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: Freeman, Lisa

CC: Nemser, Sarah; Ceric, Olgica **Sent:** 12/21/2016 1:53:14 PM

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Lisa,

I wanted to check-in and see if you were still planning to submit the potential DCM cases?

Hope you have a nice holiday, and take care, Jennifer

Jennifer Jones, DVM Veterinary Medical Officer





From: Jones, Jennifer L

Sent: Monday, October 31, 2016 7:32 AM

To: 'Freeman, Lisa'

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Sounds great! Thank you, Lisa.

Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it's been submitted.

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 3:36 PM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Thanks very much.

I'm going to have another one for you. 3 unrelated dogs in a family who've developed dilated cardiomyopathy. Supposedly on a commercial vegan diet and then small company;s dog food. Once I get more details, I'll submit that one.

Best,

Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Tufts University

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

Sent: Friday, October 28, 2016 3:07 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good afternoon Lisa.

Thank you for sending the invoices. I'll submit them for repayment.

I'll be on the look-out for the Medical records and the final blood culture result.

We will send the results of the food testing as soon as they are received. As a head's up, they usually take a few weeks.

Thank you again for your help with the investigation.

Kind regards and enjoy your weekend,

Jen

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 10:01 AM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Jennifer

Please see attached for an invoice, as well as the receipt for shipping and the invoice that includes the blood culture.

So far, the blood culture is negative but I'll send the final report when it's available.

We're getting written permission for release of records from the owner and will send those asap

Will I be updated on the results of the food analysis? That will be helpful information for treating this dog since she's not doing especially well

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Tufts University

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

Sent: Friday, October 21, 2016 11:15 AM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Dr. Freeman,

Thank you for the update. We will look for the medical records to arrive.

In the meantime, please move forward with the Listeria blood culture at IDEXX. Please send a copy of the results when finished and an invoice for the blood collection/shipping/Listeria testing.

For the open product testing, an instruction document and pre-filled out laboratory submission forms are attached. Please include those in the shipment. After shipping, please send an invoice for the shipping materials and shipping.

Please email or call with any questions.

Thank you kindly,

Jennifer

Jennifer Jones, DVM Veterinary Medical Officer

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

Sent: Friday, October 21, 2016 10:24 AM

To: Nemser, Sarah; Ceric, Olgica

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Sarah

I got information from Dr. Ceric on submitting a blood culture for Listeria but not any information on submitting the food for analysis.

I'm traveling this week but can submit an estimate for blood testing on Monday

Kind regards,

Lisa

From: Nemser, Sarah [mailto:Sarah.Nemser@fda.hhs.gov]

Sent: Friday, October 21, 2016 10:22 AM

To: Ceric, Olgica; Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dr. Freeman.

| I wanted to follow up on this | case. |
|--------------------------------|-------|
| Dr. Ceric is out of office due | В6 |

In her email below she stated that she would provide information on sending the food to the Ohio laboratory. Please let us know if that information was provided, if not we can follow up.

Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

From: Ceric, Olgica

Sent: Wednesday, October 19, 2016 2:09 PM

To: Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

If IDEXX can test blood, that would be the fastest way to get it to the lab. We will reimburse you for the charges, but we will need an estimate first, in order to prepare purchase order.

As for the food, we can test it at our network lab in Ohio, I'll send you instructions in a separate email.

We will reimburse you for the shipping charges. You'll just need to submit invoice (one for blood testing and shipping), once you ship the sample.

Olgica Ceric, DVM, PhD

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
tel: 240-402-5419

e-mail: olgica.ceric@fda.hhs.gov

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

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

Sent: Wednesday, October 19, 2016 1:43 PM

To: Ceric, Olgica

fax: 301-210-4685

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi all

We just got a blood sample from the dog (just so happened she was coming in for a recheck today so I was fortunate to catch her primary clinician before the dog left). We typically submit our blood cultures to IDEXX. I'm on the phone right now to see if they can test for Listeria. If not, can you tell me where to submit?

We do not have the ability to easily test the food for Listeria so if you could send details on that as well, I'd appreciate it

The owner did give permission to get records sent. I'm traveling through Friday but can get those submitted to you on Monday

I'll get someone to submit samples as soon as you provide info on labs, etc Thanks

Lisa

From: Ceric, Olgica [mailto:Olgica.Ceric@fda.hhs.gov]

Sent: Wednesday, October 19, 2016 10:10 AM

To: Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Dr. Freeman.

Thank you for the prompt response.

Do you have in-house lab available for testing the food? If so, please let me know the testing estimate.

Once you get approval from the owner to release medical records, please email them, or fax to: 301-210-4685.

Regarding Listeria, perhaps you could ask the owner if they are willing to submit blood for testing when you contact them regarding medical records? I understand your concerns regarding antibiotics, but we'd like to do it just in case.

Please reply to all when responding, my responses might be delayed since I'll be on leave part day by the end of the week.

Thank you,

Olgica Ceric, DVM, PhD

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
tel: 240-402-5419
fax: 301-210-4685

e-mail: <u>olgica.ceric@fda.hhs.gov</u>

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

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

Sent: Tuesday, October 18, 2016 7:28 AM

To: Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Olgica

We're happy to get permission from owners for medical records and I can get food submitted for testing next week

My question is on the blood culture. I'm not sure when the dog will be coming back in (she was discharged late last week) and am wondering if Listeria could be cultured if dog has been on antibiotics for >1 week

Thanks Lisa

From: Ceric, Olgica [mailto:Olgica.Ceric@fda.hhs.gov]

Sent: Monday, October 17, 2016 1:03 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Jones, Jennifer L

Subject: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Dr. Freeman,

We received your consumer complaint and would like to request the following:

- · a copy of full medical records for the dog
- blood culture for Listeria
- open bag testing for Listeria and Salmonella

FDA will pay for the testing.

We have a network of veterinary diagnostic laboratories and could send samples to one of them, unless your lab has the capabilities?

Please email (preferred) or fax (301) 210-4685 us the **medical records**. Please send the **full medical history**-not just for this illness event.

Attached are a copy of our network procedures. They describe how veterinarians help with our case investigations. I also attached an owner friendly version. Sincerely,

Olgica Ceric, DVM, PhD

Veterinary Medical Officer U.S. Food & Drug Administration Center for Veterinary Medicine Office of Research

Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704 Laurel, Maryland 20708 tel: 240-402-5419 fax: 301-210-4685

e-mail: <u>olgica.ceric@fda.hhs.gov</u>
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: Freeman, Lisa

CC: Ceric, Olgica; Nemser, Sarah Sent: 11/14/2016 5:20:29 PM

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Attachments: 800.193-B1624542-OH-food negative.pdf.html

Good afternoon Dr. Freeman,

The final result for the feed testing is attached. In short, the feed tested negative for *Salmonella*, *E. coli*, and *Listeria*. Please share the results with the owner.

Please also send a copy of the final *Listeria* culture results for our records.

Because the dog tested positive for Bartonellosis and our subsequent testing (*Listeria* blood culture, and open product feed testing) was negative, we believe the food was an unlikely cause of this dog's illness.

Thank you again for all of your help with this case.

Please email or call with any questions.

Thank you kindly,

Jennifer

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Saturday, November 05, 2016 7:56 AM

To: Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi Jennifer

Please see below for Bartonella results

Best, Lisa

B4

ANIMAL HEALTH TEST REPORT

| Pet Name: Owner Name B6 | | | Order Received: Report Sent: Order Number: DVM: | | 12-Oct-16 02-Nov-16 | | |
|---|----------|---------------|--|----------|------------------------|-----------------------|-------------|
| Patient ID: 317478 Clinic: Tufts Cummings School of Vet Med - Clin P | | | | | t Med - Clin P | GA16-0620 B6 | |
| Tary | get | Sample | Collection | Type | Result | Sequence | Reference |
| st ePCR | | | | | | | |
| | | | 1096/2026 | Maced | Positive | 8. vers. benkhafhi | Negative |
| Bantonel | ga etoin | GA16-0620-1-8 | EKNAT 20114 | Mancheng | P SASSECTION | CO. MUNT THE LANGUAGE | Leadingston |

Notes:

See attached sheet for test(s) interpretation

Page 1

B6

Lisa M. Freeman, DVM, PhD, DACVN Professor Cummings School of Veterinary Medicine Tufts University

From: Freeman, Lisa

Sent: Wednesday, November 02, 2016 10:50 AM

To: Jones, Jennifer L; medrec

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi Jennifer

Our medical records department is asking for your mailing address since **B6** file is rather large

Could you provide that? I'm cc'ing them here

Thanks Lisa

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

Sent: Tuesday, November 01, 2016 3:09 PM To: Freeman, Lisa < Lisa.Freeman@tufts.edu >

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good afternoon Lisa,

My accountant asked if you're able to be reimbursed by credit (VISA) or if a check was needed?

Thank you, Jennifer

Jennifer Jones, DVM Veterinary Medical Officer





From: Jones, Jennifer L

Sent: Monday, October 31, 2016 7:32 AM

To: 'Freeman, Lisa'

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Sounds great! Thank you, Lisa.

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

Sent: Friday, October 28, 2016 3:36 PM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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Lisa M. Freeman, DVM, PhD, DACVN

Professor Cummings School of Veterinary Medicine Tufts University

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Kind regards and enjoy your weekend,

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Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 10:01 AM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Tufts University

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

Sent: Friday, October 21, 2016 11:15 AM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Dr. Freeman,

Thank you for the update. We will look for the medical records to arrive.

In the meantime, please move forward with the Listeria blood culture at IDEXX. Please send a copy of the results when finished and an invoice for the blood collection/shipping/Listeria testing.

For the open product testing, an instruction document and pre-filled out laboratory submission forms are attached. Please include those in the shipment. After shipping, please send an invoice for the shipping materials and shipping.

Please email or call with any questions.

Thank you kindly,

Jennifer

Jennifer Jones, DVM Veterinary Medical Officer

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

Sent: Friday, October 21, 2016 10:24 AM

To: Nemser, Sarah; Ceric, Olgica

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Sarah

I got information from Dr. Ceric on submitting a blood culture for Listeria but not any information on submitting the food for analysis.

I'm traveling this week but can submit an estimate for blood testing on Monday

Kind regards,

Lisa

From: Nemser, Sarah [mailto:Sarah.Nemser@fda.hhs.gov]

Sent: Friday, October 21, 2016 10:22 AM

To: Ceric, Olgica; Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

From: Ceric, Olgica

Sent: Wednesday, October 19, 2016 2:09 PM

To: Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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

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

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Sent: Tuesday, October 18, 2016 7:28 AM

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Dear Olgica

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Sent: Monday, October 17, 2016 1:03 PM

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From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: Freeman, Lisa

CC: Nemser, Sarah; Ceric, Olgica Sent: 10/31/2016 11:31:34 AM

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Sounds great! Thank you, Lisa.

Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it's been submitted.

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 3:36 PM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Thanks very much.

I'm going to have another one for you. 3 unrelated dogs in a family who've developed dilated cardiomyopathy. Supposedly on a commercial vegan diet and then small company;s dog food. Once I get more details, I'll submit that one.

Best,

Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Tufts University

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

Sent: Friday, October 28, 2016 3:07 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good afternoon Lisa,

Thank you for sending the invoices. I'll submit them for repayment.

I'll be on the look-out for the Medical records and the final blood culture result.

We will send the results of the food testing as soon as they are received. As a head's up, they usually take a few weeks.

Thank you again for your help with the investigation.

Kind regards and enjoy your weekend,

Jen

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 10:01 AM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Jennifer

Please see attached for an invoice, as well as the receipt for shipping and the invoice that includes the blood culture.

So far, the blood culture is negative but I'll send the final report when it's available.

We're getting written permission for release of records from the owner and will send those asap

Will I be updated on the results of the food analysis? That will be helpful information for treating this dog since she's not doing especially well

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN Professor Cummings School of Veterinary Medicine Tufts University

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Sent: Friday, October 21, 2016 11:15 AM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

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sarah.nemser@fda.hhs.gov

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

Sent: Wednesday, October 19, 2016 1:43 PM

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: Freeman, Lisa

CC: Nemser, Sarah; Ceric, Olgica Sent: 10/28/2016 7:07:24 PM

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>

To: 'Freeman, Lisa'

CC: Nemser, Sarah; Ceric, Olgica Sent: 10/24/2016 2:56:42 PM

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Thank you, Lisa.

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Hi Jennifer

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Blood sample was submitted.

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Tufts University

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

Sent: Friday, October 21, 2016 11:15 AM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Dr. Freeman,

Thank you for the update. We will look for the medical records to arrive.

In the meantime, please move forward with the Listeria blood culture at IDEXX. Please send a copy of the results when finished and an invoice for the blood collection/shipping/Listeria testing.

For the open product testing, an instruction document and pre-filled out laboratory submission forms are attached. Please include those in the shipment. After shipping, please send an invoice for the shipping materials and shipping.

Please email or call with any questions.

Thank you kindly,

Jennifer

Jennifer Jones, DVM Veterinary Medical Officer

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

Sent: Friday, October 21, 2016 10:24 AM

To: Nemser, Sarah; Ceric, Olgica

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Sarah

I got information from Dr. Ceric on submitting a blood culture for Listeria but not any information on submitting the food for analysis.

I'm traveling this week but can submit an estimate for blood testing on Monday

Kind regards,

Lisa

From: Nemser, Sarah [mailto:Sarah.Nemser@fda.hhs.gov]

Sent: Friday, October 21, 2016 10:22 AM

To: Ceric, Olgica; Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dr. Freeman,

In her email below she stated that she would provide information on sending the food to the Ohio laboratory. Please let us know if that information was provided, if not we can follow up.

Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

From: Ceric, Olgica

Sent: Wednesday, October 19, 2016 2:09 PM

To: Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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Olgica Ceric, DVM, PhD

Veterinary Medical Officer
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Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
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tel: 240-402-5419

tel: 240-402-5419 fax: 301-210-4685

e-mail: olgica.ceric@fda.hhs.gov

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

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

Sent: Wednesday, October 19, 2016 1:43 PM

To: Ceric, Olgica

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I'll get someone to submit samples as soon as you provide info on labs, etc

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Please reply to all when responding, my responses might be delayed since I'll be on leave part day by the end

of the week.

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

Sent: Tuesday, October 18, 2016 7:28 AM

To: Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Olgica

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Thanks Lisa

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Sent: Monday, October 17, 2016 1:03 PM

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FDA will pay for the testing.

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From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8> To: 'Freeman, Lisa' CC: Nemser, Sarah; Ceric, Olgica Sent: 10/21/2016 3:15:13 PM Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity 800.193-Freeman-Ohio sub form.pdf.html; 800.193-Freeman-RequestLetter.doc.html; 800.193-Attachments: Freeman-Vet-LIRN-SubForm.pdf.html; 800.193-Vet-LIRN-Ship Inv Sheet.doc.html Good morning Dr. Freeman, Thank you for the update. We will look for the medical records to arrive. In the meantime, please move forward with the Listeria blood culture at IDEXX. Please send a copy of the results when finished and an invoice for the blood collection/shipping/Listeria testing. For the open product testing, an instruction document and pre-filled out laboratory submission forms are attached. Please include those in the shipment. After shipping, please send an invoice for the shipping materials and shipping. Please email or call with any questions. Thank you kindly, Jennifer Jennifer Jones, DVM Veterinary Medical Officer From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu] Sent: Friday, October 21, 2016 10:24 AM To: Nemser, Sarah; Ceric, Olgica Cc: Reimschuessel, Renate; Jones, Jennifer L Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity Dear Sarah I got information from Dr. Ceric on submitting a blood culture for Listeria but not any information on submitting the food for analysis. I'm traveling this week but can submit an estimate for blood testing on Monday Kind regards, Lisa **From:** Nemser, Sarah [mailto:Sarah.Nemser@fda.hhs.gov] Sent: Friday, October 21, 2016 10:22 AM To: Ceric, Olgica; Freeman, Lisa Cc: Reimschuessel, Renate; Jones, Jennifer L. Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity Dr. Freeman, I wanted to follow up on this case.

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From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: Freeman, Lisa

CC: Ceric, Olgica; Nemser, Sarah Sent: 11/14/2016 5:20:29 PM

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Attachments: 800.193-B1624542-OH-food negative.pdf.html

Good afternoon Dr. Freeman,

The final result for the feed testing is attached. In short, the feed tested negative for *Salmonella*, *E. coli*, and *Listeria*. Please share the results with the owner.

Please also send a copy of the final *Listeria* culture results for our records.

Because the dog tested positive for Bartonellosis and our subsequent testing (*Listeria* blood culture, and open product feed testing) was negative, we believe the food was an unlikely cause of this dog's illness.

Thank you again for all of your help with this case.

Please email or call with any questions.

Thank you kindly,

Jennifer

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Saturday, November 05, 2016 7:56 AM

To: Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi Jennifer

Please see below for Bartonella results

Best, Lisa



| Target | Sample | Collection | Type | Result | Sequence | Reference | |
|----------------|---------------|------------|---------|----------|--------------------|-----------|--|
| ePCR | | | | | | | |
| Bartonella spo | GA16-0620-1-8 | 10%/2016 | Mount | Positive | B. ven. berkhaftii | Negative | |
| Bartonella spp | GA16-0630-1-C | 10/6/7016 | Culture | Neguther | | Negative | |

Notes:

See attached sheet for test(s) Interpretation

Page 1

B6

Lisa M. Freeman, DVM, PhD, DACVN Professor Cummings School of Veterinary Medicine Tufts University

From: Freeman, Lisa

Sent: Wednesday, November 02, 2016 10:50 AM

To: Jones, Jennifer L; medrec

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi Jennifer

Our medical records department is asking for your mailing address since B6 file is rather large

Could you provide that? I'm cc'ing them here

Thanks Lisa

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

Sent: Tuesday, November 01, 2016 3:09 PM **To:** Freeman, Lisa < <u>Lisa.Freeman@tufts.edu</u>>

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good afternoon Lisa.

My accountant asked if you're able to be reimbursed by credit (VISA) or if a check was needed?

Thank you, Jennifer

Jennifer Jones, DVM Veterinary Medical Officer





From: Jones, Jennifer L

Sent: Monday, October 31, 2016 7:32 AM

To: 'Freeman, Lisa'

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Sounds great! Thank you, Lisa.

Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it's been submitted.

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 3:36 PM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Thanks very much.

I'm going to have another one for you. 3 unrelated dogs in a family who've developed dilated cardiomyopathy. Supposedly on a commercial vegan diet and then small company;s dog food. Once I get more details, I'll submit that one.

Best,

Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor Cummings School of Veterinary Medicine Tufts University

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

Sent: Friday, October 28, 2016 3:07 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good afternoon Lisa,

Thank you for sending the invoices. I'll submit them for repayment.

I'll be on the look-out for the Medical records and the final blood culture result.

We will send the results of the food testing as soon as they are received. As a head's up, they usually take a few weeks.

Thank you again for your help with the investigation.

Kind regards and enjoy your weekend,

Jen

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 10:01 AM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Jennifer

Please see attached for an invoice, as well as the receipt for shipping and the invoice that includes the blood culture.

So far, the blood culture is negative but I'll send the final report when it's available.

We're getting written permission for release of records from the owner and will send those asap

Will I be updated on the results of the food analysis? That will be helpful information for treating this dog since she's not doing especially well

Thanks

Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Tufts University

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From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: Freeman, Lisa

CC: Nemser, Sarah; Ceric, Olgica Sent: 10/31/2016 11:31:34 AM

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Sounds great! Thank you, Lisa.

Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it's been submitted.

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 3:36 PM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Thanks very much.

I'm going to have another one for you. 3 unrelated dogs in a family who've developed dilated cardiomyopathy. Supposedly on a commercial vegan diet and then small company;s dog food. Once I get more details, I'll submit that one.

Best,

Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Tufts University

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

Sent: Friday, October 28, 2016 3:07 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good afternoon Lisa,

Thank you for sending the invoices. I'll submit them for repayment.

I'll be on the look-out for the Medical records and the final blood culture result.

We will send the results of the food testing as soon as they are received. As a head's up, they usually take a few weeks.

Thank you again for your help with the investigation.

Kind regards and enjoy your weekend,

Jen

Jennifer Jones, DVM Veterinary Medical Officer



Ver-URN

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

Sent: Friday, October 28, 2016 10:01 AM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Jennifer

Please see attached for an invoice, as well as the receipt for shipping and the invoice that includes the blood culture.

So far, the blood culture is negative but I'll send the final report when it's available.

We're getting written permission for release of records from the owner and will send those asap

Will I be updated on the results of the food analysis? That will be helpful information for treating this dog since she's not doing especially well

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN Professor Cummings School of Veterinary Medicine Tufts University

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

Sent: Friday, October 21, 2016 11:15 AM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Dr. Freeman,

Thank you for the update. We will look for the medical records to arrive.

In the meantime, please move forward with the Listeria blood culture at IDEXX. Please send a copy of the results when finished and an invoice for the blood collection/shipping/Listeria testing.

For the open product testing, an instruction document and pre-filled out laboratory submission forms are attached. Please include those in the shipment. After shipping, please send an invoice for the shipping materials and shipping.

Please email or call with any questions.

Thank you kindly,

Jennifer

Jennifer Jones, DVM Veterinary Medical Officer

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

Sent: Friday, October 21, 2016 10:24 AM

To: Nemser, Sarah; Ceric, Olgica

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Sarah

I got information from Dr. Ceric on submitting a blood culture for Listeria but not any information on submitting the food for analysis.

I'm traveling this week but can submit an estimate for blood testing on Monday Kind regards,

Lisa

From: Nemser, Sarah [mailto:Sarah.Nemser@fda.hhs.gov]

Sent: Friday, October 21, 2016 10:22 AM

To: Ceric, Olgica; Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dr. Freeman,

I wanted to follow up on this case.

Dr. Ceric is out of office due B6

In her email below she stated that she would provide information on sending the food to the Ohio laboratory. Please let us know if that information was provided, if not we can follow up.

Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

From: Ceric, Olgica

Sent: Wednesday, October 19, 2016 2:09 PM

To: Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

If IDEXX can test blood, that would be the fastest way to get it to the lab. We will reimburse you for the charges, but we will need an estimate first, in order to prepare purchase order.

As for the food, we can test it at our network lab in Ohio, I'll send you instructions in a separate email.

We will reimburse you for the shipping charges. You'll just need to submit invoice (one for blood testing and shipping), once you ship the sample.

Olgica Ceric, DVM, PhD

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708

tel: 240-402-5419 fax: 301-210-4685

e-mail: olgica.ceric@fda.hhs.gov

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

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

Sent: Wednesday, October 19, 2016 1:43 PM

To: Ceric, Olgica

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi all

We just got a blood sample from the dog (just so happened she was coming in for a recheck today so I was fortunate to catch her primary clinician before the dog left). We typically submit our blood cultures to IDEXX. I'm on the phone right now to see if they can test for Listeria. If not, can you tell me where to submit?

We do not have the ability to easily test the food for Listeria so if you could send details on that as well, I'd appreciate it

The owner did give permission to get records sent. I'm traveling through Friday but can get those submitted to you on Monday

I'll get someone to submit samples as soon as you provide info on labs, etc Thanks Lisa

From: Ceric, Olgica [mailto:Olgica.Ceric@fda.hhs.gov]
Sent: Wednesday, October 19, 2016 10:10 AM

To: Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Dr. Freeman,

Thank you for the prompt response.

Do you have in-house lab available for testing the food? If so, please let me know the testing estimate.

Once you get approval from the owner to release medical records, please email them, or fax to: 301-210-4685.

Regarding Listeria, perhaps you could ask the owner if they are willing to submit blood for testing when you contact them regarding medical records? I understand your concerns regarding antibiotics, but we'd like to do it just in case.

Please reply to all when responding, my responses might be delayed since I'll be on leave part day by the end of the week.

Thank you,

Olgica Ceric, DVM, PhD

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e-mail: olgica.ceric@fda.hhs.gov

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

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

Sent: Tuesday, October 18, 2016 7:28 AM

To: Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Olgica

We're happy to get permission from owners for medical records and I can get food submitted for testing next

My question is on the blood culture. I'm not sure when the dog will be coming back in (she was discharged late last week) and am wondering if Listeria could be cultured if dog has been on antibiotics for >1 week

Thanks Lisa

From: Ceric, Olgica [mailto:Olgica.Ceric@fda.hhs.gov]

Sent: Monday, October 17, 2016 1:03 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Jones, Jennifer L

Subject: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Dr. Freeman,

We received your consumer complaint and would like to request the following:

- · a copy of full medical records for the dog
- blood culture for Listeria
- open bag testing for Listeria and Salmonella

FDA will pay for the testing.

We have a network of veterinary diagnostic laboratories and could send samples to one of them, unless your lab has the capabilities?

Please email (preferred) or fax (301) 210-4685 us the **medical records**. Please send the **full medical history**-not just for this illness event.

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

Sincerely,

Olgica Ceric, DVM, PhD

fax: 301-210-4685

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
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tel: 240-402-5419

e-mail: olgica.ceric@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:

Freeman, Lisa

Sent:

1/4/2017 2:37:49 PM

Subject:

RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Thank you, Lisa. Happy New Year!

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Tuesday, January 03, 2017 2:13 PM

To: Jones, Jennifer L

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Hi Jennifer

It turns out the dog's taurine level was normal and the owners went to another cardiologist for a 2nd opinion so I don't think we have anything to pursue at this point. If they come back and we get more info on the other dogs,

I'll let you know Happy New Year!

Lisa

Lisa M. Freeman, DVM, PhD, DACVN Professor Cummings School of Veterinary Medicine Tufts University

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

Sent: Wednesday, December 21, 2016 8:53 AM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Lisa,

I wanted to check-in and see if you were still planning to submit the potential DCM cases?

Hope you have a nice holiday, and take care, Jennifer

Jennifer Jones, DVM Veterinary Medical Officer





From: Jones, Jennifer L

Sent: Monday, October 31, 2016 7:32 AM

To: 'Freeman, Lisa'

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Sounds great! Thank you, Lisa.

Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it's been submitted.

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 3:36 PM

To: Jones, Jennifer L

Cc: Nemser, Sarah; Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Thanks very much.

I'm going to have another one for you. 3 unrelated dogs in a family who've developed dilated cardiomyopathy. Supposedly on a commercial vegan diet and then small company;s dog food. Once I get more details, I'll submit that one.

Best, Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Professor

Cummings School of Veterinary Medicine

Tufts University

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Sent: Friday, October 28, 2016 3:07 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Ceric, Olgica

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Good afternoon Lisa,

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I'll be on the look-out for the Medical records and the final blood culture result.

We will send the results of the food testing as soon as they are received. As a head's up, they usually take a few weeks.

Thank you again for your help with the investigation.

Kind regards and enjoy your weekend,

Jen

Jennifer Jones, DVM Veterinary Medical Officer





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

Sent: Friday, October 28, 2016 10:01 AM

To: Jones, Jennifer L

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Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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We're getting written permission for release of records from the owner and will send those asap

Will I be updated on the results of the food analysis? That will be helpful information for treating this dog since she's not doing especially well

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN Professor Cummings School of Veterinary Medicine Tufts University

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Sent: Friday, October 21, 2016 11:15 AM

To: Freeman, Lisa

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Please email or call with any questions.

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Jennifer Jones, DVM Veterinary Medical Officer

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

Sent: Friday, October 21, 2016 10:24 AM

To: Nemser, Sarah; Ceric, Olgica

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To: Ceric, Olgica; Freeman, Lisa

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|--------------------------------|-------|
| Dr. Ceric is out of office due | B6 |

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Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

From: Ceric, Olgica

Sent: Wednesday, October 19, 2016 2:09 PM

To: Freeman, Lisa

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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Olgica Ceric, DVM, PhD

Veterinary Medical Officer
U.S. Food & Drug Administration
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Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
tel: 240-402-5419
fax: 301-210-4685

e-mail: olgica.ceric@fda.hhs.gov

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

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

Sent: Wednesday, October 19, 2016 1:43 PM

To: Ceric, Olgica

Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah

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I'll get someone to submit samples as soon as you provide info on labs, etc Thanks Lisa

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Dear Dr. Freeman.

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Please reply to all when responding, my responses might be delayed since I'll be on leave part day by the end of the week.

Thank you,

Olgica Ceric, DVM, PhD

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Sent: Tuesday, October 18, 2016 7:28 AM

To: Ceric, Olgica

Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Olgica

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Thanks

Lisa

From: Ceric, Olgica [mailto:Olgica.Ceric@fda.hhs.gov]

Sent: Monday, October 17, 2016 1:03 PM

To: Freeman, Lisa

Cc: Nemser, Sarah; Jones, Jennifer L

Subject: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Good morning Dr. Freeman,

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- a copy of full medical records for the dog
- blood culture for Listeria
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FDA will pay for the testing.

We have a network of veterinary diagnostic laboratories and could send samples to one of them, unless your lab has the capabilities?

Please email (preferred) or fax (301) 210-4685 us the **medical records**. Please send the **full medical history**-not just for this illness event.

Attached are a copy of our network procedures. They describe how veterinarians help with our case investigations. I also attached an owner friendly version. Sincerely,

Olgica Ceric, DVM, PhD

Veterinary Medical Officer
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fax: 301-210-4685 e-mail: <u>olgica.ceric@fda.hhs.qov</u>

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:

Freeman, Lisa

Sent:

7/15/2019 11:05:21 AM

Subject:

RE: FDA Update Links-Live 6/27/2019

Hi Lisa.

Yes, I absolutely have time. I'll gather my group here and send a few calendar appointments.

Thank you,

Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>

Sent: Friday, July 05, 2019 4:02 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> **Subject:** RE: FDA Update Links-Live 6/27/2019

Hi Jen

It would probably make the most sense to schedule a time to chat with Darcy and me.

Do you have some time in the next couple weeks?

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Board Certified Veterinary NutritionistTM

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: Friday, July 05, 2019 6:50 AM

To: Freeman, Lisa < <u>Lisa.Freeman@tufts.edu</u>> **Cc:** Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>

Subject: RE: FDA DCM Update Links-Live 6/27/2019

Hi Lisa,

No, I did not hear about any preliminary data from Bill. I'd love to read anything you're willing to share.

Thanks again,

Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Freeman, Lisa < Lisa.Freeman@tufts.edu>

Sent: Thursday, June 27, 2019 11:20 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>> **Cc:** Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>

Subject: Re: FDA DCM Update Links-Live 6/27/2019

Hi Jen. I heard rumors of something coming so thanks for letting me know. Did you hear from Bill B 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
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Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
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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: Freeman, Lisa <Lisa.Freeman@tufts.edu>

To: Jones, Jennifer L Sent: 7/5/2019 8:02:25 PM

Subject: RE: FDA Update Links-Live 6/27/2019

Hi Jen

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Do you have some time in the next couple weeks?

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary NutritionistTM
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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>

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Subject: RE: FDA DCM Update Links-Live 6/27/2019

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Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



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Thank you and take care, Jen

Jennifer L. A. Jones, DVM

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<image005.png> <image006.png>

From:

Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

B6

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: Sent: Reimschuessel, Renate

9/2/2016 3:44:54 PM

Subject:

RE: final report for review-800.180

Attachments:

800.180-FinalReport-Reed.pdf.html

Please submit for signature J

Jennifer Jones, DVM Veterinary Medical Officer

From: Reimschuessel, Renate

Sent: Wednesday, August 31, 2016 1:37 PM

To: Jones, Jennifer L

Subject: RE: final report for review-800.18(B6

Minimal edits J

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: Thursday, August 25, 2016 7:53 AM

To: Reimschuessel, Renate

Subject: final report for review-800.180

F:\6-CASES\1-Working on report\800.180-EON-266814

B6

taurine\6-REPORT

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: CC: Freeman, Lisa

Sent:

Jones, Jennifer L

8/6/2018 10:48:20 PM

Subject:

Re: Follow up call?

That would work for me as well. Thank you! Darcy

On Mon, Aug 6, 2018 at 11:00 AM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

That works for me

Thanks

LIsa

----Original Message----

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

Sent: Monday, August 6, 2018 10:47 AM

To: Darcy Adin < <u>dbadin@ncsu.edu</u>>

Cc: Freeman, Lisa < lisa.freeman@tufts.edu>

Subject: RE: Follow up call?

Good morning Darcy and Lisa,

Would you be available Wed at 4 pm?

Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

----Original Message----

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

Sent: Friday, August 03, 2018 11:29 PM

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

Cc: Lisa Freeman < lisa.freeman@tufts.edu>

Subject: Follow up call?

Hi Dr. Jones,

Dr. Freeman and I are wondering if your group would be willing to have another conference call as a follow-up to discuss the nutritionally based DCM cases? As you know, since the release of the FDA statement, there has been much discussion among the public and the veterinary community, and we thought it could be useful to reconvene.

Thank you for your thoughts!

Darcy

--

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

Sent:

8/6/2018 3:00:21 PM

Subject:

RE: Follow up call?

That works for me Thanks LIsa

----Original Message-----

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

Sent: Monday, August 6, 2018 10:47 AM To: Darcy Adin dbadin@ncsu.edu>

Cc: Freeman, Lisa < lisa.freeman@tufts.edu>

Subject: RE: Follow up call?

Good morning Darcy and Lisa, Would you be available Wed at 4 pm? Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

----Original Message-----

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

Cc: Lisa Freeman < lisa.freeman@tufts.edu>

Subject: Follow up call?

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Thank you for your thoughts! Darcy

From:

Darcy Adin <dbadin@ncsu.edu>

To:

Freeman, Lisa

CC:

Jones, Jennifer L

Sent: Subject: 8/6/2018 11:33:09 PM Re: Follow up call?

Hi Jennifer

Would it be ok to invite the others who were previously involved in our call? If so, I'll ask them if they are available at that time.

Thank you!

Darcy

On Aug 6, 2018, at 6:48 PM, Darcy Adin dbadin@ncsu.edu wrote:

That would work for me as well. Thank you!

Darcy

On Mon, Aug 6, 2018 at 11:00 AM, Freeman, Lisa < <u>Lisa.Freeman@tufts.edu</u>> wrote:

That works for me

Thanks

LIsa

----Original Message-----

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

Sent: Monday, August 6, 2018 10:47 AM

To: Darcy Adin < dbadin@ncsu.edu >

Cc: Freeman, Lisa < lisa.freeman@tufts.edu>

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Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421

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Sent: Friday, August 03, 2018 11:29 PM

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

Cc: Lisa Freeman < lisa.freeman@tufts.edu>

Subject: Follow up call?

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Darcy B. Adin, DVM, DACVIM (Cardiology) Clinical Assistant Professor of Cardiology North Carolina State University NC State Veterinary Hospital 1060 William Moore Drive Raleigh, NC 27607 919-513-6032 From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-

ANNE.NORRIS>

To:

Jones, Jennifer L; Rotstein, David; Reimschuessel, Renate; Ceric, Olgica

CC: Sent: DeLancey, Siobhan 4/13/2018 1:28:28 PM

Subject:

RE: FYI-FW: Call to discuss DCM cases

Thanks, Jen!

From: Jones, Jennifer L

Sent: Friday, April 13, 2018 9:06 AM

To: Rotstein, David < David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate

<Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

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

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' <<u>dbadin@ncsu.edu</u>> 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: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-

ANNE.NORRIS>

To:

Carey, Lauren; Jones, Jennifer L; Burkholder, William; Stamper, Carmela; Rotstein, David;

Queen, Jackie L; Atkinson, Krisztina Z; Palmer, Lee Anne

CC:

Glover, Mark; Conway, Charlotte; DeLancey, Siobhan

Sent:

6/8/2018 5:40:51 PM

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 < Lee Anne.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.

B5

B5

From: Jones, Jennifer L.

Sent: Thursday, June 07, 2018 2:09 PM

To: Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Stamper, Carmela < <u>Carmela.Stamper@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L < <u>Jackie.Queen@fda.hhs.gov</u>>; Atkinson, Krisztina Z < <u>Krisztina.Atkinson@fda.hhs.gov</u>>; Palmer, Lee Anne < Lee Anne.Palmer@fda.hhs.gov>

 $\textbf{Cc:} \ \ Norris, \ Anne < \underline{Anne.Norris@fda.hhs.gov} >; \ \ Glover, \ \ Mark < \underline{Mark.Glover@fda.hhs.gov} >; \ \ Conway, \ \ Charlotte$

<<u>Charlotte.Conway@fda.hhs.gov</u>> **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

Stamper, Carmela < $\underline{Carmela.Stamper@fda.hhs.gov}$ >; Rotstein, David < $\underline{David.Rotstein@fda.hhs.gov}$ >; Queen, Jackie L < $\underline{Jackie.Queen@fda.hhs.gov}$ >; Atkinson, Krisztina Z < $\underline{Krisztina.Atkinson@fda.hhs.gov}$ >; Palmer, Lee Anne < $\underline{LeeAnne.Palmer@fda.hhs.gov}$ >

Cc: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Glover, Mark <<u>Mark.Glover@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>

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 < Lee Anne.Palmer@fda.hhs.gov >

Cc: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Glover, Mark <<u>Mark.Glover@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>

Subject: RE: Grain-Free Diet Effects

nterestina

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

<<u>Carmela.Stamper@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L <<u>Jackie.Queen@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Atkinson, Krisztina Z

< Krisztina. Atkinson@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

Cc: Norris, Anne < Anne. Norris@fda.hhs.gov >; Glover, Mark < Mark. Glover@fda.hhs.gov >; Conway, Charlotte

<<u>Charlotte.Conway@fda.hhs.gov</u>> **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.

On a side note, the speaker has a paper coming out on pet foods. They tested various pet foods for various metals like lead and arsenic. It appears all levels found were very, very low and not of concern for chronic health, etc.

From: Carey, Lauren

Sent: Thursday, June 07, 2018 12:42 PM

To: Burkholder, William < William. Burkholder@fda.hhs.gov>; Stamper, Carmela

<<u>Carmela.Stamper@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L

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< Krisztina. Atkinson@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne. 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

Thanks! Piggy backing off this with some more thoughts on grain-free diets. Someone at DCAVM did ask about the discussion around grain free foods and taurine/cardiomyopathy. (They worded it as a low taurine issue in

| grain free foods.) |
|--|
| B6 mentioned the 2006 lamb and brown rice issue and the high ash in the product as an absorption issue (?) although nothing could be recreated in the lab. B5 |
| B5 |
| On the recent issue, he suspects the legumes are having the same reaction as the brown rice meal in the lamb and brown rice products. He also mentioned a possible fermentation issue. The cooking of the legumes essentially starts a fermentation reaction and this results in something (his exact word there "something") overgrowing in the GIT. His recommendation is that these diets need supplementation with methionine and/or taurine. There was discussion about the fiber and non-soluble vs. soluble fiber amounts and how different it is |
| for the grain diet fiber sources and the grain-free diet fiber sources. B5 |
| B5 |
| He's seeing this all related to recent trends: anthropomorphizing of pet foods, plus corn and grain became expensive and it was cheaper to add potatoes and stamp it "grain-free." It's sort of snowballed downhill from there. He sees this as a concern for these pet food companies that don't have a nutritionist on board and aren't looking at supplementing or thinking about fiber. |
| 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: too much Maillard reaction due to high starch content of the diets. He also said that if any of the implicated diets contain potato to add glycoalkaloid analysis of those foods. Passing along because I said I would." |
| Some things to think about. |
| Bill Burkholder |

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(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 5:54:55 PM

Subject:

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Subject: RE: Grain-Free Diet Effects

Interesting.

B5

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Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





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Cc: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Glover, Mark <<u>Mark.Glover@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>

Subject: Grain-Free Diet Effects

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Bill Burkholder

From:

Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To:

Carey, Lauren; 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 6:08:40 PM

Subject:

RE: Grain-Free Diet Effects

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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 < Lee Anne.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

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Cc: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Glover, Mark <<u>Mark.Glover@fda.hhs.gov</u>>; Conway, Charlotte

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Interesting

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Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





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<<u>Jackie.Queen@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Atkinson, Krisztina Z

< Krisztina. Atkinson@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

Cc: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Glover, Mark <<u>Mark.Glover@fda.hhs.gov</u>>; 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.

On a side note, the speaker has a paper coming out on pet foods. They tested various pet foods for various metals like lead and arsenic. It appears all levels found were very, very low and not of concern for chronic health, etc.

From: Carey, Lauren

Sent: Thursday, June 07, 2018 12:42 PM

To: Burkholder, William < William.Burkholder@fda.hhs.gov >; Stamper, Carmela

<<u>Carmela.Stamper@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L <<u>Jackie.Queen@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Atkinson, Krisztina Z

< Krisztina. Atkinson@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >

<<u>Charlotte.Conway@fda.hhs.gov</u>> **Subject**: RE: Grain-Free Diet Effects

Thanks! Piggy backing off this with some more thoughts on grain-free diets. Someone at DCAVM did ask about the discussion around grain free foods and taurine/cardiomyopathy. (They worded it as a low taurine issue in grain free foods.)

| B6 mentioned the 2006 lamb and brown rice issue and the high ash | n in the product as an absorption |
|---|---|
| issue (?) although nothing could be recreated in the lab | B5 |
| B5 | |
| On the recent issue, he suspects the legumes are having the same reaction a and brown rice products. He also mentioned a possible fermentation issue. The essentially starts a fermentation reaction and this results in something (his exa overgrowing in the GIT. His recommendation is that these diets need supplem taurine. There was discussion about the fiber and non-soluble vs. soluble fiber for the grain diet fiber sources and the grain-free diet fiber sources. | ne cooking of the legumes act word there "something") entation with methionine and/or |
| B5 | |

He's seeing this all related to recent trends: anthropomorphizing of pet foods, plus corn and grain became expensive and it was cheaper to add potatoes and stamp it "grain-free." It's sort of snowballed downhill from there. He sees this as a concern for these pet food companies that don't have a nutritionist on board and aren't looking at supplementing or thinking about fiber.

From: Burkholder, William

Sent: Thursday, June 07, 2018 10:49 AM

To: Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Stamper, Carmela <<u>Carmela.Stamper@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L <<u>Jackie.Queen@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Atkinson, Krisztina Z <<u>Krisztina.Atkinson@fda.hhs.gov</u>>; Palmer, Lee

Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Glover, Mark <<u>Mark.Glover@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>

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: too much Maillard reaction due to high starch content of the diets. He also said that if any of the implicated diets contain potato to add glycoalkaloid analysis of those foods. Passing along because I said I would."

Some things to think about.

Bill Burkholder

From:

Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To:

Carey, Lauren; 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 5:04:04 PM

Subject:

RE: Grain-Free Diet Effects

Interesting

B5

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

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<Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z

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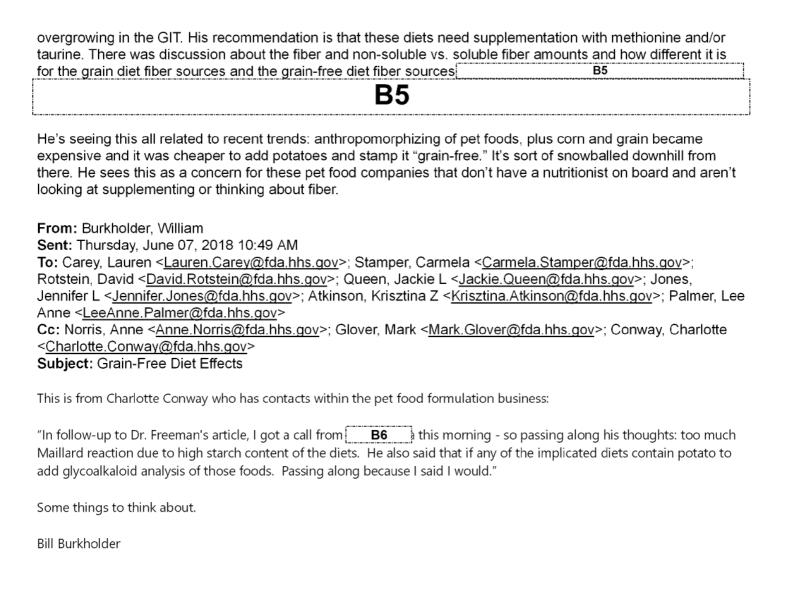
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B5

B5

On the recent issue, he suspects the legumes are having the same reaction as the brown rice meal in the lamb and brown rice products. He also mentioned a possible fermentation issue. The cooking of the legumes essentially starts a fermentation reaction and this results in something (his exact word there "something")



| From: To: CC: Sent: Subject: Attachments: | Jones, Jennifer L Rotstein, David; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L Ceric, Olgica 7/13/2017 6:44:24 PM RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519 EON-323515-19 B6 Case summatv-7.13.2017.doc.html B6 PDF.html; B6 PDF.html |
|---|--|
| | B5 |
| rDVM, treated w/ and recheck, hos feeding, dog regu B6 euthanized PE B6 P 160 bp synchronous jug | plaint B6 dyspnea, cough of 3 week duration-wheezing type more frequent at night a formula in the spitalized and treated for pneumonia, regurgitated at B6 inappetance, vomiting B8 dyspneic spitalized and treated for pneumonia, regurgitated at B6 treated as outpatient, B6 as syring surgitated and had marked dyspnea at ER at refer to NCSU at B6 pout on mechanical ventilator at the spitalized and place in the spitalized a |
| Labwork: | B6 |
| B6 seve wors +/- pneum post | ern for aspiration pneumonia diomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudodorsally, hepatomegaly, dec abdominal serosal contrast ere generalized cardiomegaly with biventricular heart failure, improved vs rDVM rads sening cardiogenic pulmonary edema, cannot exclude lung induced injury nonia ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar oved CHF with possible concern for bronchopneumonia, suspected hiatal hernia kedly progressive alveolar pattern with significantly worse cardiogenic edema |

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 В6 В6 episodes of collapse, first occurred mid February, fall 6 seconds without losing Presented consciousness à immediately return to normal à2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February; à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's 6/22 PE: P 130 bpm, R pant, mild increased breath sounds in all lung fields murmur Labs: **B6** Rads: left sided congestive heart failure **B6 B6** moderate left sided cardiomegaly without heart failure, moderate hepatomegaly Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM 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,

so I don't think that could be ruled out.

I do like the exploration of other causes.

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)





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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, yet talked to B4 who said there was B4 in this food, but that doesn't rule out treats.

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

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

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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; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L CC: Ceric, Olgica Sent: 7/13/2017 6:44:24 PM Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519 B6 -case summary-7.13.2017.doc.html; B6 Autopsy.PDF.html; Attachments: PDF.html; B6 B6 June Visit.PDF.html; ве PDF.html Medical Record Review: dyspnea, cough of 3 week duration-wheezing type more frequent at night à Presenting complaint rDVM, treated w for kennel cough à **B6** nappetance, vomiting à **B6** dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à B6 treated as outpatient, B6 as syring feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU & **B6** ut on mechanical ventilator à **B6** euthanized **B6** raus B6 concern for aspiration pneumonia cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudodorsally, 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 eumonia bost ultrafiltration, improved cardiogenic edema, hypovolemia, residual interstitial to patchy alveolar improved CHF with possible concern for bronchopneumonia, suspected hiatal hernia markedly progressive alveolar pattern with significantly worse cardiogenic edema 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

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| B5 |
| Jennifer Jones, DVM Veterinary Medical Officer U.S. FOOD & DRUG ADMINISTRATION |
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| B5 |
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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)





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



| From: | Jones, Jennifer L | | |
|---|--|--|--|
| (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8> | | | |
| Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Laure | | | |
| CC: | Ceric, Olgica | | |
| Sent: | 7/27/2017 11:24:38 AM | | |
| Subject: Attachments: | RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519 Ismahil et al-Oral Acrolein DCM-rats-2011.pdf.html; Re Pet food concern (800.218).html | | |
| Attaciments. | ishlanii et al-oral Aciolein Bowl-rats-2011.par.html, rec'i et lood concent (000.210).html | | |
| We received the foo | od and plan to test fc B5 The vet also mentioned two items of interest: | | |
| brings us to | ed 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. The 4 DCM dogs recently eating this food. | | |
| | can consider taurine and other types of testing? | | |
| | ded me an article about B5 n't believe our labs or Covance can test for this. Eurofins can test for this. | | |
| a. I dor | 1 t believe our labs or Covance can test for this. Eurofins can test for this. | | |
| Thoughts from the g | group? | | |
| Jennifer Jones, DVM | | | |
| Veterinary Medical Off | ficer | | |
| | | | |
| ADMINISTR | DD & DRUG | | |
| Cc: Ceric, Olgica | | | |
| Ok, thanks, Dave. I'l | Il check B5 | | |
| Jennifer Jones, DVM | | | |
| √eterinary Medical Off | ficer | | |
| | | | |
| ADMINISTR | DD & DRUG | | |
| From: Rotstein, David | d | | |
| Sent: Thursday, July | | | |
| | 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 | | |
| think testing is wo | orth 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)

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| 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 < 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 | | |
|--|--|--|
| B5 | | |
| B5 B5 | | |
| Medical Record Review: B6 | | |
| B 6 | | |

B6

Rads

oncern for aspiration pneumonia

cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudodorsally, 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

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Thoughts: B5
B5

| Veterinary Medical Officer | 1 1 ₂ 150.2 |
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| [con2] | |
| | an and an analysis of the second seco |
| From: Rotstein, David Sent: Tuesday, July 11, 201 | 7 12:44 PM |
| To: Jones, Jennifer L; Reims | schuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L |
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| David Rotstein, DVM, M CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place, RM 240-402-5613 (Office) (N 240-506-6763 (BB) | 120 |
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| Cc: Ceric, Olgica | Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L |
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| | B5 |
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Jennifer Jones, DVM Veterinary Medical Officer

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Sent: Tuesday, July 11, 2017 11:51 AM

To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

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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



Rads

oncern for aspiration pneumonia

cardiomegaly, severe diffuse mixed interstitial to alveolar pattern most severe caudodorsally, 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

Echd 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

| From: | B4 < B4 |
|--|--|
| To: | Darcy Adin |
| CC: | Joshua A Stern; B6 Fries, Ryan C; Freeman, Lisa; Jones, Jennifer L |
| Sent: | 8/7/2018 12:29:58 PM |
| Subject: | Re: hold-FDA call w/ NCSU & Tufts re: DCM |
| | |
| Hi Darcy and other | s, |
| | B6 |
| В6 | |
| On Tue, Aug 7, 20 Hi Josh B6 Ry | 18 at 7:08 AM, Darcy Adin < <u>dbadin@ncsu.edu</u> > wrote: yan and B6 |
| we would love to h | otice but if any of you are available to conference with Dr. Jones and her group at the FDA, ave you join us tomorrow (wednesday) at 4pm EST to discuss where we are with the FDA statement release. |
| Thanks! Darcy and Lisa | |
| Date: Mon, Aug 6, Subject: hold-FDA To: "Norris, Anne" "Rotstein, David" < "Carey, Lauren" < <u>I</u> gov>, "Ceric, Olgio | ifer L < <u>Jennifer.Jones@fda.hhs.gov</u> > |
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| +1-877-465-7975 US 7 | |
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--

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

--

B6 DVM, DACVIM (Cardiology)

B6

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-

ANNE.NORRIS>

To:

Edwards, David; Hartogensis, Martine; Murphy, Jeanette; Conway, Charlotte; Jones, Jennifer L;

Burkholder, William; Rotstein, David; Carey, Lauren

Sent:

2/7/2019 8:19:54 PM

Subject:

RE: INPUT NEEDED: DCM stakeholder outreach on Monday

Great. Thank you!

From: Edwards, David

Sent: Thursday, February 7, 2019 3:19 PM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein,

David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: RE: INPUT NEEDED: DCM stakeholder outreach on Monday

Some of the people have changed below, so I updated them. I am willing to contact AAFCO as well.

Dave

From: Norris, Anne

Sent: Thursday, February 07, 2019 3:11 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Murphy, Jeanette

<<u>Jenny.Murphy@fda.hhs.gov</u>>; Edwards, David <<u>David.Edwards@fda.hhs.gov</u>>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren

<Lauren.Carey@fda.hhs.gov>

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Could you please take a look at the stakeholder outreach list below and make adjustments/suggestions /additions as you see fit? I volunteered people in a few spots for stakeholder outreach, but there are still some gaps to fill in.

| Org | Contact | CVM POC |
|-------------------------|----------------------------|---------------------|
| PFI | Peter Tabor | Jenny Murphy |
| | 202-791- B6 | |
| | peter@petfoodinstitute.org | |
| AAFCO | Bob Geiger, Sue Hays | Dave Edwards |
| | B6 exec@aafco.org | |
| AFIA | Leah Wilkinson | Dave Edwards |
| | lwilkinson@afia.org | |
| American Pulse | Tim McGreevy | Martine Hartogensis |
| Association / USA Dry | B6 | |
| Pea and Lentil Council | | |
| National Potato Council | John Keeling | Martine Hartogensis |
| | B6 | |
| AVMA | | Martine Hartogensis |

| CVCA | Steve Rosenthal? steven.rosenthal@cvcavets.com | Jennifer Jones |
|------|--|----------------|
| | Dr. Lisa Freeman | Jennifer Jones |
| | Dr. Josh Stern | Jennifer Jones |
| | Dr. Darcy Adin | Jennifer Jones |
| | Dr. Greg Aldrich? | |

Thanks! Anne

Anne Norris

Strategic Initiatives

Office of the Director Center for Veterinary Medicine U.S. Food & Drug Administration

O: 240-402-0132 M: 240-704-0579 Anne Norris@fda.hhs.gov



From: Edwards, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF3E3D2AE5AB4C7DABEC7ECEA8A82404-

DAVID.EDWAR>

To:

Norris, Anne; Hartogensis, Martine; Murphy, Jeanette; Conway, Charlotte; Jones, Jennifer L;

Burkholder, William; Rotstein, David; Carey, Lauren

Sent:

2/7/2019 8:19:26 PM

Subject:

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Some of the people have changed below, so I updated them. I am willing to contact AAFCO as well. Dave

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Sent: Thursday, February 07, 2019 3:11 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Murphy, Jeanette

<Jenny.Murphy@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren

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| | B6 exec@aafco.org | |
| AFIA | Leah Wilkinson | Dave Edwards |
| | B6 | |
| American Pulse | Tim McGreevy | Martine Hartogensis |
| Association / USA Dry | B6 | |
| Pea and Lentil Council | | |
| National Potato Council | John Keeling | Martine Hartogensis |
| | B6 | |
| AVMA | <u> </u> | Martine Hartogensis |
| CVCA | Steve Rosenthal? | Jennifer Jones |
| | steven.rosenthal@cvcavets.com | |
| | Dr. Lisa Freeman | Jennifer Jones |
| | Dr. Josh Stern | Jennifer Jones |
| | Dr. Darcy Adin | Jennifer Jones |
| | Dr. Greg Aldrich? | |

Thanks! Anne

Anne Norris

Strategic Initiatives

Office of the Director Center for Veterinary Medicine U.S. Food & Drug Administration

O: 240-402-0132 M: 240-704-0579 Anne.Norris@fda.hhs.gov



From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-

ANNE.NORRIS>

To: Jones, Jennifer L Sent: 2/8/2019 3:11:33 PM

Subject: RE: INPUT NEEDED: DCM stakeholder outreach on Monday

Perfect. Thanks!

From: Jones, Jennifer L

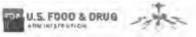
Sent: Friday, February 8, 2019 10:09 AM To: Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: INPUT NEEDED: DCM stakeholder outreach on Monday

Steve is the primary POC for the collaboration and signed our Confidentiality agreement.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Norris, Anne

Sent: Friday, February 08, 2019 10:07 AM

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

Subject: RE: INPUT NEEDED: DCM stakeholder outreach on Monday

Is Steve the right guy to contact at CVCA? I didn't have another name to use, but if you have a point of contact you're more comfortable with or that makes better sense, glad to go with that.

From: Jones, Jennifer L

Sent: Friday, February 8, 2019 10:02 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Charlotte Charlotte Charlotte.conway@fda.hhs.gov; Burkholder, William William.Burkholder@fda.hhs.gov; Rotstein,

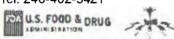
David <<u>David.Rotstein@fda.hhs.gov>;</u> Carey, Lauren <<u>Lauren.</u>Carey@fda.hhs.gov>

Subject: RE: INPUT NEEDED: DCM stakeholder outreach on Monday

Updated contact info for mine.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Friday, February 08, 2019 9:58 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Murphy, Jeanette Jeanette <a href="mailto:specification-number-L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: RE: INPUT NEEDED: DCM stakeholder outreach on Monday

Updated AVMA 🚳

From: Norris, Anne

Sent: Thursday, February 07, 2019 3:20 PM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>; Murphy, Jeanette <<u>Jenny.Murphy@fda.hhs.gov</u>>; Conway, Charlotte

<<u>Charlotte.Conway@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Burkholder, William

< <u>William.Burkholder@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Carey, Lauren

<Lauren.Carey@fda.hhs.gov>

Subject: RE: INPUT NEEDED: DCM stakeholder outreach on Monday

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Sent: Thursday, February 7, 2019 3:19 PM

To: Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Murphy, Jeanette <<u>Jenny.Murphy@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Rotstein,

David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

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Sent: Thursday, February 07, 2019 3:11 PM

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<Jenny.Murphy@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren

<Lauren.Carey@fda.hhs.gov>

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| | 202-791-9432 | |
| | B6 | |
| AAFCO | Bob Geiger, Sue Hays | Dave Edwards |
| | B6 , exec@aafco.org | |
| AFIA | Leah Wilkinson | Dave Edwards |
| | В6 | |
| American Pulse | Tim McGreevy | Martine Hartogensis |
| Association / USA Dry | tmcgreevy@usapulses.org | |
| Pea and Lentil Council | | |

| National Potato Council | John Keeling B6 B6 | Martine Hartogensis |
|-------------------------|--|---------------------|
| AVMA | Ashley S. Morgan, DVM, CAE Director Division of State Advocacy American Veterinary Medical Association o: B6 c B6 www.avma.org | Martine Hartogensis |
| CVCA | Steve Rosenthal steven.rosenthal@cvcavets.com | Jennifer Jones |
| | Dr. Lisa Freeman Lisa Freeman@tufts.edu | Jennifer Jones |
| | Dr. Josh Stern, Dr. Andrea Fascetti (UC Davis Aminoaciduria Lab) istern@ucdavis.edu aifascetti@ucdavis.edu | Jennifer Jones |
| | Dr. Darcy Adin adind@ufl.edu | Jennifer Jones |
| | Dr. Greg Aldrich? | |

Thanks! Anne

Anne Norris

Strategic Initiatives

Office of the Director Center for Veterinary Medicine U.S. Food & Drug Administration O: 240-402-0132 M: 240-704-0579 Anne.Norris@fda.hhs.gov



From: Conway, Charlotte </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93384CEEA9DF43B5B8DBC7D1FB58FE67-

CCONWAY>

To:

DeLancey, Siobhan; Rotstein, David; Norris, Anne; Hartogensis, Martine; Jones, Jennifer L;

Burkholder, William

Sent:

7/3/2018 10:24:38 PM

Subject:

RE: Interesting article on legumes in pet foods

Sorry, me neither. I think the Aldrich articles are a separate subscription.

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

Date: July 3, 2018 at 6:22:55 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>, Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: RE: Interesting article on legumes in pet foods

If Bill or Charlotte don't have a subscription, we might be able to get it through the library.

Siobhan DeLancey, RVT, MPH

O: 240-402-9973 M: 202-510-4177

From: Rotstein, David

Sent: Tuesday, July 03, 2018 6:21 PM

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>

Subject: Re: Interesting article on legumes in pet foods

Sorry. I don't, but would like to read it!

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

Date: July 3, 2018 at 6:18:32 PM EDT

To: Norris, Anne < Anne. Norris@fda.hhs.gov>, Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>, Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>, Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>, Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>, Burkholder,

William < William. Burkholder@fda.hhs.gov>

Subject: Interesting article on legumes in pet foods

Just thought I would flag this article in Pet Food Industry/Ingredient Issues Library—quite timely! Unfortunately, it's behind a pay wall. Does anyone have a subscription?

https://www.petfoodindustry.com/articles/7277-legume-seed-oligosaccharides-how-much-is-just-right-in-dog-and-cat-diets?v=preview&utm_source=KnowledgeMarketing&utm_medium=email&utm_content=Pet%20eNews&utm_campaign=18_07_03_PetENews&eid=419410523&bid=2161214



From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-

SARAH.PELOQ>

To: Sent:

Jones, Jennifer L 6/14/2019 12:41:16 PM

Subject:

RE: link to VL DCM update for June 2019

You're welcome!



Sarah Peloquin, DVM

Veterinary Medical Officer

tel: 240-402-1218

From: Jones, Jennifer L

Sent: Friday, June 14, 2019 8:41 AM

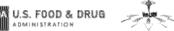
To: Peloguin, Sarah <Sarah.Peloguin@fda.hhs.gov> Subject: RE: link to VL DCM update for June 2019

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

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|------|---------|----|-------|--------|-------|--------|--------|---|
| AHU. | auaii i | | SUITE | 111115 | vvIII | \Box | Caucin | |

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

F:\6-CASES\800.267-EON-Multi-DCM-Cluster\1-Mtgs-Strategy\2-CVM Communications\1-CVM Web Updates\03-June 2019

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



From:

Freeman, Lisa <Lisa.Freeman@tufts.edu>

To:

Jones, Jennifer L

Sent:

7/16/2019 7:06:27 PM

Subject:

RE: Meeting to discuss ACVIM findings

Hi Jen

I could make any of those work

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Board Certified Veterinary NutritionistTM

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 16, 2019 1:23 PM

To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; ADIN,DARCY BRITTAIN <adind@ufl.edu>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne

 $<\!\!Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <\!\!Siobhan.Delancey@fda.hhs.gov>; Rotstein, David + (Siobhan.Delancey) + (Siobhan.Dela$

<David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>

Subject: Meeting to discuss ACVIM findings

Good afternoon everyone,

Lisa mentioned sharing some updates on the preliminary DCM findings from work with Darcy. The work was previously presented at ACVIM. Please reply by voting on the best day and time to meet to discuss their update. If the voting does not work, here are the dates/times.

Tues July 30 at 2pm Mon Aug 5 at 11am Mon Aug 12 at 1pm

Looking forward to chatting with you.

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



From:

Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-

LAUREN.CARE>

To:

Jones, Jennifer L 7/16/2019 5:26:16 PM

Sent: Subject:

RE: Meeting to discuss ACVIM findings

Hi Jen.

All days are good for me, but I'll put in a vote. Can we also invite Aurelie Pohl? She's a new teammate who will be helping me out with some pet food work, so we're going to try to get her caught up.

Thanks, Lauren

From: Jones, Jennifer L

Sent: Tuesday, July 16, 2019 1:23 PM

To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; ADIN,DARCY BRITTAIN <adind@ufl.edu>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne

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

<David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>

Subject: Meeting to discuss ACVIM findings

Good afternoon everyone,

Lisa mentioned sharing some updates on the preliminary DCM findings from work with Darcy. The work was previously presented at ACVIM. Please reply by voting on the best day and time to meet to discuss their update. If the voting does not work, here are the dates/times.

Tues July 30 at 2pm Mon Aug 5 at 11am Mon Aug 12 at 1pm

Looking forward to chatting with you.

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 a

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



From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

To: Sent:

Jones, Jennifer L 7/16/2019 5:24:44 PM

Subject:

RE: Meeting to discuss ACVIM findings

Hi Jen – any of those work! Thanks.

From: Jones, Jennifer L

Sent: Tuesday, July 16, 2019 1:23 PM

To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; ADIN,DARCY BRITTAIN <adind@ufl.edu>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne

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

<David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>

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



From:

Freeman, Lisa <Lisa.Freeman@tufts.edu>

To:

Jones, Jennifer L

Sent:

7/16/2019 7:06:27 PM

Subject:

RE: Meeting to discuss ACVIM findings

Hi Jen

I could make any of those work

Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN

Board Certified Veterinary NutritionistTM

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>

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To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; ADIN,DARCY BRITTAIN <adind@ufl.edu>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne

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

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



From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-

JENNIFER.JO>

To: Carey, Lauren

Sent: 7/17/2019 10:24:57 AM

Subject: RE: Meeting to discuss ACVIM findings

Absolutely!

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Carey, Lauren

Sent: Tuesday, July 16, 2019 1:26 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Meeting to discuss ACVIM findings

Hi Jen,

All days are good for me, but I'll put in a vote. Can we also invite Aurelie Pohl? She's a new teammate who will be helping me out with some pet food work, so we're going to try to get her caught up.

Thanks, Lauren

From: Jones, Jennifer L

Sent: Tuesday, July 16, 2019 1:23 PM

To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; ADIN,DARCY BRITTAIN <adind@ufl.edu>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne

>; DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov>; Rotstein, David

<<u>David.Rotstein@fda.hhs.gov</u>>; Peloquin, Sarah <<u>Sarah.Peloquin@fda.hhs.gov</u>>; Burkholder, William

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Take care.

new tel: 240-402-5421

Jen

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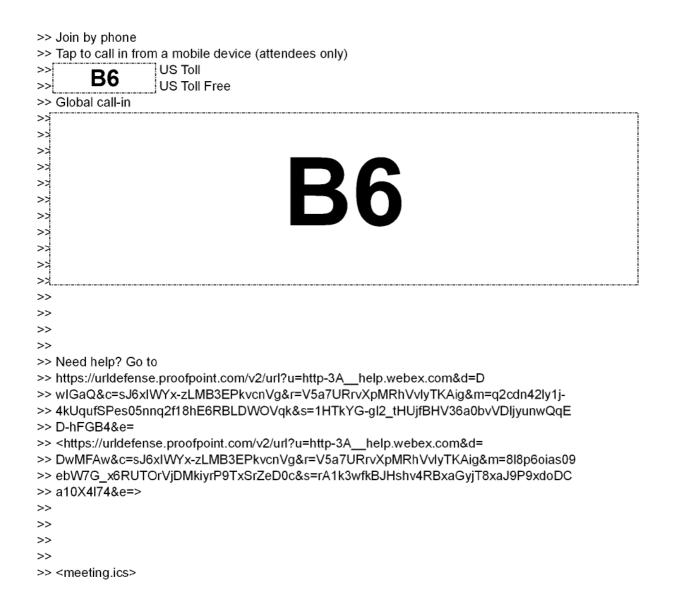
e-mail: jennifer.jones@fda.hhs.gov





```
From:
                        Freeman, Lisa <Lisa.Freeman@tufts.edu>
To:
                         Jones, Jennifer L
CC:
                        ADIN, DARCY BRITTAIN
Sent:
                        7/23/2019 12:25:23 PM
Subject:
                        Re: Meeting with Tufts and UFL-discuss ACVIM findings
Hi Jen.
Any of these work except 8/27 at 8 am
Thanks. Lisa
Sent from my iPhone
> On Jul 23, 2019, at 7:07 AM, Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov> wrote:
> Would any of these dates work well?
> 8/13 at either 8 am or 10 am
> 8/19 at 10 am
> 8/26 at 10 am or 11 am
> 8/27 at 8 am or 10 am
>
> Jennifer Jones, DVM
> Veterinary Medical Officer
> Tel: 240-402-5421
>
>
> ----Original Message-----
> From: ADIN, DARCY BRITTAIN < adind@ufl.edu>
> Sent: Thursday, July 18, 2019 11:00 AM
> To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Freeman, Lisa < Lisa.Freeman@tufts.edu>
> Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings
> Hi Jennifer,
> Monday and Tuesday mornings work best for me if there are any dates where that would work for you?
> Thanks!
> Darcy
> ----Original Message-----
> From: Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>
> Sent: Thursday, July 18, 2019 10:30 AM
> To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; ADIN,DARCY BRITTAIN <adind@ufl.edu>
> Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings
> Absolutely! Darcy, when are some good dates for you in August?
> Jennifer Jones, DVM
> Veterinary Medical Officer
> Tel: 240-402-5421
>
> ----Original Message-----
> From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
> Sent: Thursday, July 18, 2019 10:27 AM
> To: ADIN,DARCY BRITTAIN <adind@ufl.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
> Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings
```

| > Hi Jen |
|--|
| > I'd love to have Darcy there. Could we look a little farther out for a date when she is available? |
| > Thanks |
| > Lisa |
| > |
| > Lisa M. Freeman, DVM, PhD, DACVN > Board Certified Veterinary NutritionistTM Professor Cummings School of Veterinary Medicine Friedman School of Nutrition Science and Policy Tufts Clinical and Translational Science Institute Tufts University https://urldefense.proofpoint.com/v2/url?u=http-3Awww.petfoodology.org&d=DwlGaQ&c=sJ6xIWYx-zLMB3EPkvcnVg&r=V5a7URrvXpMRhVvlyTKAig&m=q2cdn42ly1j-4kUqufSPes05nnq2f18hE6RBLDWOVqk&s=uQ-QwXWfNT9U4KBuYqDEDHtfFvlnFDP3gFpILADaRfM&e= |
| > |
| > |
| > |
| >Original Message > From: ADIN,DARCY BRITTAIN <adind@ufl.edu> > Sent: Wednesday, July 17, 2019 9:18 PM > To: Jones, Jennifer L <jennifer.jones@fda.hhs.gov> > Cc: Freeman, Lisa <lisa.freeman@tufts.edu> > Subject: Re: Meeting with Tufts and UFL-discuss ACVIM findings ></lisa.freeman@tufts.edu></jennifer.jones@fda.hhs.gov></adind@ufl.edu> |
| > Hi Jen, |
| > Unfortunately I won't be able to make the call but hopefully Dr. Freeman will be able to? |
| > Take care |
| > Darcy |
| > |
| >> On Jul 17, 2019, at 10:23 AM, Jones, Jennifer L < Jennifer. Jones @fda.hhs.gov> wrote: |
| >> |
| >> Please forward if I missed anyone. This time seemed to work well for most folks. |
| >> |
| |
| >> Do not delete or change any of the following text |
| >> |
| >> |
| >> \Alban idla dina inin yawa \Alaban na adina basa |
| >> When it's time, join your Webex meeting here. |
| » |
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| >> Meeting number (access code): B6 >> |
| >> Meeting password: B6 |
| >> Wideting password: B6 ; |
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From: ADIN,DARCY BRITTAIN <adind@ufl.edu>

To: Jones, Jennifer L; Freeman, Lisa

Sent: 7/23/2019 11:26:12 AM

Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings

Hi Jen,

Any of those times will work for me!

Thanks so much,

Darcy

----Original Message-----

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

Sent: Tuesday, July 23, 2019 7:07 AM

To: ADIN, DARCY BRITTAIN <adind@ufl.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>

Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings

Would any of these dates work well?

8/13 at either 8 am or 10 am

8/19 at 10 am

8/26 at 10 am or 11 am

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Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

----Original Message-----

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Sent: Thursday, July 18, 2019 11:00 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Freeman, Lisa <Lisa.Freeman@tufts.edu>

Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings

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Thanks!

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Sent: Thursday, July 18, 2019 10:30 AM

To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; ADIN,DARCY BRITTAIN <adind@ufl.edu>

Subject: RE: Meeting with Tufts and UFL-discuss ACVIM findings

Absolutely! Darcy, when are some good dates for you in August?

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421

----Original Message-----

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>

Sent: Thursday, July 18, 2019 10:27 AM

To: ADIN,DARCY BRITTAIN <adind@ufl.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

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Hi Jen

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Thanks Lisa

Lisa M. Freeman, DVM, PhD, DACVN Board Certified Veterinary NutritionistTM Professor Cummings School of Veterinary Medicine Friedman School of Nutrition Science and Policy Tufts Clinical and Translational Science Institute Tufts University https://urldefense.proofpoint.com /v2/url?u=http-3A__www.petfoodology.org&d=DwIGaQ&c=sJ6xlWYx-zLMB3EPkvcnVg&r=V5a7URrvXpMRhVvlyTKAig& m=q2cdn42ly1j-4kUqufSPes05nnq2f18hE6RBLDWOVqk&s=uQ-QwXWfNT9U4KBuYqDEDHtfFvlnFDP3gFplLADaRfM&e= ----Original Message----From: ADIN, DARCY BRITTAIN < adind@ufl.edu> Sent: Wednesday, July 17, 2019 9:18 PM To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov> Cc: Freeman, Lisa <Lisa.Freeman@tufts.edu> Subject: Re: Meeting with Tufts and UFL-discuss ACVIM findings Hi Jen, Unfortunately I won't be able to make the call but hopefully Dr. Freeman will be able to? Darcy > On Jul 17, 2019, at 10:23 AM, Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov> wrote: > Please forward if I missed anyone. This time seemed to work well for most folks. > > > -- Do not delete or change any of the following text. --> > When it's time, join your Webex meeting here. > > > Meeting number (access code): > Meeting password: > > > **B6** > Join > Join by phone > Tap to call in from a mobile device (attendees only) Toll **B6** Toll Free Global call-in ×

В6

> Need help? Go to
> https://urldefense.proofpoint.com/v2/url?u=http-3A_help.webex.com&d=D
> wlGaQ&c=sJ6xlWYx-zLMB3EPkvcnVg&r=V5a7URrvXpMRhVviyTKAig&m=q2cdn42ly1j> 4kUqufSPes05nnq2f18hE6RBLDWOVqk&s=1HTkYG-gl2_tHUjfBHV36a0bvVDljyunwQqE
> D-hFGB4&e=
> <nttps://urldefense.proofpoint.com/v2/url?u=http-3A_help.webex.com&d=
> DwMFAw&c=sJ6xlWYx-zLMB3EPkvcnVg&r=V5a7URrvXpMRhVviyTKAig&m=8l8p6oias09
> ebW7G_x6RUTOrVjDMkiyrP9TxSrZeD0c&s=rA1k3wfkBJHshv4RBxaGyjT8xaJ9P9xdoDC
> a10X4l74&e=>
> <meeting.ics>

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To:

Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren; Peloquin, Sarah; Burkholder, William;

Freeman, Lisa; ADIN, DARCY BRITTAIN; Pohl, Aurelie; Norris, Anne; DeLancey, Siobhan

CC: Ceric, Olgica

Sent:

8/13/2019 12:42:31 PM

Subject:

RE: Meeting with Tufts and UFL-discuss ACVIM findings

Attachments:

Histopathologic Findings – Confirmed and Non-Confirmed DCM [Autosaved] [Autosaved].pptx

Please do not forward.

thanks

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











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----Original Appointment----

From: Jones, Jennifer L

Sent: Wednesday, July 17, 2019 10:19 AM

To: Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren; Rotstein, David; Peloquin, Sarah; Burkholder, William;

Freeman, Lisa; ADIN, DARCY BRITTAIN; Pohl, Aurelie; Norris, Anne; DeLancey, Siobhan

Cc: Ceric, Olgica

Subject: Meeting with Tufts and UFL-discuss ACVIM findings

When: Tuesday, August 13, 2019 8:00 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: virtual meeting

Please forward if I missed anyone.

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

When it's time, join your Webex meeting here.

Meeting number (access code): Meeting password:

<u>Join</u>

Join by phone

Tap to call in from a mobile device (attendees only)

- +1-210-795-0506 US Toll
- +1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

Need help? Go to http://help.webex.com

From:

Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: CC: Darcy Adin Ceric, Olgica

Sent:

8/22/2017 12:45:55 PM

Subject:

RE: Pet food concern (800.218)

Attachments:

800.218-Covance-Taurine-Carnitine.pdf.html

We evaluated the taurine/carnitine results based on the "Kangaroo" protein variety. The results are attached. In short, the taurine was 0.26% (on DMB calculated using label moisture max) and the carnitine was 0.0077% (on DMB calculated using label moisture max). There are no AAFCO minimums for taurine and carnitine. However, there is an AAFCO minimum for taurine only in cats: 0.1% for extruded foods.

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

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 B5 We'll wait for the taurine and carnitine, 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. B5 |
| can be done (e. B5 Thanks so much! |
| Darcy |
| |
| On Aug 22, 2017, at 7:54 AM, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> > 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 |
| <pre><image001.png> <image002.png></image002.png></image001.png></pre> |
| 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 fo 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></image003.png></image001.png> |
| -Imageou i.prigz - Imageou s.prigz |
| 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) |
| Subject. Re. Pet 1000 concern (600.216) |
| 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 |
| 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? |
| any information about the cases yet? |
| any information about the cases yet? Thanks! |
| any information about the cases yet? |
| any information about the cases yet? Thanks! |
| any information about the cases yet? Thanks! Darcy Adin |
| 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. |
| 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: |
| 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 |

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 < <u>Jennifer.Jones@fda.hhs.gov</u>> 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

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Sent: Tuesday, July 25, 2017 10:36 PM

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Subject: Re: Pet food concern (800.218)

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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.

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|----|--------------------------|--|---|
| ~1 | consistently). B5 | B5 | |

Collect open bag of California Naturals food to test for **B5**

- 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

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 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 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 **B6** Cc: Reimschuessel, Renate: **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 or I can be paged from **B6 B6** Thank you! Darcy

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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

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https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm1824@3.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

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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 11:37:31 AM

Subject:

RE: Pet food concern (800,218)

Attachments:

800.218-TAMU- **B5** neg.pdf.html

Good morning Dr. Adin,

We received results of the product testing for the standard testing 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 < <u>Jennifer.Jones@fda.hhs.gov</u>> 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 < <u>Jennifer.Jones@fda.hhs.gov</u>> 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.

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Thank you! Darcy

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To: Sent:

ве ; Darcy Adin 7/28/2017 1:18:56 PM

Subject:

RE: Pet food concern (800.218)

Excellent, will do. Thank you.

Jennifer Jones, DVM Veterinary Medical Officer





From:

B6

[mailto:

Sent: Thursday, July 27, 2017 11:07 AM

To: Darcy Adin; Jones, Jennifer L

Subject: Re: Pet food concern (800.218)

Hi Jennifer,

we figured out a way to get reimbursed for the shipping. Would you be able to call our hospital accountant and she can take a credit card over the phone. You can give her your client# of 103797. The total is \$25.98.

We really appreciate you working with us, and hopefully we can figure out what is going on with our patients and a possible connection to that food.

Thank you,

В6

RVT, VTS (Cardiology)

NCSU CVM. VTH

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| 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 (1) for 2023228 (1) for B6 I've also attached the visit summaries for B6 (2) and B6 (1) as well a 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 | or consistently) B5 |
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| | 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 < <u>Jennifer.Jones@fda.hhs.gov</u> > 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></image010.png></image001.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 < <u>Jennifer.Jones@fda.hhs.gov</u> > 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). 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></image004.png></image001.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.

 $\underline{https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm}$

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,

В6

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: | B6 |
|---|--|
| To: | Jones, Jennifer L |
| CC: | Guag, Jake; Andrea Fascetti; Jennifer Bones Larsen |
| Sent: | 10/3/2018 1:53:06 AM |
| Subject: | Re: Questions about Control Urine Samples |
| Attachments: | Normal_dog_20Nov17.xls |
| Hi Dr. Jones, | |
| | ne column from noise and we don't use it. I have fixed the problem by moving the umns forward. See attached corrected file. |
| Kind Regards, | |
| В6 | |
| | |
| Sent: Monday, Oc To: B6 Cc: Guag, Jake; A | nifer L <jennifer.jones@fda.hhs.gov> tober 1, 2018 7:54 AM Indrea Fascetti; Jennifer Bones Larsen as about Control Urine Samples</jennifer.jones@fda.hhs.gov> |
| Hi B6 | |
| , , | ng well. I imagine things are busy right now left I am preparing the reference ranges resentation, and I had a few questions about the data you sent. |
| | Contation, and mad a rew questions about the data you sent. |
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| | B5 |
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Thank you again. I'll be forwarding a copy of the powerpoint presentation for your feedback later this week.

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





DOCUMENT PRODUCED IN NATIVE

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To: Peloquin, Sarah; Guag, Jake; Jones, Jennifer L

Sent: 5/22/2019 3:46:27 PM

Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy

(DCM) 2018

Fantastic!!!

From: Peloquin, Sarah < Sarah. Peloquin@fda.hhs.gov>

Date: May 22, 2019 at 11:07:09 AM EDT

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

<Jennifer.Jones@fda.hhs.gov>

Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM)

2018

Found it—I was looking for the owner's last name. Thanks!

Sarah Peloquin, DVM

Veterinary Medical Officer

tel: 240-402-1218

From: Rotstein, David

Sent: Wednesday, May 22, 2019 10:58 AM

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

Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM)

2018

I thought that I had forwarded this one on already-but here you go

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: Guag, Jake Sent: Wednesday, May 22, 2019 10:54 AM To: Rotstein, David < David.Rotstein@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov > Cc: Peloquin, Sarah < Sarah.Peloquin@fda.hhs.gov > Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018 |
|---|
| Dave, Do you have a report for the B6 Jen is B6 |
| Jake |
| |
| From: B6 Sent: Wednesday, May 22, 2019 10:47 AM To: Guag, Jake < Jake.Guag@fda.hhs.gov > Subject: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018 |
| Good morning, |
| I recently submitted a pet food report via the FDA Safety Reporting Portal on a deceased patient named B6 B6 Was a 4yo CM Boxer with severe DCM who had been eating a grain-free dog food for the last two years. Dr. Lisa Freeman (PI for on-going DCM study here at Tufts) would like to submit collected samples (heart) to the FDA for further analysis. The sample was promptly placed in 10% NBF approximately 30 minutes post mortem on B6 Would it be possible to have boxes sent to us for sample submission? |
| Thank you, |
| B6 |

| From: | B6 < | B6 | <u> </u> | |
|---|---|--------------------|-------------------------------|-------------------------------|
| To: | Jones, Jennifer L | | · | |
| Sent: | 8/23/2019 3:29:15 PM | | | |
| Subject: | RE: Suspect grain free | canine DCM case- | ·800.267-cc-211 | |
| anything. | le to get any information for n | ne? The owner cor | ntinues to call us and is ver | y upset that we haven't heard |
| Thank you, B6 | | | | |
| | fer L <jennifer.jones@fda.hhs< td=""><td>s.gov></td><td></td><td></td></jennifer.jones@fda.hhs<> | s.gov> | | |
| To: B6 | ust 12, 2019 10:17 AM | | | |
| | ct grain free canine DCM case | e-800.267-cc-211 | | |
| Thank you, B6 I | t should have been read, and I | 'll double-check w | ith the pathologist. | |
| Jennifer Jones, DVM | | | | |
| Veterinary Medical O. Tel: 240-402-5421 | fficer | | | |
| | | | | |
| ADMINISTRATION | | | | |
| To: Jones, Jennifer | st 09, 2019 12:49 PM L <jennifer jones@fda.hhs.go<br="">ct grain free canine DCM case</jennifer> | | | |
| | g in to see when the histopath | | ient ill be available. | |
| | 1 | 1 31 | | |
| Thank you, B6 | | | | |
| | fer L < Jennifer Jones@fda.hhs | s.gov> | | |
| To: B6 | le 13, 2019 7:19 AM | } | | |
| L | ct grain free canine DCM case | e-800.267-cc-211 | | |
| Hi[B6], | 4 dh - historiadh als an ah anl dha | | 2 | |
| | t the histopathology should be if you need additional updates | | -3 Weeks. | |
| Jen | n you need additional apactes. | , . <i>)</i> | | |
| Jennifer Jones, DVM | | | | |
| Veterinary Medical O. Tel: 240-402-5421 | fficer | | | |
| 12. U.S. FOOD & DRUG | | | | |
| ADMINISTRATION | | | | |
| From: B6 | | <u> </u> | | |
| Sent: Friday, June (| 7, 2017 J.U7 FIVI | | | |

 $\textbf{To: Jones, Jennifer } L < \underline{Jennifer.Jones@fda.hhs.gov} >$

Subject: RE: Suspect grain free canine DCM case-800.267-cc-211

I apologize that I keep harassing you but are there any updates as far as when the histopath will be available? My client has called several times and if I can give him an ETA that would be very helpful.

Thank you, B6

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

Sent: Monday, May 06, 2019 4:05 AM

To: B6 В6 Subject: RE: Suspect grain free canine DCM case-800.267-cc-211

Good morning **B6**

The tissues are being prepped for histopathology. As soon as they are done, our pathologist will review them. I'll send the results as soon as possible.

Thank you,

Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: В6

Sent: Friday, May 03, 2019 5:40 PM

To: Jones, Jennifer L < Jennifer Jones afda.hhs.gov>

Subject: RE: Suspect grain free canine DCM case-800.267-cc-211

Hi Jen, I was just following up on the samples I submitted for **B6** several months ago to see if there are any results.

Thank you,

B6

From: Jones, Jennifer L < Jennifer Jones a fda hhs gov>

Sent: Wednesday, March 13, 2019 4:01 AM

Cc: Peloquin, Sarah < Sarah Peloquin afda.hhs.gov >

Subject: RE: Suspect grain free canine DCM case-800.267-cc-211

Good morning B6

Thank you for the email. We should be scheduling an appointment to prepare the next set of tissues for histopathology in the coming weeks. It'll then be a few more weeks after that to get the slides prepared and read by our pathologist.

I'll let you know as soon as I get a report.

Thank you again for helping with the investigation, Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



Sent: Tuesday, March 12, 2019 7:55 PM

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

Subject: RE: Suspect grain free canine DCM case-800.267-cc-211 Hi Jen, I was just curious if you had any idea about how long it takes to hear back after submitting samples. Thanks, B6 From: Jones, Jennifer L < Jennifer Jones @fda.hhs.gov> Sent: Thursday, January 31, 2019 6:31 AM To: B6 < Cc: Peloquin, Sarah < Sarah Peloquin a fda hhs.gov> Subject: RE: Suspect grain free canine DCM case-800,267-cc-211 Good morning B6 Thank you for submitting the report. We can send you 2 boxes to collect the fixed and frozen samples. You will reuse the boxes we send and package the samples per the instructions in the box. You'll affix the prepaid shipping label to the box and call UPS for a pick-up on Monday-Wednesday. Please send me the following information so I can prepare the boxes: Approximate size and weight of each set of samples (frozen and fixed) • Address for where to ship the boxes. Thank you kindly for your help, Jen Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 🗓 U.S. FOOD & DRUG B6 B6 Sent: Monday, January 07, 2019 2:59 PM **To:** Jones, Jennifer L < Jennifer Jones @fda.hhs.gov> Subject: RE: Suspect grain free canine DCM case I was just following up regarding the grain free DCM case I had contacted you about prior to the holidays with ICSR number is 2060525 and the report ID is 250430. I was hoping to find out about receiving shipping materials for our samples. Thank you and hope you had a great holiday, **B6** From: В6 Sent: Saturday, December 22, 2018 2:21 PM To: Jones, Jennifer L < Jennifer Jones @fda.hhs.gov> Cc: Reimschuessel, Renate < Renate Reimschuessel @fda.hhs.gov >; Peloquin, Sarah < Sarah Peloquin @fda.hhs.gov > Subject: Re: Suspect grain free canine DCM case Thank you so much for your help. I submitted a complain with as much information as I could. The ICSR number is 2060525 and the report ID is 250430.

Have a great holiday and new year,

В6

| From: Jones, Jennifer L < Jennifer Jones a fda hhs gov > Sent: Wednesday, December 19, 2018 11:39:49 AM To: B6 Cc: Reimschuessel, Renate; Peloquin, Sarah Subject: RE: Suspect grain free canine DCM case |
|---|
| Hi B6 We would absolutely appreciate collecting those samples. In order for me to send you a box to collect the samples, I'll need an official report. You can mention in the report, that I recommended you submit a complaint. Can you please submit a consumer complaint here? https://www.safetyreporting.hhs.gov/ Please send me the ICSR number (confirmation code) to help me locate the report. I'll ship a box to you after the new year because of the holidays. Thank you again for your help and collaboration. Happy Holidays, Jen |
| Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 U.S. FOOD & DRUG |
| From: B6 |
| liver, and serum so I have frozen and fixed samples from the left ventricle, skeletal muscle, and liver and there should be some serum in the fridge. I would love to send these samples in if they will be at all helpful. Please let me know if you would like me to proceed with sending samples to Vet-LIRN. |
| Thank you for all of your help, B6 |
| CONFIDENTIALITY NOTICE: Information contained in this message and any attachments is intended only for the addressee(s). If you believe that you have received this message in error, please notify the sender immediately by return electronic mail, and please delete it without further review, disclosure, or copying.) |
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|---|
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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

> (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo> Rotstein, David; Nemser, Sarah; Ceric, Olgica; Palmer, Lee Anne; Carey, Lauren; Glover, Mark;

To: Queen, Jackie L

4/9/2018 5:05:03 PM Sent:

Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon:

EON-350487

Re: FDA Case Investigation for **B6** 1 yr FS Afghan Hound) Attachments:

Recommend NFA-Trend-dog initially had a mild murmur at 8 yr old (2/2015) and it wasn't diagnosed on other PEs until 2/2018; When murmur was initially detected, I suspect a different food was fed, because this dog at Fromm's dry dog food in 3/2017. Also the dog was getting a variety of the TOW Flavors. The lot/bb info for those is attached.

| Presenting complaint 2/12/2018: vet prescribed B6 ; b/c 4/5 dogs got kennel cough at a dog show in |
|--|
| January à owner called 2/28-dog coughing after 4 days of doxy, vomiting pills, not exercise intolerant à vet |
| prescribed B6 a 3/13 to rDVM for continued regular & frequent coughing a to |
| cardiologist on 3/19: cough is worse with stress and middle of night, recent abdominal distension, hyporexia, |
| arthitic, on Grain Free Taste of the Wile Adult Dog food à treated for CHF with taurine, carnitine, d |
| ве precheck 4/2: irregular heart beat, no significant cough, better energy, no |
| abdominal distention, 10 lb weight loss, some pulse deficits |
| PE 3/13: irregular heart, occ bounding pulses, irregular with heart, slight taught/distended abdomen, Gr II-III/VI |
| and all and a state of the stat |

systolic, upper right heart base, mild increased respiratory effort, HR ~200 at times

3/19: frequent hacking/wheezing cough at rest, nervous, aggitated, HR 188-196, irregular A-fib rhythm, Gr III/VI PMI MV & TV, pant, mild tachypnea when closed mouth, markedly increased bronchovesicular soundsd, abdomen w/ moderate ascites, femoral pulse variable intensity

Labs:

Rads 3/13: cardiomegaly, tracheal elevation, may be early CHF-patchy perihilar opacities;

EKG 3/13: suspected atrial fibrillation

-4/2: a-fib

Echo 3/19: sev LV hypertrophy, mod MV regurge, sev LA dilation, mild TV regurg, mod RV & sev RA dilation, sev decreased indices of systolic function, A-fib, mod ascites, hepatic venous distension = CHF Prior MHx: 2/2015 Gr I/VI systolic murmur PMI near MV (8 yr old), declined cardiac consultation, no clinical cough, dyspnea, or exercise intolerance; 2/2016: moderate dental calculus; 2/2017 minimal dental calculus, slight gingivitis, trazadone for anxiety management; 3/2017 Fromms dry dog food, lipoma on carpus, LS-OU

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Thursday, April 05, 2018 12:25 PM

To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren

<Lauren.Carey@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Queen, Jackie L

<Jackie.Queen@fda.hhs.gov>

| Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: B6 - EON-350487 |
|---|
| Sounds good! Thanks |
| |
| From: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov> Date: April 5, 2018 at 12:23:25 PM EDT To: Rotstein, David < David.Rotstein@fda.hhs.gov>, Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>, Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov>, Carey, Lauren < Lauren.Carey@fda.hhs.gov>, Glover, Mark < Mark.Glover@fda.hhs.gov>, Queen, Jackie L < Jackie.Queen@fda.hhs.gov> Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: |
| We can collect full MRx for review. |
| Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 U.S. FOOD & DRUG ADMINISTRATION |
| From: Rotstein, David Sent: Wednesday, April 04, 2018 4:23 PM To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne < LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>; Glover, Mark < Mark.Glover@fda.hhs.gov>; Queen, Jackie L < Jackie.Queen@fda.hhs.gov> Subject: Fwd: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: B6 |
| From: PFR Event <pre>pfreventcreation@fda.hhs.gov> Date: April 4, 2018 at 4:20:51 PM EDT To: Cleary, Michael * < Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification <hqpetfoodreportnotification@fda.hhs.gov>, B6 </hqpetfoodreportnotification@fda.hhs.gov></pre> B6 Subject: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: B6 =CON-350487 |
| A PFR Report has been received and PFR Event [EON-350487] has been created in the EON System. |
| A "PDF" report by name "2045119-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 "2045119-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350487

ICSR #: 2045119

EON Title: PFR Event created for Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon;

2045119

| AE Date | 03/19/2018 | Number Fed/Exposed | 1 |
|-------------------|-------------------|--------------------|----------------------------|
| Best By Date | | Number Reacted | 1 |
| Animal Species | Dog | Outcome to Date | Better/Improved/Recovering |
| Breed | Hound - Afghan | | |
| Age | 11 Years | | |
| District Involved | PFR- B6 DO | | |

| Ρı | bo | uct | info | rmai | tion |
|----|----------|-----|------|------|------|
| | ········ | uvi | mo | ша | uvi |

Individual Case Safety Report Number: 2045119

Product Group: Pet Food

Product Name: Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon

Description as a history of cough - she was initially treated for kennel cough. Developed ascites and was evaluated by cardiology practice on 3/19/18. Diagnosed with advanced dilated cardiomyopathy, atrial fibrillation with rapid ventricular response rate and right-sided congestive heart failure with ascites. Started on medical therapy and taurine and l-carnitine supplementation - will recheck echo in 4-5 months. Diet is Taste of the Wild Grain Free - rotates through all varieties except for those containing chicken. There is concern that the diet provides insufficient levels of taurine, contributing to the development of **B6** lilated cardiomyopathy.

Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product) **Outcome of reaction/event at the time of last observation:** Better/Improved/Recovering

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

| Product Name | Lot Number or ID | Best By Date |
|--|---------------------|-----------------|
| Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon | | |

| Sender information | |
|--------------------|--|
| B 6 | |
| USA | |

To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-350487

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=366875

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| From: | CVCA B6 CVCA B6 cvca B6 cvcavets.com> |
|---|---|
| To: Sent: | Jones, Jennifer L 4/5/2018 8:47:58 PM |
| Subject: | Re: FDA Case Investigation for B6 (11 yr FS Afghan Hound) |
| | |
| B6 gave the | e information below (said that it was very hard to read, some numbers/letters may be off): |
| #1 Best By: 2/20/2019 | 9 - 8051 OA (?) - TDSG208D31STP B015-14 |
| #2 Best By: 2/18/2019 | 9 - 8049 - TDp0214D12SCPO02-02 |
| #3 TC50208D31sTPB | 05-18(?) |
| Thank you, | |
| B6 Veterinary N | Nurse |
| On Thu, Apr 5, 2018 a wrote: Good Afternoon, | at 2:02 PM, CVCA B6 CVCA B6 Cvca B6 @cvcavets.com> |
| able to get any addition | medical history for attached below. I have called the client to see if we were onal information on the grain free food product but had to leave a message. If we hear back ure to forward that information as well. Please let us know if you need anything else from |
| Thank you, | |
| B6 Team Leade | er, B6 |
| On Thu, Apr 5, 2018 a | at 12:36 PM, Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> > wrote: |
| Good afternoon B6 | |
| Thank you for submitt | ting your consumer complaint to FDA. I'm sorry to hear abou B6 Ilness. |
| As part of our investig | gation, we'd like to request: |
| event). • Do you have any | nail (preferred) or fax (301-210-4685) a copy of B6 entire medical history (not just this y information on the Grain Free Food, including lot or best by date? |
| Additiona | ally, is there any open or unopened product available? |

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





The Doctors and Staff of CVCA

CVCA - Cardiac Care for Pets

| | В | 6 | | | |
|------|---------|----|---|---------|-------|
| Phon | e: | В6 | | | |
| Fax: | E | 36 | | | |
| Emai | l: cvca | В | @ | cvcavet | s.com |

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"Follow" us on Instagram at: https://instagram.com/cvcavets/

We want to hear from you! Access our online survey by clicking here.

If there is anything that we can do to improve our service for you, please do not hesitate to contact us directly. We would greatly appreciate your feedback and invite you to fill out a survey based on your experience with CVCA.

Share your photos with us!

If you have a photo that you would like to share, we would love to post it on our Facebook page. Like us on Facebook and post to our wall or you can email the image with a fun fact to eveainfo@eveavets.com and we will forward it to our Facebook administrator. Note -- ** Images are usually posted within 1 month.

The Doctors and Staff of CVCA

CVCA - Cardiac Care for Pets

| | B6 | |
|------|-------|--|
| Phon | e: B6 | |
| Fax: | B6 | |
| - | | |

Email: cvca B6 @cvcavets.com

Visit our website at: www.cvcavets.com
"Like" our Fan Page at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: https://instagram.com/cvcavets/

We want to hear from you! Access our online survey by clicking here.

If there is anything that we can do to improve our service for you, please do not hesitate to contact us directly. We would greatly appreciate your feedback and invite you to fill out a survey based on your experience with CVCA.

Share your photos with us!

If you have a photo that you would like to share, we would love to post it on our Facebook page. Like us on <u>Facebook</u> and post to our wall or you can email the image with a fun fact to <u>eveainfo@eveavets.com</u> and we will forward it to our Facebook administrator.

Note -- ** Images are usually posted within 1 month.

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

KUISIEIII, DAVIU Y/O-EACHANGELADS/OU-EACHANGE ADIVIINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To:

Hartogensis, Martine; Jones, Jennifer L; Carey, Lauren; Palmer, Lee Anne; Norris, Anne

Sent:

6/13/2018 11:46:38 AM

Subject:

RE: Thanks again for the call today re grain-free diets

B5

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











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From: Hartogensis, Martine

Sent: Wednesday, June 13, 2018 7:40 AM

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

Subject: RE: Thanks again for the call today re grain-free diets

Ok, thank you!

From: Rotstein, David

Sent: Wednesday, June 13, 2018 7:36 AM

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

<Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: Thanks again for the call today re grain-free diets

B5

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

240-506-6763 (BB)











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From: Hartogensis, Martine

Sent: Wednesday, June 13, 2018 7:34 AM

To: Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>

Subject: RE: Thanks again for the call today re grain-free diets

Hi Dave,

B5

Martine

From: Rotstein, David

Sent: Wednesday, June 13, 2018 7:28 AM

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

<Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Subject: RE: Thanks again for the call today re grain-free diets

В5

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



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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 13, 2018 6:59 AM

To: Hartogensis, Martine < Martine < Martine < Martine Hartogensis@fda.hhs.gov; Rotstein, David Martine.Hartogensis@fda.hhs.gov; Norris, Martine.Hartogensis@fda.hhs.gov; Norris,

Anne < Anne. Norris@fda.hhs.gov>

Subject: RE: Thanks again for the call today re grain-free diets

From one of our contacts reporting Grain Free DCM cases.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Tuesday, June 12, 2018 9:53 PM

To: Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Norris, Anne < Anne.Norris@fda.hhs.gov>

Subject: RE: Thanks again for the call today re grain-free diets



From: Carey, Lauren

Sent: Tuesday, June 12, 2018 7:32 PM

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

<Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Subject: RE: Thanks again for the call today re grain-free diets

That's an excellent idea. That seems like the sort of thing PFI would track/report on?

From: Jones, Jennifer L

Sent: Tuesday, June 12, 2018 3:12 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Subject: RE: Thanks again for the call today re grain-free diets

I reviewed my notes from the call we had with NCSU, Tufts, Davis, etc. The shortest interval the experts saw between consuming the food and developing DCM was ~9 months. One dog had been fed a Kangaroo & Lentil diet for years.

B5

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

FDA-CVM-FOIA-2019-1704-017933



From: Hartogensis, Martine

Sent: Tuesday, June 12, 2018 12:03 PM

To: Palmer, Lee Anne < Lee Anne . 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>

Subject: RE: Thanks again for the call today re grain-free diets

Ok, thank you Lee Anne!

Martine

From: Palmer, Lee Anne

Sent: Tuesday, June 12, 2018 11:30 AM

To: Hartogensis, Martine < Martine. Hartogensis@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>

Subject: RE: Thanks again for the call today re grain-free diets



From: Hartogensis, Martine

Sent: Tuesday, June 12, 2018 10:55 AM

To: Palmer, Lee Anne < Lee Anne. 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 >

Subject: FW: Thanks again for the call today re grain-free diets

Good morning...

Martine

From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Tuesday, June 12, 2018 10:49 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov > Subject: RE: Thanks again for the call today re grain-free diets

Great – many thanks, Martine. On a somewhat related note, is FDA monitoring or seeing any similar issue with

vegan pet food diets?

Regards,

Peter

O: +1.202.791.9432 M: + B6

From: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

Sent: Tuesday, June 12, 2018 7:57 AM

To: Tabor, Peter peter@petfoodinstitute.org>

Subject: RE: Thanks again for the call today re grain-free diets

Thank you and good morning. Here are the slides from Dr. Jones' presentation yesterday. Please let us know if you have any questions.

Martine

Martine Hartogensis, DVM FDA Center for Veterinary Medicine Deputy Director, Office of Surveillance & Compliance (240) 402-7178

From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Monday, June 11, 2018 9:27 PM

To: Hartogensis, Martine < Martine < Martine Hartogensis@fda.hhs.gov

Great - many thanks and have a good night, Martine.

Sent using OWA for iPhone

From: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

Sent: Monday, June 11, 2018 9:09:16 PM

To: Tabor, Peter

Subject: RE: Thanks again for the call today re grain-free diets

Hi Peter,

Thank you so much for the call today. We really appreciate your willingness to work with us and collaborate on this very interesting issue. I promise to send the slides asap...just need to resolve one minor issue and they are yours!

I apologize for the delay and will get back to you first thing tomorrow.

Thanks again!

Martine

Martine Hartogensis, DVM FDA Center for Veterinary Medicine Deputy Director, Office of Surveillance & Compliance (240) 402-7178 From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Monday, June 11, 2018 2:43 PM

To: Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>> **Subject:** Thanks again for the call today re grain-free diets

Thanks, Dr Hartogensis, for pulling your colleagues together this morning to share information on FDA and veterinarian findings re grain-free diets and DCM. There was mention, by Jennifer, I think, of slides that could be shared with PFI. We'd like to include those slides in our message to members, if you agree doing so would be appropriate. If so, please send those slides over ASAP. We'd like to include them in our message to members in the next day or so.

Thanks and we'll be in touch.

Regards,

Peter Tabor
Vice President, Regulatory & International Affairs
Pet Food Institute
O: +1.202.791.9432
M: + B6

E: peter@petfoodinstitute.org

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From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

To:

Hartogensis, Martine

CC:

Jones, Jennifer L; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Norris, Anne;

Carey, Lauren

Sent:

8/17/2018 5:28:35 PM

Subject:

RE: Time to chat today? - PFI numbers since the 7.12.18 update for MH - ALMOST done...

Attachments:

Ingredients - products in the 94 reports.docx



From: Palmer, Lee Anne

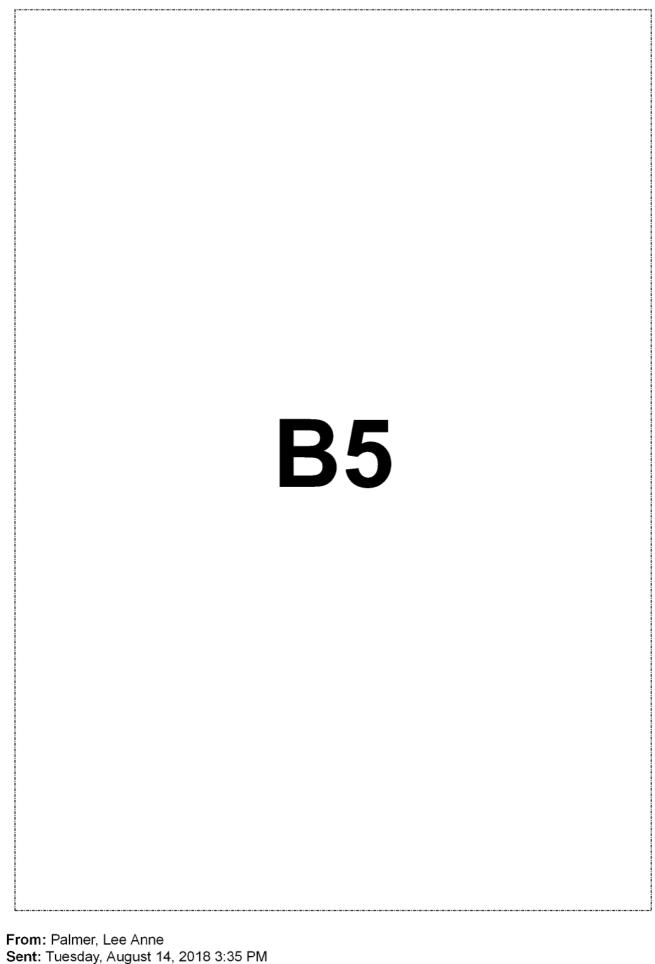
Sent: Friday, August 17, 2018 12:06 PM

| Cc: Jones, Jennifer L <jennifer.jones@fda.hhs.gov>; Rotstein, David <david.rotstein@fda.hhs.gov>; Burkholder, William <william.burkholder@fda.hhs.gov>; DeLancey, Siobhan <siobhan.delancey@fda.hhs.gov>; Norris, Anne <anne.norris@fda.hhs.gov>; Carey, Lauren <lauren.carey@fda.hhs.gov> Subject: RE: Time to chat today? - PFI numbers since the 7.12.18 update for MH - ALMOST done</lauren.carey@fda.hhs.gov></anne.norris@fda.hhs.gov></siobhan.delancey@fda.hhs.gov></william.burkholder@fda.hhs.gov></david.rotstein@fda.hhs.gov></jennifer.jones@fda.hhs.gov> |
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FDA-CVM-FOIA-2019-1704-017938

| < <u>Laurer</u> Subject Hi – the | an.Delancey@fda.hhs.gov>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> >; Carey, Lauren h.Carey@fda.hhs.gov>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u> > t: RE: Time to chat today? - PFI numbers since the 7.12.18 update for MH lion's share of the credit goes to Lauren, as well as to Jen, Dave and Sarah P. for all the great complaint p & work going on. |
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Burkholder, William < William.Burkholder@fda.hhs.gov >; DeLancey, Siobhan



To: Hartogensis, Martine < Martine Hartogensis@fda.hhs.gov >

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Thanks again!

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From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Tuesday, August 14, 2018 2:31 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

Subject: FW: Time to chat today?

Regards,

Peter

O: +1.202.791.9432

B6

From: Tabor, Peter

Sent: Monday, August 13, 2018 9:18 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: Re: Time to chat today?

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How many new cases of DCM has FDA received since 12 July and from what sources (reported to FDA, from vets cardiologists, etc)?

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To: Tabor, Peter

Subject: RE: Time to chat today?

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Thanks!

Martine

Martine Hartogensis, DVM FDA Center for Veterinary Medicine Deputy Director, Office of Surveillance & Compliance (240) 402-7178

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| From: | Palmer, Lee Anne | | | | | |
|--|--|--|-----------------------|--|--|--|
| _ | LPALMER> | | | | | |
| To: CC: | Hartogensis, Martine Jones, Jennifer L; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Norris, Anne; | | | | | |
| CC. | Carey, Lauren | i, David, Burkiloider, William, DeLancey, S | lobitan, Norns, Anne, | | | |
| Sent: | 8/17/2018 4:05:53 PM | | | | | |
| Subject: | | PFI numbers since the 7.12.18 update for | MH - ALMOST done | | | |
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| slow, but all lost th | 515 | | | | | |
| To: Palmer, Lee Ar Cc: Jones, Jennife Burkholder, William <siobhan.delance <lauren carey@fo<="" td=""><td>st 17, 2018 8:53 AM nne <leeanne.palmer@fda.h r L <jennifer.jones@fda.hhs n <william.burkholder@fda.hl y@fda.hhs.gov>; Norris, Anno la.hhs.gov></william.burkholder@fda.hl </jennifer.jones@fda.hhs </leeanne.palmer@fda.h </td><td>.gov>; Rotstein, David < David. Rotsteir</td><td></td></lauren></siobhan.delance | st 17, 2018 8:53 AM nne <leeanne.palmer@fda.h r L <jennifer.jones@fda.hhs n <william.burkholder@fda.hl y@fda.hhs.gov>; Norris, Anno la.hhs.gov></william.burkholder@fda.hl </jennifer.jones@fda.hhs </leeanne.palmer@fda.h | .gov>; Rotstein, David < David. Rotsteir | | | | |
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| Date: August 16, 2 To: Hartogensis, M Cc: Jones, Jennife Burkholder, William < <u>Siobhan.Delance</u> < <u>Lauren.Carey@fo</u> | n < <u>William.Burkholder@fda.hl</u> y <u>@fda.hhs.gov</u> >, Norris, Anno la.hhs.gov> | @fda.hhs.gov> .gov>, Rotstein, David < <u>David.Rotsteir</u> | | | | |
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Sent: Thursday, August 16, 2018 4:19 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

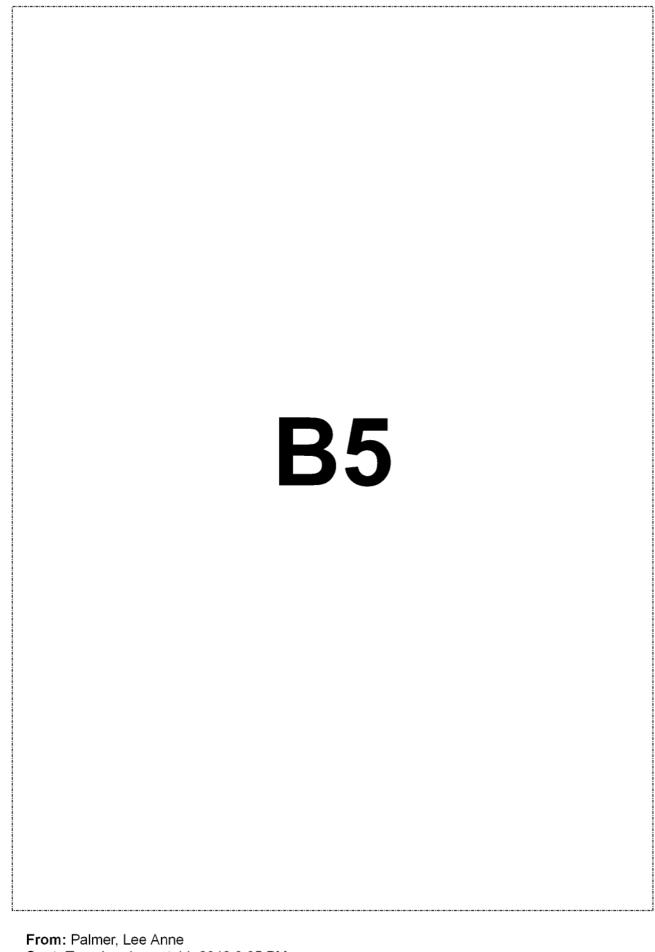
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Subject: FW: Time to chat today?

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

To:

Hartogensis, Martine

CC:

Jones, Jennifer L; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Norris, Anne;

Carey, Lauren

Sent:

8/17/2018 5:30:38 PM

Subject:

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I meant to add, this is only for the cases received from 7/12/2018 to 8/14/2018.

From: Palmer, Lee Anne

Sent: Friday, August 17, 2018 1:28 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

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

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

Burkholder, William < William.Burkholder@fda.hhs.gov >; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Carey, Lauren

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The main question from PFI is – how many reports we are seeing since the July 12th update? He was hopeful

we could chat once a week and give updates on numbers, any significant findings, etc. I think it would be fair to share that information with them if it is not too burdensome for your folks...? Perhaps just a total number of DCM reports and if they involved a veterinary cardiologist, echocardiogram, etc.

Let me know your thoughts and I copied the rest of the team in case they have input.

Thanks again!

Martine

From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Tuesday, August 14, 2018 2:31 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: FW: Time to chat today?

Regards,

Peter

O: +1.202.791.9432

B6

From: Tabor, Peter

Sent: Monday, August 13, 2018 9:18 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: Re: Time to chat today?

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How often will FDA issue investigation updates?

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LPALMER>

To:

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CC:

Jones, Jennifer L; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Norris, Anne;

Carey, Lauren

Sent:

8/16/2018 11:38:47 PM

Subject:

RE: Time to chat today? - PFI numbers since the 7.12.18 update for MH

B5

Will get back with you in the AM.

From: Hartogensis, Martine

Sent: Thursday, August 16, 2018 5:09 PM

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

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

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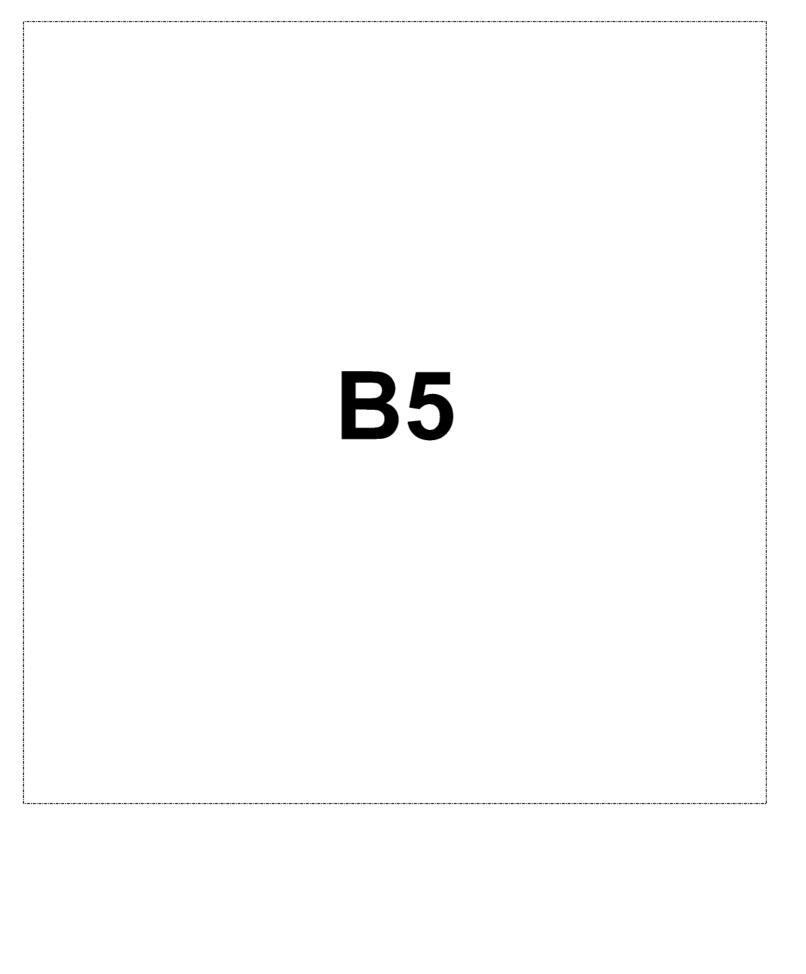
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MHARTOGE>

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Jones, Jennifer L; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Norris, Anne;

Carey, Lauren

Sent:

8/16/2018 9:08:45 PM

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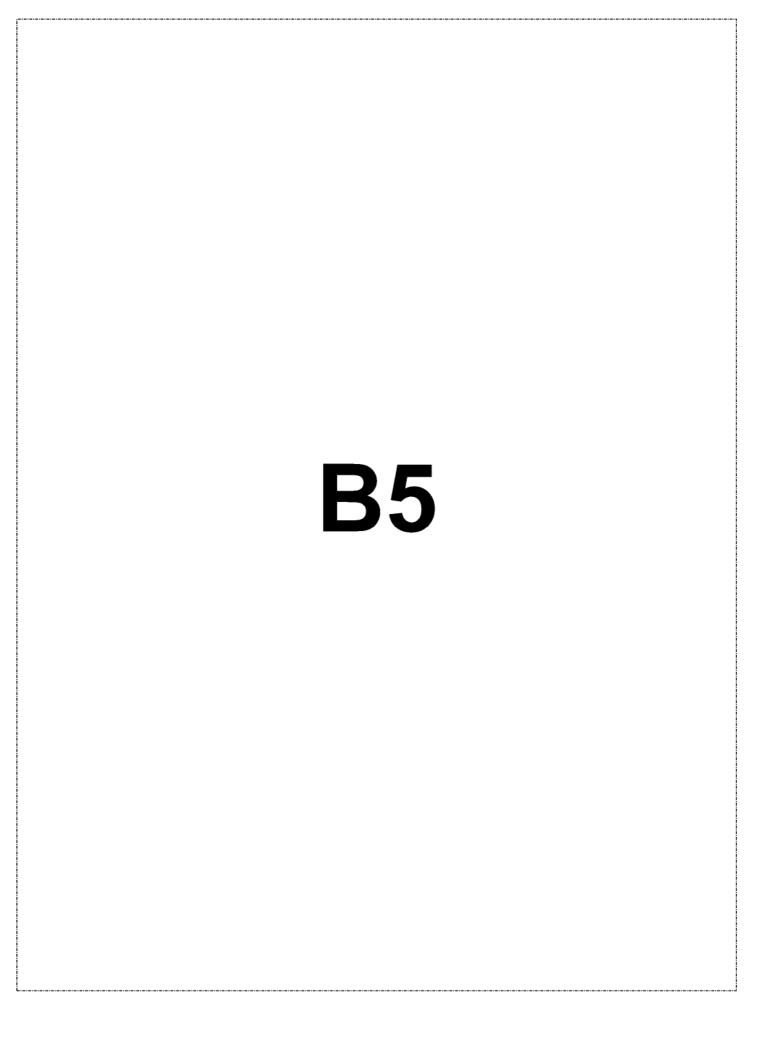
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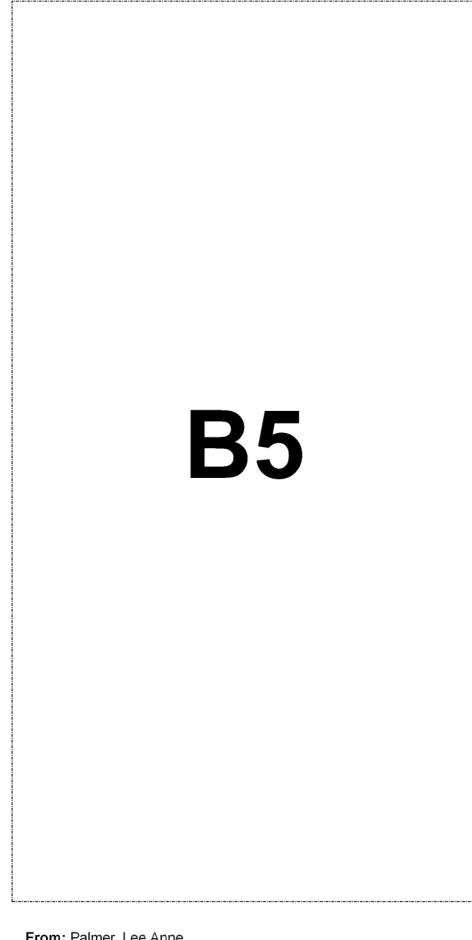
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PFI's Nutrition Subcommittee is beginning to gather information on this issue, appropriate parts of which it will share with PFI members and also with FDA. We take this issue very seriously and will devote significant resources to examining it to determine what type of relationship (if any) exists between DCM and certain pet food products.

How many new cases of DCM has FDA received since 12 July and from what sources (reported to FDA, from vets cardiologists, etc)?

How often will FDA issue investigation updates?

How many inquiries has FDA received from concerned pet owners?

Is FDA focusing on formulations of pet foods containing legumes and potatoes or just the ingredients themselves? Current messaging indicates the latter which is troubling since our understanding is that many formulations containing these ingredients and/or labeled as grain-free are not associated with cases of DCM. The answer to Q12 appears to suggest (or could be taken to suggest) that pet owners should stop feeding any pet food containing legumes or potatoes. Is that FDA's intent?

Instead of focusing simply on the pet food ingredients, why don't the Qs and As focus on the condition of the dog as the main concern? There is a very real possibility that pet owners may do either of the following after reading the Qs and As: change their dog's diet even if the dog exhibits no DCM symptoms and/or conclude that changing their dog's diet will address the DCM issue.

The answer to Q14 is somewhat meaningless given its placement in the Q&A and given the information provided in the preceding answers. Was it FDA's intent to discourage the feeding of any pet food containing legumes or potatoes or any pet food labeled as grain-free?

Thanks for considering these questions and thoughts, Martine. I look forward to speaking with you later today if possible or tomorrow.

Sent using OWA for iPhone

From: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Sent: Monday, August 13, 2018 8:35:18 AM

To: Tabor, Peter

Subject: RE: Time to chat today?

Hi Peter,

I am available this morning until 9, if that works for you? I have several meetings this afternoon.

Thanks!

Martine

Martine Hartogensis, DVM FDA Center for Veterinary Medicine Deputy Director, Office of Surveillance & Compliance (240) 402-7178

From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Monday, August 13, 2018 8:33 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: Time to chat today?

Good morning, Martine. Please let me know if you're available to chat this afternoon. I have a few questions and an update re the DCM issue. Thanks.

Sent using OWA for iPhone

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

To:

Hartogensis, Martine

CC:

Jones, Jennifer L; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Norris, Anne;

Carey, Lauren

Sent:

8/14/2018 7:35:00 PM

Subject:

RE: Time to chat today?

That should work! I think Friday's do-able, if not before then.

From: Hartogensis, Martine

Sent: Tuesday, August 14, 2018 3:33 PM

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

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

Burkholder, William < William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Carey, Lauren

<Lauren.Carey@fda.hhs.gov>
Subject: RE: Time to chat today?

Perfect and thank you!!!

Peter is planning to call back Friday, so let me know if that works for you.

Thanks again!

Martine

From: Palmer, Lee Anne

Sent: Tuesday, August 14, 2018 3:30 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

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

Burkholder, William < William.Burkholder@fda.hhs.gov >; DeLancey, Siobhan

< Siobhan. Delancey@fda.hhs.gov>; Norris, Anne < Anne. Norris@fda.hhs.gov>; Carey, Lauren

<<u>Lauren.Carey@fda.hhs.gov</u>> **Subject:** RE: Time to chat today?

Hi Martine – I'm sure we could do that. I'm still crawling out of the email pile after last week's vacation, but Lauren has been doing a great job of keeping the numbers, and Jen and Dave with all the follow up info.

В5

OK? Thanks.

From: Hartogensis, Martine

Sent: Tuesday, August 14, 2018 3:24 PM

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

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

Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Norris, Anne < Anne.Norris@fda.hhs.gov>

Subject: FW: Time to chat today?

Hi Lee Anne.

I spoke with Peter Tabor from PFI today regarding his questions below. I explained our thinking since the last call – we are gathering more reports, explaining the signal, etc.

The main question from PFI is – how many reports we are seeing since the July 12th update? He was hopeful we could chat once a week and give updates on numbers, any significant findings, etc. B5

B5

Let me know your thoughts and I copied the rest of the team in case they have input.

Thanks again!

Martine

From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Tuesday, August 14, 2018 2:31 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: FW: Time to chat today?

Regards,

Peter

O: +1 202 791 9432

B6

From: Tabor, Peter

Sent: Monday, August 13, 2018 9:18 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: Re: Time to chat today?

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possible or tomorrow.

Sent using OWA for iPhone

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Sent: Monday, August 13, 2018 8:35:18 AM

To: Tabor, Peter

Subject: RE: Time to chat today?

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Thanks!

Martine

Martine Hartogensis, DVM FDA Center for Veterinary Medicine Deputy Director, Office of Surveillance & Compliance (240) 402-7178

From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

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To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: Time to chat today?

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Sent using OWA for iPhone

| From: Hartogensis, Martine | | | | | | | |
|--|--|--|--|--|--|--|--|
| | MHARTOGE> | | | | | | |
| To: | Palmer, Lee Anne | | | | | | |
| CC: | Jones, Jennifer L; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Norris, Anne; Carey, Lauren | | | | | | |
| Sent: Subject: | 8/14/2018 7:32:52 PM RE: Time to chat today? | | | | | | |
| Perfect and than | k you!!! | | | | | | |
| Peter is planning | to call back Friday, so let me know if that works for you. | | | | | | |
| Thanks again! | | | | | | | |
| Martine | | | | | | | |
| To: Hartogensis, Cc: Jones, Jenn Burkholder, Willia <siobhan.deland <lauren.carey@ Subject: RE: Tir</lauren.carey@ </siobhan.deland | August 14, 2018 3:30 PM , Martine <martine.hartogensis@fda.hhs.gov> ifer L <jennifer.jones@fda.hhs.gov>; Rotstein, David <david.rotstein@fda.hhs.gov>; am <william.burkholder@fda.hhs.gov>; DeLancey, Siobhan cey@fda.hhs.gov>; Norris, Anne <anne.norris@fda.hhs.gov>; Carey, Lauren @fda.hhs.gov> me to chat today?</anne.norris@fda.hhs.gov></william.burkholder@fda.hhs.gov></david.rotstein@fda.hhs.gov></jennifer.jones@fda.hhs.gov></martine.hartogensis@fda.hhs.gov> | | | | | | |
| | sure we could do that. I'm still crawling out of the email pile after last week's vacation, but n doing a great job of keeping the numbers, and Jen and Dave with all the follow up info. B5 | | | | | | |
| | B5 | | | | | | |
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| To: Palmer, Lee Cc: Jones, Jenn Burkholder, Willi < <u>Siobhan.Deland</u> | sis, Martine August 14, 2018 3:24 PM Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u> > ifer L < <u>Jennifer.Jones@fda.hhs.gov</u> >; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u> >; am < <u>William.Burkholder@fda.hhs.gov</u> >; DeLancey, Siobhan cey@fda.hhs.gov>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u> > me to chat today? | | | | | | |
| Hi Lee Anne, | | | | | | | |
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| Let me know you | ur thoughts and I copied the rest of the team in case they have input. | | | | | | |
| Thanks again! | | | | | | | |

FDA-CVM-FOIA-2019-1704-017975

Martine

From: Tabor, Peter [mailto:peter@petfoodinstitute.org]

Sent: Tuesday, August 14, 2018 2:31 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >

Subject: FW: Time to chat today?

Regards,

Peter

O: +1.202.791.9432

B6

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Sent: Monday, August 13, 2018 9:18 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

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Subject: Time to chat today?

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Sent using OWA for iPhone

From:

Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To:

Reimschuessel, Renate

CC:

Tkachenko, Andriy; Nemser, Sarah; Peloguin, Sarah

Sent:

10/16/2018 10:19:07 AM

Subject:

RE: UC Davis versus Wisconsin Taurine levels

We are going to chat first, next Tuesday during part of the Weekly Case Review. I want to hear from Andriy what he thinks is the issue.

B5

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Reimschuessel. Renate

Sent: Monday, October 15, 2018 8:29 PM

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

Cc: Tkachenko, Andriy <Andriy.Tkachenko@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>;

Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

What did we decide this morning

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: Monday, October 15, 2018 1:52 PM

To: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Queen, Jackie L < <u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Peloquin, Sarah <<u>Sarah.Peloquin@fda.hhs.gov</u>>; Tkachenko, Andriy <<u>Andriy.Tkachenko@fda.hhs.gov</u>>

Subject: RE: UC Davis versus Wisconsin Taurine levels

FYI-Wisconsin has identified a problem with their testing and stopped performing Taurine testing until it is resolved. **B5**

B5

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Jones, Jennifer L

Sent: Wednesday, September 19, 2018 6:46 AM

To: Burkholder, William < William.Burkholder@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >; Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >; Queen, Jackie L < <u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

Ok-we can chat about some options. There are only 2 labs in the US that measure taurine for dogs-Davis and WVDL.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Burkholder, William

Sent: Tuesday, September 18, 2018 4:14 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov>; Queen, Jackie L < <u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

B5

From: Rotstein, David

Sent: Tuesday, September 18, 2018 4:06 PM

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

<a href="mailto:<marker-100g/mailto:Martine.Hartogensis@fda.hhs.gov">, Ceric, Olgica , Burkholder, William

< William.Burkholder@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 >; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

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













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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, September 18, 2018 3:49 PM

To: Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Queen, Jackie L <<u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov>; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

When we get the control blood for the CVCA collaboration,

B5

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



From: Rotstein, David

Sent: Tuesday, September 18, 2018 3:29 PM

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

< Martine. Hartogensis@fda.hhs.gov >; Ceric, Olgica < Olgica. Ceric@fda.hhs.gov >; Burkholder, William

<<u>William.Burkholder@fda.hhs.gov</u>>; Queen, Jackie L <<u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne

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Cc: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Peloquin, Sarah

<<u>Sarah.Peloquin@fda.hhs.gov</u>>

Subject: RE: UC Davis versus Wisconsin Taurine levels

| That's a good question. | B5 |
|-------------------------|----|
| B5 | |

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

Date: September 18, 2018 at 3:22:04 PM EDT

To: Hartogensis, Martine < Martine.Hartogensis@fda.hhs.gov >, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >, Burkholder, William < William.Burkholder@fda.hhs.gov >, 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 >, Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

Interesting twist-

The owner's vet just called. They tested a plasma Taurine in a 10 mo labrador retriever today with degenerative MV disease, and it's LOW. Dog was on Purina Puppy Chow? Food.

My thoughts B5

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





From: Hartogensis, Martine

Sent: Tuesday, September 18, 2018 1:13 PM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>>; Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L

<<u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Carey, Lauren

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Cc: Reimschuessel, Renate < Renate Reimschuessel@fda.hhs.gov >; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

Thanks Jen for the heads up!

Martine

From: Jones, Jennifer L

Sent: Tuesday, September 18, 2018 12:25 PM

To: Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L <<u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Peloquin, Sarah

<<u>Sarah.Peloquin@fda.hhs.gov</u>>

Subject: RE: UC Davis versus Wisconsin Taurine levels

According to the owner-they've tested the same samples.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Ceric, Olgica

Sent: Tuesday, September 18, 2018 12:22 PM

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

<Martine.Hartogensis@fda.hhs.gov>; Burkholder, William.Surkholder@fda.hhs.gov>; Rotstein, David

<<u>David.Rotstein@fda.hhs.gov</u>>; Queen, Jackie L <<u>Jackie.Queen@fda.hhs.gov</u>>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>

Subject: RE: UC Davis versus Wisconsin Taurine levels

Jen,

Do you know if they have tested the same samples by both methods?

Olgica Ceric, DVM, PhD

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G529
Laurel, Maryland 20708
tel: 240-402-5419

fax: 301-210-4685
e-mail: olgica.ceric@fda.hhs.gov

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

From: Jones, Jennifer L

Sent: Tuesday, September 18, 2018 12:18 PM

To: Hartogensis, Martine < Martine Hartogensis@fda.hhs.gov >; Burkholder, William

<<u>William.Burkholder@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>; 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 < Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Peloquin, Sarah < Sarah.Peloquin@fda.hhs.gov >

Subject: UC Davis versus Wisconsin Taurine levels

Just talked to an owner-

1. She had a lot of thanks and appreciation for our investigation

- 2. She mentioned the much lower Taurine levels diagnosed at Wisconsin vs. UC Davis. She talked to Keith Paulson (director of Lab) who said that sometime was off with the calibration, but it's been corrected. On Wisconsin's website, I see different information but wanted to give everyone a head's up/something to keep in mind?
 - a. https://www.wvdl.wisc.edu/index.php/recent-findings-have-led-to-increase-in-taurine-testing-caseload/

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:

'Freeman, Lisa'

Sent:

12/3/2018 11:55:56 AM

Subject:

RE: updates

Received. Thanks, Lisa.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Freeman, Lisa <Lisa.Freeman@tufts.edu> Sent: Sunday, December 02, 2018 8:16 PM

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

Subject: updates

Hi Jen

Attached are follow up echoes on 2 of the cases I reported.

B6

I have a bunch of new ones to report that I'll submit asap

Thanks

lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary NutritionistTM
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: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-

RREIMSCH>

To:

Ceric, Olgica

CC:

Jones, Jennifer L; Nemser, Sarah

Sent:

8/2/2019 11:52:26 AM

Subject:

RE: VET LIRN updates for AVMA?

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: Ceric, Olgica

Sent: Friday, August 02, 2019 6:48 AM

To: Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov>

Subject: Fwd: VET LIRN updates for AVMA?

See below

From: Huebner, Katherine < Katherine. Huebner@fda.hhs.gov>

Date: August 1, 2019 at 10:51:59 PM GMT+2 **To:** Ceric, Olgica < <u>Olgica Ceric@fda.hhs.gov</u>> **Subject:** VET LIRN updates for AVMA?

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|---|----|--------|----|---|
| | ш | \sim | U | a |

I will be heading to the AVMA council meeting for public health on behalf of Diana Link this September to provide CVM updates.

B5

B5

Thanks!

Katherine (Kate) Huebner, VMD Veterinary Medical Officer

Center for Veterinary Medicine Office of Surveillance and Compliance Division of Surveillance - Medical Review Team U.S. Food & Drug Administration Tel: 240-402-4347

katherine.huebner@fda.hhs.gov





From: Nemser, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC1EB8D2F5944ECAA02F40E225C2054-

SNEMSER>

To:

Jones, Jennifer L; Reimschuessel, Renate

Sent:

8/7/2019 6:50:43 PM

Subject:

RE: VET LIRN updates for AVMA?

No edits.

S

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

From: Jones, Jennifer L

Sent: Wednesday, August 7, 2019 12:53 PM

To: Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov>

Cc: Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: VET LIRN updates for AVMA?

No, I think this looks excellent.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Reimschuessel, Renate

Sent: Wednesday, August 07, 2019 11:46 AM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>
Cc: Nemser, Sarah < <u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: VET LIRN updates for AVMA?

I updated this – take a look – am I missing something we want to share with AVMA?

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Reimschuessel, Renate

Sent: Tuesday, August 6, 2019 12:32 PM

To: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>
Cc: Nemser, Sarah < <u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: VET LIRN updates for AVMA?

Can one of you proof this for me?

thanks

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Jones, Jennifer L

Sent: Friday, August 2, 2019 8:02 AM

To: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >

Cc: Nemser, Sarah < Sarah. Nemser@fda.hhs.gov > Subject: RE: VET LIRN updates for AVMA?

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Reimschuessel, Renate

Sent: Friday, August 02, 2019 7:52 AM

To: Ceric, Olgica < Olgica. Ceric@fda.hhs.gov>

Cc: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: VET LIRN updates for AVMA?

B5



B5

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: Ceric, Olgica

Sent: Friday, August 02, 2019 6:48 AM

To: Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov >

Subject: Fwd: VET LIRN updates for AVMA?

See below

From: Huebner, Katherine < <u>Katherine.Huebner@fda.hhs.gov</u>>

Date: August 1, 2019 at 10:51:59 PM GMT+2 **To:** Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u>> **Subject:** VET LIRN updates for AVMA?

Hi Olga,

I will be heading to the AVMA council meeting for public health on behalf of Diana Link this September to provide CVM updates B5

B5

Thanks!

Katherine (Kate) Huebner, VMD Veterinary Medical Officer

Center for Veterinary Medicine
Office of Surveillance and Compliance
Division of Surveillance - Medical Review Team
U.S. Food & Drug Administration

Tel: 240-402-4347

katherine.huebner@fda.hhs.gov





From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-

RREIMSCH>

To: CC: Jones, Jennifer L Nemser, Sarah

Sent:

8/7/2019 3:45:30 PM

Subject:

RE: VET LIRN updates for AVMA?

Attachments:

Vet-LIRN update for AVMA-08-07-2019-v1.docx

I updated this - take a look - am I missing something we want to share with AVMA?

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Reimschuessel, Renate

Sent: Tuesday, August 6, 2019 12:32 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>Cc: Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>Subject: RE: VET LIRN updates for AVMA?

Can one of you proof this for me?

thanks

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN

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Cc: Nemser, Sarah < Sarah. Nemser@fda.hhs.gov > Subject: RE: VET LIRN updates for AVMA?

B5

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



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Sent: Friday, August 02, 2019 7:52 AM

To: Ceric, Olgica < Olgica. Ceric@fda.hhs.gov>

Cc: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: VET LIRN updates for AVMA?

B5

B5 B5

B5

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

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Katherine (Kate) Huebner, VMD Veterinary Medical Officer

Center for Veterinary Medicine Office of Surveillance and Compliance Division of Surveillance - Medical Review Team U.S. Food & Drug Administration

Tel: 240-402-4347

katherine.huebner@fda.hhs.gov





From:

Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-

RREIMSCH>

To: CC: Jones, Jennifer L Nemser, Sarah

Sent:

8/6/2019 4:32:22 PM

Subject:

RE: VET LIRN updates for AVMA?

Attachments:

Vet-LIRN update for AVMA-08-06-2019-v1.docx

Can one of you proof this for me?

thanks

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Jones, Jennifer L

Sent: Friday, August 2, 2019 8:02 AM

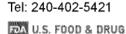
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Cc: Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: VET LIRN updates for AVMA?

B5

Jennifer Jones, DVM Veterinary Medical Officer





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Sent: Friday, August 02, 2019 7:52 AM

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Cc: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov>

Subject: RE: VET LIRN updates for AVMA?

В5

B5

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Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

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Center for Veterinary Medicine Office of Surveillance and Compliance Division of Surveillance - Medical Review Team U.S. Food & Drug Administration Tel: 240-402-4347

katherine.huebner@fda.hhs.gov



From:

Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-

MHARTOGE>

To:

Norris, Anne; Murphy, Jeanette; Edwards, David; Conway, Charlotte; Jones, Jennifer L.

CC: Sent: DeLancey, Siobhan 6/27/2019 1:34:28 PM

Subject:

RE: Your role in DCM stakeholder outreach today

Hi Anne,

I did finally touch base with

B6

at Blue Buffalo.

Jenny and I called Peter Tabor @PFI.

I left messages for Ashley Morgan (AVMA) – emailed too, Tim McGreevy (Dry Pea/Lentil Council), and John Keeling (National Potato Council).

I did not give an exact time of posting, but said it would be later today.

Let me know if I missed anyone.

Martine

From: Norris, Anne

Sent: Thursday, June 27, 2019 7:38 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; Murphy, Jeanette

<Jenny.Murphy@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Conway, Charlotte

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

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov> **Subject:** Your role in DCM stakeholder outreach today

Hi all,

Reminder that you're on the comms plan as POCs for DCM outreach today. The comms and complaint spreadsheet are slated to post at 10:30 and I'll circulate those links when they're live. Attached is the comms plan and pasted below is the stakeholder outreach info. Please yell if you have any questions or concerns.

Thanks, Anne

STAKEHOLDER OUTREACH

Industry

| Org | Contact | CVM POC | | |
|-------|-------------------------------------|--------------|--|--|
| PFI | Peter Tabor | Jenny Murphy | | |
| | 202-791-9432 | | | |
| | peter@petfoodinstitute.org | | | |
| AAFCO | Bob Geiger, Sue Hays | Dave Edwards | | |
| | geigerrl@purdue.edu, exec@aafco.org | | | |
| AFIA | Leah Wilkinson | Dave Edwards | | |
| | lwilkinson@afia.org | | | |

| American Pulse Association / USA Dry Pea and Lentil Council | Tim McGreevy tmcgreevy@usapulses.org | Martine Hartogensis |
|--|---|---------------------|
| National Potato Council | John Keeling | Martine Hartogensis |
| | B6 johnk@nationalpotatocouncil.org | |

Veterinary

| Org | Contact | CVM POC | |
|------|-------------------------------------|---------------------|--|
| AVMA | Ashley Morgan | Martine Hartogensis | |
| | amorgan@avma.org | | |
| | o: 202.289.3210 | | |
| | C: B6 | | |
| CVCA | Steve Rosenthal | Jennifer Jones | |
| | steven.rosenthal@cvcavets.com | | |
| | Dr. Lisa Freeman | Jennifer Jones | |
| | <u>Lisa.Freeman@tufts.edu</u> | | |
| | Dr. Josh Stern, Dr. Andrea Fascetti | Jennifer Jones | |
| | (UC Davis Aminoaciduria Lab) | | |
| | jstern@ucdavis.edu | | |
| | ajfascetti@ucdavis.edu | | |
| | Dr. Darcy Adin | Jennifer Jones | |
| | adind@ufl.edu | | |

Anne Norris

Strategic Initiatives

Office of the Director **Center for Veterinary Medicine** U.S. Food & Drug Administration O: 240-402-0132

M: 240-704-0579 Anne.Norris@fda.hhs.gov













From:

Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-

MHARTOGE>

To:

Norris, Anne; Murphy, Jeanette; Edwards, David; Conway, Charlotte; Jones, Jennifer L

CC: Sent: DeLancey, Siobhan 6/27/2019 1:34:28 PM

Subject:

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Sent: Thursday, June 27, 2019 7:38 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; Murphy, Jeanette

<Jenny.Murphy@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Conway, Charlotte

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

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|-------|-------------------------------------|--------------|--|--|
| PFI | Peter Tabor | Jenny Murphy | | |
| | 202-791-9432 | | | |
| | peter@petfoodinstitute.org | | | |
| AAFCO | Bob Geiger, Sue Hays | Dave Edwards | | |
| | geigerrl@purdue.edu, exec@aafco.org | | | |
| AFIA | Leah Wilkinson | Dave Edwards | | |
| | lwilkinson@afia.org | | | |

| American Pulse Association / USA Dry Pea and Lentil Council | Tim McGreevy tmcgreevy@usapulses.org | Martine Hartogensis |
|--|---|---------------------|
| National Potato Council | John Keeling | Martine Hartogensis |
| | B6 | |
| | johnk@nationalpotatocouncil.org | |

Veterinary

| Org | Contact | CVM POC | |
|------|-------------------------------------|---------------------|--|
| AVMA | Ashley Morgan | Martine Hartogensis | |
| | amorgan@avma.org | | |
| | o: 202.289.3210 | | |
| | c: <u>B6</u> | | |
| CVCA | Steve Rosenthal | Jennifer Jones | |
| | steven.rosenthal@cvcavets.com | | |
| | Dr. Lisa Freeman | Jennifer Jones | |
| | Lisa.Freeman@tufts.edu | | |
| | Dr. Josh Stern, Dr. Andrea Fascetti | Jennifer Jones | |
| | (UC Davis Aminoaciduria Lab) | | |
| | jstern@ucdavis.edu | | |
| | ajfascetti@ucdavis.edu | | |
| | Dr. Darcy Adin | Jennifer Jones | |
| | adind@ufl.edu | | |

Anne Norris

Strategic Initiatives

Office of the Director **Center for Veterinary Medicine** U.S. Food & Drug Administration O: 240-402-0132 M: 240-704-0579 Anne.Norris@fda.hhs.gov













| From: | B6 |
|--------------------------|--|
| To: | Jones, Jennifer L |
| Sent: Subject: | 8/27/2019 1:09:35 PM Re[2]: 800.267-cc-297-FDA Case Investigation for B6 and B6 (cc-297) |
| oubject. | (co 201) |
| | |
| Thank you. | |
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| | |
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| | |
| | |
| | |
| | B6 |
| | |
| Original Me | ssage |
| | nifer L" < <u>Jennifer.Jones@fda.hhs.gov</u> > |
| To: '[| B6 }; "Peloquin, Sarah" |
| < <u>Sarah.Peloquin@</u> | <u>pfda.hhs.gov</u> > |
| Sent: 8/27/2019 7: | |
| Subject: RE: 800.26 | 67-cc-297-FDA Case Investigation for B6 and B6 (cc-297) |
| | |
| _ | 'll submit this today, and someone from our business team should call your office in the next |
| iew busiliess days v | with our VISA information. |
| Jennifer Jones, DVM | |
| Veterinary Medical Of | ficer |
| Tel: 240-402-5421 | |
| U.S. FOOD & DRUG | |
| | |
| From: | B6 |
| | ust 26, 2019 6:16 PM |
| | n < <u>Sarah.Peloquin@fda.hhs.gov</u> > L < <u>Jennifer.Jones@fda.hhs.gov</u> > |
| | 67-cc-297-FDA Case Investigation for B6 r and B6 h (cc-297) |
| | |
| Sarah, | , |
| I have attached th | e invoice for B6 and B6 necropsy. Thank you for the reminder. |
| Doot | |
| Best | |
| B6 | |
| | |



| B6 |
|--|
| Original Message From: "Peloquin, Sarah" <sarah.peloquin@fda.hhs.gov> To: B6 Cc: "Jones, Jennifer L" < Jennifer.Jones@fda.hhs.gov> Sent: 8/15/2019 9:08:36 AM Subject: 800.267-cc-297-FDA Case Investigation for B6 and B6 (cc-297)</sarah.peloquin@fda.hhs.gov> |
| Good morning Dr. Ellis! |
| Please send us the invoices for B6 and B6 necropsies at your earliest convenience (by email or fax to 301-210-4685). We want to make sure we reimburse your hospital for these costs. |
| Thank you! Sarah |
| Sarah Peloquin, DVM Veterinary Medical Officer tel: 240-402-1218 |
| From: Jones, Jennifer L Sent: Friday, June 14, 2019 9:10 AM To B6 Subject: RE: Re[2]: 800.267-cc-297-FDA Case Investigation for B6 (cc-297) |
| Absolutely. We will send a copy of the results as soon as they are read. |
| Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 U.S. FOOD & DRUG ADMINISTRATION |
| From B6 Sent: Friday, June 14, 2019 8:55 AM To: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov > Subject: Re[2]: 800.267-cc-297-FDA Case Investigation for B6 (cc-297) |

Also, I believe that I read I should get a copy of the pathology results. Is this correct? I am interested

Thank you Jennifer. I did receive an email from Jake.

| in the results from B6 |
|--|
| Thank you again. I appreciate the work you all are doing for this. |
| B6 |
| B6 |
| B6 |
| Original Message From: "Jones, Jennifer L" < Jennifer.Jones@fda.hhs.gov > To: B6 |
| U.S. FOOD & DRUG |
| From: B6 Sent: Tuesday, June 11, 2019 9:22 AM To: Peloquin, Sarah < <u>Sarah.Peloquin@fda.hhs.gov</u> > Cc: Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u> > Subject: Re: 800.267-FDA Case Investigation for B6 [cc-297] |
| Good morning, Weights for the samples from B6 are as follows: Frozen tissue is 6ounces Refrigerated samples (urine and small intestinal fluid) 2ounces Formalin fixed samples 2 pounds 6 ounces |
| Thank you |
| B6 |



| De |
|---|
| B6 |
| Original Message From: "Peloquin, Sarah: <sarah.peloquin@fda.hhs.gov> To: " B6 Cc: "Jones, Jennifer L" <jennifer.jones@fda.hhs.gov> Sent: B6 11:59:32 AM Subject: 800.267-FDA Case Investigation for B6 (cc-297)</jennifer.jones@fda.hhs.gov></sarah.peloquin@fda.hhs.gov> |
| Good morning Dr B6 |
| I'm filling in on the DCM case investigation for Dr. Jennifer Jones this week. Dr. Lisa Freeman informed me that will be euthanized—I'm sorry to hear this. If you are willing, please collect the same samples from B6 as you did for B6 (i.e. intact heart in formalin; and if possible, fixed/frozen tissues as described in the rapid necropsy document). |
| Dr. Jones will return at the end of next week, and we will send you boxes then for shipment. |
| Please send me the approximate weights of the samples, as you did for B6 |
| Let me know if you have any additional questions. |
| Thank you! Dr. Sarah Peloquin |
| Sarah K. Peloquin, DVM Veterinary Medical Officer |
| U.S. Food & Drug Administration Center for Veterinary Medicine Veterinary Laboratory Investigation and Response Network (Vet-LIRN) tel: 240-402-1218 fax: 301-210-4685 e-mail: sarah.peloquin@fda.hhs.gov U.S. FOOD & DRUG |

This email has been checked for viruses by AVG antivirus software. www.avg.com

From: Jones, Jennifer L </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>

To:

B6

CC:

Ceric, Olgica

Sent:

7/18/2017 12:39:11 PM

Subject:

Vet-LIRN request for open product fumonisin testing (800,218)

Attachments:

800.218-Medical Record Review doc.html; EON-323515-

B6

Calif Naturals-dog

1.pdf.html; EON-323519

B6

Calif Naturals-dog 2.pdf.html

Good morning **B6**

Vet-LIRN received a report about two genetically unrelated Miniature Schnauzer dogs in the same household that may have developed Dilated cardiomyopathy after eating a dog food. The complaints and a medical record summary are attached.

We'd like to request open dog food testing for fumosin.

Please let me know if you're able to do the testing.

Please also plan to bill the Vet-LIRN infrastructure grant for the testing.

Thank you kindly,

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To: Edwards, David; Burkholder, William

CC: Rotstein, David

Sent: 6/13/2018 12:19:02 PM

Subject: FW: 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,

We have been passing around a draft for an update about the DCM issue. I've put the link below for comment.

In talking with Martine this morning, we have emails that have been exchanged with DAF and discussions at our Wednesday Outbreak meeting. We don't have anything that is a little more formal.

CVM Update - Canine DCM & GF Diets

Thank you

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













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From: Jones, Jennifer L.

Sent: 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.

B5

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 < Lee Anne. Palmer@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >; Reimschuessel, Renate

<<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Edwards, David <<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>

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

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 Reimschuessel@fda.hhs.gov; Edwards, David.Edwards@fda.hhs.gov; Hartogensis, Martine Burkholder, William Surkholder, William Jelancey, Siobhan Siobhan.Delancey@fda.hhs.gov Cc: Carey, Lauren Lauren Lovell, Randall A Randall.Lovell@fda.hhs.gov> Ceric, Olgica Olgica Olgica Olgica Olgica Sarah Sarah Sarah.Nemser@fda.hhs.gov> ; Conway, Charlotte Charlotte.Conway@fda.hhs.gov> ; Atkinson, Krisztina Z Krisztina.Atkinson@fda.hhs.gov ; Hodges, April April April April Nemser, Atkinson, Krisztina Z Krisztina.Atkinson@fda.hhs.gov> ; Hodges, April April April April April April

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 <a href="mailto: 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 <a href="mailto: 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 <a href="mailto:April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

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













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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

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

Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov>; Edwards, David

<David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren < Lauren. Carey@fda.hhs.gov>; Lovell, Randall A < Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <a href="mailto: 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

<a href="mailto: ; 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





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

I know that the goal would be

B5

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













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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David David.Edwards@fda.hhs.gov">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; Lovell, Randall A Jennifer.Jones@fda.hhs.gov; Ceric, Olgica Jennifer.Jones@fda.hhs.gov; Atkinson, Krisztina Z Jennifer.Jones@fda.hh

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">David.Rotstein@fda.hhs.gov; Hartogensis, Martine David.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 Lovell, Randall AReimschuessel, 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">Charlotte.Conway@fda.hhs.gov; Atkinson, Krisztina Z Krisztina.Atkinson@fda.hhs.gov; Hodges, April

<a href="mailto: 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 240-506-6763 (BB)













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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">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

<<u>Charlotte.Conway@fda.hhs.gov</u>>; Edwards, David <<u>David.Edwards@fda.hhs.gov</u>>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

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

<a href="mailto: ; DeLancey, Siobhan ; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William Burkholder@fda.hhs.gov>; Carey, Lauren < Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne, Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

| Thanks, Jen, very interesting issue! | | B5 | |
|--------------------------------------|-----------|----|-----------------------------|
| | B5 | | |
| I also cleaned up this one out! | B5 | | Thanks – 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

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 | | |
| | | | i |
| 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

B5 Yes, excellent work! One question though... **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 < Lee Anne 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 **B**5 From: Palmer, Lee Anne < Lee Anne . 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 Surkholder@fda.hhs.gov>, Carey, Lauren < Lauren.Carey@fda.hhs.gov>, Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>, Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>, 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 < Lee Anne. 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

В6 As luck would have it, I'm at CE today listening to talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne < Lee Anne. 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">David Rotstein@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 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: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <
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

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 < Lee Anne. Palmer@fda.hhs.gov>

Cc: Burkholder, William william.Burkholder@fda.hhs.gov; Carey, Lauren william.Burkholder@fda.hhs.gov; Carey, Lauren william.Burkholder@fda.hhs.gov; Carey, Lauren william.Burkholder@fda.hhs.gov; DeLancey, Siobhan william.Burkholder@fda.hhs.gov; DeLancey, Siobhan william.Burkholder@fda.hhs.gov; DeLancey, Siobhan william.Burkholder@fda.hhs.gov; DeLancey, Siobhan william.Burkholder@fda.hhs.gov; Reimschuessel, Renate william.Burkholder@fda.hhs.gov; Reimschuessel, Reimschue

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: 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 < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; 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 < Lee Anne . 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 <<u>Anne Norris@fda.hhs.gov</u>>, DeLancey, Siobhan <<u>Siobhan Delancey@fda.hhs.gov</u>>, 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 < <u>David.Rotstein@fda.hhs.gov</u>>; Hartogensis, Martine < <u>Martine.Hartogensis@fda.hhs.gov</u>>;

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 < Lee Anne. 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 < Lee Anne . Palmer@fda.hhs.gov >

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David < <u>David Rotstein@fda.hhs.gov</u>>, Hartogensis, Martine < <u>Martine Hartogensis@fda.hhs.gov</u>>,

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 Hi there - it is still VERY ROUGH (will final it up next week sometime) -**B**5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>; 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

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| Dounds very | 111 | 1115 | CHILL | 5 | ÷ | ŝ |

From: Palmer, Lee Anne < Lee Anne 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 Surkholder@fda.hhs.gov>, Carey, Lauren < Lauren. Carey@fda.hhs.gov>,

Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 PM

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

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

Cc: Burkholder, William < William. Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren. Carey@fda.hhs.gov >;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne. 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** ardiac 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:

В5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place 240-506-6763 (BB)













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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

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

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr.

B6

https://www.cvcavets.com/doctor_directory/

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

В5

B5

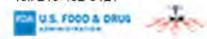
B5

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 <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>

Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.



Looping in Jen.

Thanks for the update!

dave

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













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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David < David Rotstein@fda.hhs.gov>; Palmer, Lee Anne < Lee Anne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

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: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

To:

Norris, Anne; Rotstein, David; Jones, Jennifer L; 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:

5/22/2018 1:12:50 PM

Subject:

RE: 800.267-DCM and meeting with Cardiac Care for Pets



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 <<u>David.Rotstein@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Edwards, David <<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>> Cc: Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Ceric,

FDA-CVM-FOIA-2019-1704-018024

Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah <<u>Sarah.Nemser@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z <<u>Krisztina.Atkinson@fda.hhs.gov</u>>; Hodges, April <<u>April.Hodges@fda.hhs.gov</u>>

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 < Reimschuessel@fda.hhs.gov >; Edwards, David

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William

 $<\!\underline{William.Burkholder@fda.hhs.gov}\!\!>; Palmer, Lee Anne <\!\underline{LeeAnne.Palmer@fda.hhs.gov}\!\!>; DeLancey, Siobhan \\$

<Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren < Lauren.Carey@fda.hhs.gov >; Lovell, Randall A < Randall.Lovell@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah < Sarah.Nemser@fda.hhs.gov >; Conway, Charlotte < Charlotte.Conway@fda.hhs.gov >; Atkinson, Krisztina Z < Krisztina.Atkinson@fda.hhs.gov >; Hodges, April < April.Hodges@fda.hhs.gov >

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne.

Agreed.

B5

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













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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

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

Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov >; Edwards, David

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William <<u>William.Burkholder@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; 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

; Burkholder, William < William. Burkholder@fda.hhs.gov; Palmer, Lee

Anne < Lee Anne. Palmer@fda.hhs.gov >; De Lancey, 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

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William

< William.Burkholder@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne.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

<<u>Sarah.Nemser@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>; 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

В5

CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place 240-506-6763 (BB)













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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David < David. Edwards@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >;

Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William

< William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne < Lee Anne.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



Just some food for thought rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1-240-402-5404 Fax 301-210-4685

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; Carey, Lauren Lovell, Randall A Reimschuessel, 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 <<u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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











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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!



Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

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">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



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

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

| | B5 | |
|---------------------------------------|----|-----------------------------|
| I also cleaned up and { this one out! | B5 | Thanks – hope we can figure |

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

В5

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

<<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>; 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 < Lee Anne . Palmer@fda.hhs.gov >, Hartogensis, Martine

<<u>Martine.Hartogensis@fda.hhs.gov</u>>, Jones, Jennifer L <<u>Jennifer.Jones@fda.hhs.gov</u>>, Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>

Cc: Burkholder, William William Surkholder@fda.hhs.gov>, Carey, Lauren Lauren Carey@fda.hhs.gov>, Norris, Anne Reimschuessel, Renate Reimschuessel, Reimschuessel@fda.hhs.gov, Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

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

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan Siobhan Delancey@fda.hhs.gov>, Hartogensis, Martine

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

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William "

<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

| To: Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs</u> < <u>Martine.Hartogensis@fda.hhs.gov</u> >; Jones, Jenni <david.rotstein@fda.hhs.gov></david.rotstein@fda.hhs.gov> | |
|--|---|
| <david rotstein@fda.hhs.gov=""></david> | |
| The state of the s | |
| | hhs.gov>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u> >; |
| | Randall A < Randall.Lovell@fda.hhs.gov>; Reimschuessel, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah |
| <sarah.nemser@fda.hhs.gov></sarah.nemser@fda.hhs.gov> | enc, Orgica <u>Orgica.Cenc@ida.nins.gov</u> >, Nemser, Saran |
| Subject: RE: 800.267-DCM and meetign with Card | diac Care for Pets |
| Subject: The seed of Point and Theodight Wall Care | |
| As luck would have it, I'm at CE today listening to | B6 from B6 talk about nutrition and |
| cardiomyopathies. See attached slide. | kananananananananananananananananananan |
| | |
| From: Palmer, Lee Anne < <u>LeeAnne Palmer@fda.</u> h | the gov> |
| Date: May 17, 2018 at 2:06:04 PM EDT | ills.gov |
| 그리 그렇게 그리고 적으로 있다면 하면 그리고 그 그렇게 하는 바람이 되었다. 그리고 그렇게 하지 않는 것이다. | da hhs.gov>, Jones, Jennifer L < Jennifer Jones@fda.hhs.gov |
| Rotstein, David David | |



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">Lauren.Carey@fda.hhs.gov; Norris, Anne < Anne.Norris@fda.hhs.gov; DeLancey, Siobhan < Siobhan.Delancey@fda.hhs.gov; Reimschuessel, Renate < Reimschuessel@fda.hhs.gov; Reimschuessel, 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

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 william.Burkholder@fda.hhs.gov; Carey, Lauren william.Burkholder@fda.hhs.gov; Carey, Lauren william.Burkholder@fda.hhs.gov; DeLancey, Siobhan william.Burkholder@fda.hhs.gov; DeLancey, Siobhan william.Burkholder@fda.hhs.gov; DeLancey, Siobhan william.Burkholder@fda.hhs.gov; Reimschuessel, Renate william.gov; Reimschuessel, Renate wi

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 < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; 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 < Lee Anne. Palmer@fda.hhs.gov >, Rotstein, David < David.Rotstein@fda.hhs.gov >, Jones,

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

Cc: Burkholder, William Surkholder@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 < Lee Anne. 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 This is fantastic.

From: Palmer, Lee Anne < Lee Anne. 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 Surkholder@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 Hi there – it is still VERY ROUGH (will final it up next week sometime) -В5 **B5**

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne



From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne < Lee Anne. 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 < Lee Anne. 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 Surkholder@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 –

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!

| 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></leeanne.palmer@fda.hhs.gov></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 |
| Good Afternoon, |
| I spoke with B6 @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point. |
| Just some basic information: |
| |
| B5 |
| |
| As a side note, there is a facebook page dedicated to this issue: |
| |
| https://www.facebook.com/groups/1952593284998859/about/ |
| |
| David Rotstein, DVM, MPVM, Dipl. ACVP |
| CVM Vet-LIRN Liaison |
| CVM OSC/DC/CERT |
| 7519 Standish Place |
| 240-506-6763 (BB) |
| FDA U.S. FOOD & DRUG |
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| ADMINISTRATION |
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| |
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| 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></leeanne.palmer@fda.hhs.gov> |
| Subject: RE: DCM |
| Tome#TITU (AEC TIM) |

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr.

FDA-CVM-FOIA-2019-1704-018038

Keep us posted!

Thanks again!

Martine

Hi Martine,



I'm happy to share more info as needed.

Jen

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





From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Palmer, Lee Anne < LeeAnne. Palmer@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >

Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

dave

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













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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

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 B5 B5 Vet-LIRN

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: Palmer, Lee Anne; Rotstein, David; Reimschuessel, Renate

Sent: 5/22/2018 12:51:51 PM

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Absolutely, Lee Anne.

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:49 AM

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

Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov> Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Jen, can you let me have a look before it goes to the wider distribution list?

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:47 AM

To: Rotstein, David < David.Rotstein@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne.Palmer@fda.hhs.gov >;

Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov> Subject: RE: 800,267-DCM and meeting with Cardiac Care for Pets

I'm typing up our plan this morning, and can send it to the larger group. What else would we like to share?

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:46 AM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >;

Reimschuessel, Renate < Renate. Reimschuessel@fda.hhs.gov> Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

The distribution list got a little bigger.

B5

B5

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











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From: 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 <<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z <<u>Krisztina.Atkinson@fda.hhs.gov</u>>; Hodges, April <a href="mailto: 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 Jones, Jennifer L 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 < <u>William.Burkholder@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; 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.

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













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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

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

Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David

<David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William

< William.Burkholder@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne.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

<<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z <<u>Krisztina.Atkinson@fda.hhs.gov</u>>; Hodges, April

<April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

В5

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

; 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

В5

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

<<u>William.Burkholder@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L

<<u>Jennifer.Jones@fda.hhs.gov</u>>; DeLancey, Siobhan <<u>Siobhan.Delancey@fda.hhs.gov</u>>

Cc: Carey, Lauren < Lauren. Carey@fda.hhs.gov >; Norris, Anne < Anne. Norris@fda.hhs.gov >; Lovell, Randall A

< Randall.Lovell@fda.hhs.gov >; Ceric, Olgica < Olgica.Ceric@fda.hhs.gov >; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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





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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>;

Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

<Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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">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 240-506-6763 (BB)













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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!

Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >;

Hartogensis, Martine < Martine < Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan. Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <<u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; 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



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 <<u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah <<u>Sarah.Nemser@fda.hhs.gov</u>>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

| Thanks, Jen, very interesting issue! | | B5 |
|--------------------------------------|----|-----------------------------|
| | B5 | |
| I also cleaned up and this one out! | B5 | Thanks – 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

<<u>Siobhan.Delancey@fda.hhs.gov</u>>; Palmer, Lee Anne <<u>LeeAnne.Palmer@fda.hhs.gov</u>>; Rotstein, David <<u>David.Rotstein@fda.hhs.gov</u>>

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 < 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>

- Odran. Nemsen (Citatinis. 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 TON U.S. FOOD & DRUG 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

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 < Lee Anne Palmer@fda.hhs.gov >, Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David

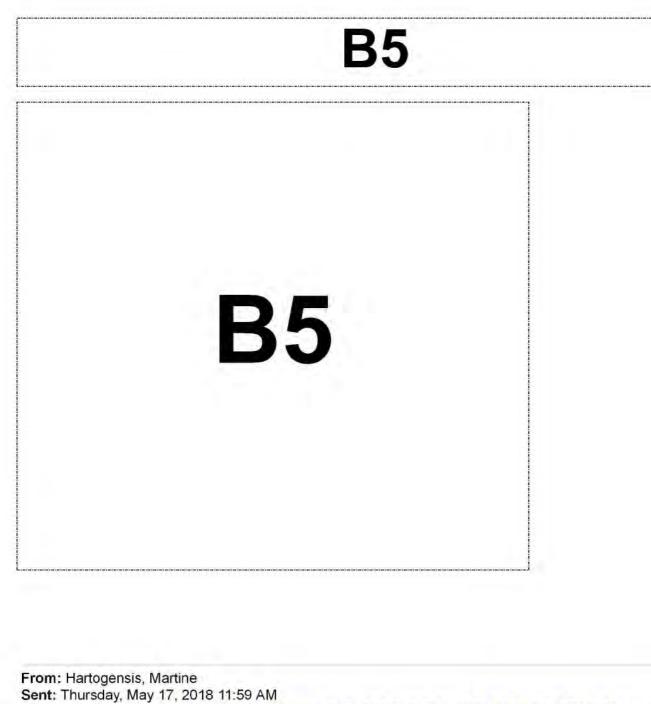
<David.Rotstein@fda.hhs.gov>

Norris, Anne <Anne Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate < Renate Reimschuessel@fda.hhs.gov>, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah, Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

From: Palmer, Lee Anne < Lee Anne. 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 < Lee Anne. 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 **B6** As luck would have it, I'm at CE today listening to talk about nutrition and cardiomyopathies. See attached slide. From: Palmer, Lee Anne < Lee Anne. 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> 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** HI there – is the slide set for tomorrow's meeting? Great work!



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

Lee Anne < Lee Anne. 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 Reimschuessel@fda.hhs.gov; Reimschuessel, 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 | |
|-----------------------|----|--|
| | DE | |
| | DO | |
| | | |

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 < <u>Martine.Hartogensis@fda.hhs.gov</u>>; Palmer, Lee Anne < <u>LeeAnne.Palmer@fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>

Cc: Burkholder, William < <u>William.Burkholder@fda.hhs.gov</u>>; Carey, Lauren < <u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; 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 < Lee Anne. 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 From: Rotstein, David Sent: Friday, May 11, 2018 4:14 PM To: Palmer, Lee Anne < Lee Anne. 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** This is fantastic. From: Palmer, Lee Anne < Lee Anne 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 " Norris, Anne < Anne. Norris@fda.hhs.gov>, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>, Lovell, Randall A < Randall.Lovell@fda.hhs.gov>

B5

B5

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there



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 < Lee Anne. 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 < Lee Anne. 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 Surkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>,

Norris, Anne < Anne, Norris@fda.hhs.gov>, DeLancey, Siobhan < Siobhan Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 PM

To: Rotstein, David David Rotstein@fda.hhs.gov; Jones, Jennifer L Jennifer.Jones@fda.hhs.gov; Palmer,

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >;

Norris, Anne < Anne. Norris@fda.hhs.gov >; DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne. 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.

B5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

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













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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

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

Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr.

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed. Jen

Jennifer Jones, DVM

Veterinary Medical Officer Tel: 240-402-5421





From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov >; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov >

Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.



Looping in Jen.

Thanks for the update!

dave

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





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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David David David Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov

Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

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

В5

35

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To: Palmer, Lee Anne; Jones, Jennifer L; Reimschuessel, Renate

Sent: 5/22/2018 12:50:31 PM

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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| |

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





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From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:48 AM

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

Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

I think it expanded late Friday. Dave, did you mean to include an attachment? Wasn't sure which info. Thanks.

From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:46 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>> **Subject:** RE: 800.267-DCM and meeting with Cardiac Care for Pets

The distribution list got a little bigger.

B5

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











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From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:39 AM

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 <<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z <<u>Krisztina.Atkinson@fda.hhs.gov</u>>; Hodges, April <a href="mailto: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

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William < William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne < Lee Anne.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.

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

240-506-6763 (BB)











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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

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

Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; 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

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

<<u>David.Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; Burkholder, William

< William.Burkholder@fda.hhs.gov >; Palmer, Lee Anne < Lee Anne.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

<<u>Sarah.Nemser@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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





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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David David David.Rotstein@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

<u>April.Hodges@fda.hhs.gov</u>>
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 240-506-6763 (BB)











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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!

Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only

reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne < Lee Anne. 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 <<u>Lauren.Carey@fda.hhs.gov</u>>; Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<<u>Charlotte.Conway@fda.hhs.gov</u>>; Edwards, David <<u>David.Edwards@fda.hhs.gov</u>>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets



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! | | В5 | |
|--------------------------------------|----|----|-----------------------------|
| | B5 | | |
| I also cleaned up and this one out! | B5 | | Thanks – hope we can figure |
| Lee Anne | | Q | |

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

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. Surkholder@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





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 <<u>Jennifer.Jones@fda.hhs.gov</u>>; 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

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

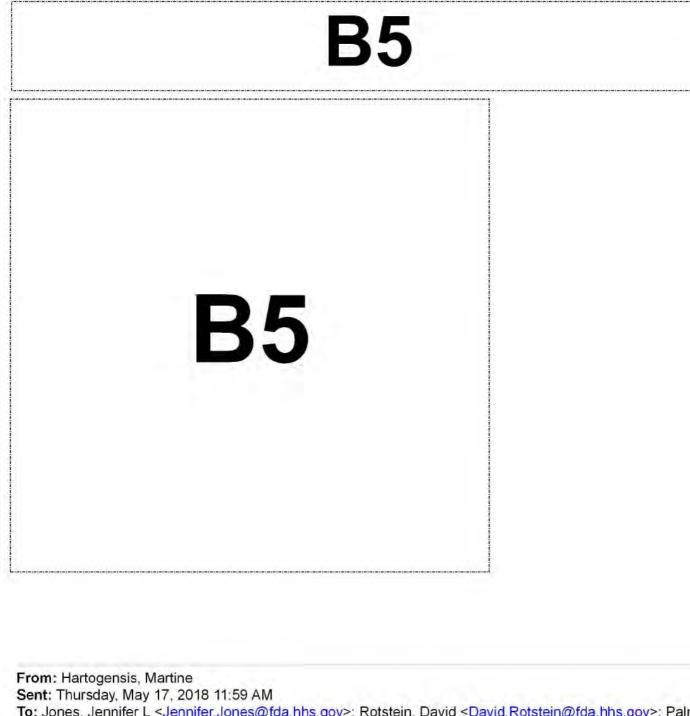
<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William "Milliam Surkholder@fda.hhs.gov">"Milliam Surkholder@fda.hhs.gov">"M

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the

| vegan formulation - and a few other niche brands I didn't catch. |
|--|
| From: Palmer, Lee Anne < Lee Anne. 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 |
| < <u>Sarah.Nemser@fda.hhs.gov</u> > |
| 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</leeanne.palmer@fda.hhs.gov> |
| <a href="mailto:square: wind and a square: wind a square:</td></tr><tr><td><pre><David.Rotstein@fda.hhs.gov></pre></td></tr><tr><td>Cc: Burkholder, William < William.Burkholder@fda.hhs.gov >; Carey, Lauren < Lauren.Carey@fda.hhs.gov >;</td></tr><tr><td>Norris, Anne <<u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A <<u>Randall.Lovell@fda.hhs.gov</u>>; Reimschuessel,</td></tr><tr><td>Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Ceric, Olgica <<u>Olgica.Ceric@fda.hhs.gov</u>>; Nemser, Sarah <<u>Sarah.Nemser@fda.hhs.gov</u>></td></tr><tr><td>Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets</td></tr><tr><td></td></tr><tr><td>As luck would have it, I'm at CE today listening to B6 from B6 talk about nutrition and</td></tr><tr><td>cardiomyopathies. See attached slide.</td></tr><tr><td></td></tr><tr><td>From: Palmer, Lee Anne < Lee Anne. Palmer @fda.hhs.gov></td></tr><tr><td>Date: May 17, 2018 at 2:06:04 PM EDT</td></tr><tr><td>To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov >, Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov ></td></tr><tr><td>Rotstein, David < David.Rotstein@fda.hhs.gov></td></tr><tr><td>Cc: Burkholder, William < William Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren Carey@fda.hhs.gov >,</td></tr><tr><td>Norris, Anne <anne.Norris@fda.hhs.gov>, DeLancey, Siobhan , 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 - B5 |
| B5 |
| |
| B5 |
| |
| |



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 Just a few questions.

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David 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 < Reimschuessel@fda.hhs.gov; Reimschuessel, 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.Delancey@fda.hhs.gov>; Lovell,

Randall A < Randall Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5 Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David David.Rotstein@fda.hhs.gov>, Jones,

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

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

Norris, Anne < Anne. Norris@fda.hhs.gov >, DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov >, Lovell,

Randall A < Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting.

B5

. . . .

B5

Martine

From: Palmer, Lee Anne Sent: Friday, May 11, 2018 4:30 PM To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov> Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A < Randall.Lovell@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets **B**5 From: Rotstein, David Sent: Friday, May 11, 2018 4:14 PM To: Palmer, Lee Anne < Lee Anne. 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** This is fantastic. From: Palmer, Lee Anne < Lee Anne. 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 Surkholder@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

Hi there -



I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne



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 < Lee Anne. 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 – B5

B5

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 PM

To: Rotstein, David Pavid.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,

D Cardiac Care for Pets. He is going to look into times/dates with the cardiologists I spoke with **B6** there and we can set the meeting up from that point.

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

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













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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 Dr.

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





Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine < Martine. Hartogensis@fda.hhs.gov>; Palmer, Lee Anne < Lee Anne. Palmer@fda.hhs.gov>; Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Subject: RE: DCM

Martine.

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.



Looping in Jen.

Thanks for the update!

dave

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





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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David David Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov

Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

| B5 | |
|----|--|
| 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

| B5 | 1 |
|--------|---|
| | |
| B5 | |
| 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: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-

MHARTOGE>

To:

Reimschuessel, Renate; Jones, Jennifer L.

CC: Sent: Rotstein, David

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: 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

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 a fda.hhs.gov>; Reimschuessel, Renate < Reimschuessel a fda.hhs.gov>

Cc: Rotstein, David < David Rotstein a 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 a fda.hhs.gov >; Palmer, Lee Anne < Lee Anne Palmer a fda.hhs.gov >; Rotstein, David < David Rotstein a fda hhs gov >; Reimschuessel, Renate < Renate Reimschuessel a fda hhs gov >; Edwards, David < David Edwards a fda hhs.gov : Hartogensis. Martine < Martine Hartogensis a fda hhs.gov : Burkholder, William

<William Burkholder@fda.hhs.gov>; DeLancey, Siobhan Siobhan Delancey@fda.hhs.gov> Cc: Carey, Lauren < Lauren. Carey a fda. hhs. gov >; Lovell, Randall A < Randall. Lovell a 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, 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 DA U.S. FOOD & DRUG From: Norris, Anne Sent: Tuesday, May 22, 2018 9:24 AM To: Palmer, Lee Anne < Lee Anne Palmer afda.hhs.gov >; Rotstein, David < David Rotstein afda.hhs.gov >; Jones, Jennifer L < Jennifer Jones a fda hhs.gov >; Reimschuessel, Renate < Reimschuessel a fda hhs.gov >; Edwards, David < <u>David Edwards@fda.hhs.gov</u>>; Hartogensis, Martine < <u>Martine Hartogensis@fda.hhs.gov</u>>; 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 a fda.hhs.gov >; Nemser, Sarah < Sarah Nemser a fda.hhs.gov >; Conway, Charlotte < Charlotte Conway@fda.hhs.gov>; Atkinson, Krisztina Z < Krisztina, Atkinson@fda.hhs.gov>; Hodges, April

<April Hodges a 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 a fda. hhs. gov >; Rotstein, David < David Rotstein a fda. hhs. gov >; Jones, Jennifer L < <u>Jennifer.Jones@fda.hhs.gov</u>>; Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u>>; Edwards, David <<u>David Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine Hartogensis@fda.hhs.gov</u>>; 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

<<u>Olgica Ceric@fda.hhs.gov</u>>; Nemser, Sarah <<u>Sarah Nemser@fda.hhs.gov</u>>; Conway, Charlotte

< Charlotte Conway@fda.hhs.gov>; Atkinson, Krisztina Z < Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April Hodges a 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">LeeAnne.Palmer@fda.hhs.gov; Rotstein, David David.Rotstein@fda.hhs.gov; Jones, Jennifer

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

< <u>Charlotte Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z < <u>Krisztina Atkinson@fda.hhs.gov</u>>; Hodges, April

<April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

That should be fine

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

<<u>Jennifer.Jones@fda.hhs.gov</u>>; Reimschuessel, Renate <<u>Renate.Reimschuessel@fda.hhs.gov</u>>; Edwards, David

<<u>David Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine.Hartogensis@fda.hhs.gov</u>>; 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 a fda.hhs.gov>

Subject: RE: 800,267-DCM and meeting with Cardiac Care for Pets

Anne.

Agreed.

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













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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L < Jennifer Jones a fda.hhs.gov>; Rotstein, David < David Rotstein a 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 a fda.hhs.gov>; Atkinson, Krisztina Z < Krisztina Atkinson a 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 a fda.hhs.gov>; Reimschuessel, Renate < Renate.Reimschuessel a fda.hhs.gov>; Edwards, David County Edwards afda.hhs.gov ; Hartogensis, Martine (Martine Hartogensis afda.hhs.gov); Burkholder, William William William William William William.Burkholder@fda.hhs.gov

Palmer, Lee Anne William.Burkhol <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

<<u>Sarah Nemser@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte Conway@fda.hhs.gov</u>>; 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





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 Jones, Jennifer L 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



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













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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David < David Edwards @fda.hhs.gov >; Rotstein, David < David Rotstein @fda.hhs.gov >; Hartogensis, Martine Martine 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. Delancev@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

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets



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 a fda.hhs.gov >; Hartogensis, Martine < Martine.Hartogensis a fda.hhs.gov >;

Burkholder, William William.Burkholder@fda.hhs.gov; Jones,

Jennifer L < Jennifer Jones a fda.hhs.gov>; DeLancey, Siobhan < Siobhan Delancey a fda.hhs.gov>

Cc: Carey, Lauren < Lauren, Carey afda.hhs.gov >; Norris, Anne < Anne Norris afda.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

< <u>Charlotte Conway a fda hhs.gov</u>>; Atkinson, Krisztina Z < <u>Krisztina Atkinson a fda hhs.gov</u>>; Hodges, April

<April Hodges@fda.hhs.gov>

Subject: RE: 800,267-DCM and meetign with Cardiac Care for Pets

Hi everyone,



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 afda.hhs.gov >; Norris, Anne < Anne.Norris afda.hhs.gov >; Lovell, Randall A < Randall Loyell @fda.hhs.gov>; Reimschuessel, Renate < Renate, Reimschuessel @fda.hhs.gov>; Ceric, Olgica

<Olgica Cerica fda.hhs.gov>; Nemser, Sarah <Sarah Nemser a fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina. Atkinson@fda.hhs.gov>: Hodges, April <April Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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













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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William Surkholder afda.hhs.gov>; Palmer, Lee Anne Schene Palmer afda.hhs.gov>; Jones, Jennifer L < Jennifer. Jones @fda.hhs.gov>; DeLancey, Siobhan < Siobhan Delancey @fda.hhs.gov>; Rotstein, David <David Rotstein a fda.hhs.gov>

Cc: Carey, Lauren < Lauren, Carey a fda.hhs.gov >: Norris, Anne < Anne, Norris a fda.hhs.gov >; Lovell, Randall A <Randall.Loyell@fda.hhs.gov>; Reimschuessel. Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric. Olgica

< Olgica. Ceric a fda. hhs.gov>; Nemser, Sarah < Sarah Nemser a fda. hhs.gov>; Conway. Charlotte

< Charlotte. Conway@fda.hhs.gov>; Edwards, David < David. Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

< Krisztina. Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov; Jones, Jennifer L 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; Rotstein, David

Cc: Carey, Lauren < Lauren. Carev@fda.hhs.gov>; Norris, Anne < Anne. Norris@fda.hhs.gov>; Lovell, Randall A < Randall Lovell@fda.hhs.gov>; Reimschuessel, Renate < Reimschuessel@fda.hhs.gov>; Ceric, Olgica

< Olgica Ceric a fda.hhs.gov >; Nemser, Sarah < Sarah Nemser a fda.hhs.gov >; Conway, Charlotte

< Charlotte Conway a fda.hhs.gov >; Edwards, David < David Edwards a fda.hhs.gov >; Atkinson, Krisztina Z

<Krisztina Atkinson a 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 a fda.hhs.gov>; Hartogensis, Martine < Martine Hartogensis a fda.hhs.gov>;

DeLancey, Siobhan Siobhan. Delancey a fda.hhs.gov>; Rotstein, David Sovid Rotstein a fda.hhs.gov>

Cc: Burkholder, William < William Burkholder a fda.hhs.gov>; Carey, Lauren < Lauren Carey a fda.hhs.gov>; Norris, Anne

<Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate

< Renate Reimschuessel a fda.hhs.gov>; Ceric, Olgica < Olgica Ceric a 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

I also cleaned up and out!

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine < Martine Hartogensis a fda.hhs.gov >; DeLancey, Siobhan Siobhan Delancey a fda.hhs.gov >;

Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David David Rotstein@fda.hhs.gov>

Cc: Burkholder, William Surkholder a fda.hhs.gov>; Carey, Lauren < Lauren Carey a 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: 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 < Lee Anne.Palmer@fda.hhs.gov>; Rotstein, David < David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William Burkholder a fda.hhs.gov >; Carey, Lauren < Lauren Carey a fda.hhs.gov >; Norris, Anne

<a href="mailto: , Reimschuessel, Renate Anne.Norris@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 ; Rotstein, David ; Rotstein, David ;

Cc: Burkholder, William Surkholder@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 a fda.hhs.gov>; Ceric, Olgica < Olgica Ceric a 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

DA U.S. FOOD & DRUG



From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey. Siobhan Siobhan Siobhan Siobhan Siobhan.Delancey@fda.hhs.gov; Palmer, Lee Anne LeeAnne.Palmer@fda.hhs.gov; Jones,

Jennifer L < Jennifer Jones a fda hhs.gov>; Rotstein, David < David Rotstein a fda hhs.gov>

Cc: Burkholder, William < William Burkholder afda.hhs.gov >; Carey, Lauren < Lauren, Carey afda.hhs.gov >; Norris, Anne

B5

<a href="mailto: Anne.Norris@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!

DE

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 < Lee Anne. 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>

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

| vegan formulation - and a few other niche brands I didn't catch. |
|--|
| |
| From: Palmer, Lee Anne < Lee Anne 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 < <u>Anne.Norris@fda.hhs.gov</u> >, Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u> >, Reimschuessel, Renate < <u>Renate.Reimschuessel@fda.hhs.gov</u> >, Ceric, Olgica < <u>Olgica.Ceric@fda.hhs.gov</u> >, Nemser, Sarah |
| < <u>Sarah.Nemser@fda.hhs.gov</u> > 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 Lee Anne Palmer a fda.hhs.gov ; Hartogensis, Martine Martine.Hartogensis/a fda.hhs.gov ; |
| Jones, Jennifer L < Jennifer. Jones a fda. hhs.gov > , Rotstein, David < David. Rotstein a fda. hhs.gov > |
| Cc: Burkholder, William William.Burkholder@fda.hhs.gov ; Carey, Lauren Lauren.Carey@fda.hhs.gov ; Norris, Anne Norris@fda.hhs.gov; Lovell, Randall A Reimschuessel, 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 < Lee Anne. 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 < <u>David.Rotstein@fda.hhs.gov</u> > |
| 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 < 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 – į |
| B5 |
| B5 |
| |

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the



B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L < Jennifer Jones a fda.hhs.gov >; Rotstein, David < David Rotstein a fda.hhs.gov >; Palmer, Lee Anne

<LeeAnne Palmer a fda.hhs.gov>

Cc: Burkholder, William < William Burkholder a fda.hhs.gov>; Carey, Lauren < Lauren Carey a 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

Excellent work Jen!!

Just a few questions. 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 <Lee Anne. Palmer@fda.hhs.gov> Cc: Burkholder, William < William Burkholder afda.hhs.gov>; Carey, Lauren < Lauren Carev afda.hhs.gov>; Norris, Anne <a href="mailto: , Lovell, Randall A , 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 В5 Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 U.S. FOOD & DRU From: Rotstein, David Sent: Monday, May 14, 2018 10:22 AM To: Hartogensis, Martine Martine Martine Martine.Hartogensis@fda.hhs.gov; Palmer, Lee Anne Martine.Hartogensis@fda.hhs.gov; Jones, Jennifer L < Jennifer. Jones a fda. hhs.gov> Cc: Burkholder, William < William Burkholder a fda.hhs.gov>; Carey, Lauren < Lauren Carey a fda.hhs.gov>; Norris, Anne <Anne Norris@fda.hhs.gov>; DeLancev, Siobhan Siobhan Delancev@fda.hhs.gov; Lovell, Randall A <Randall.Lovell@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets 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 Lee Anne.Palmer@fda.hhs.gov, Rotstein, David David.Rotstein@fda.hhs.gov, Jones, Jennifer L < Jennifer. Jones @fda.hhs.gov> Cc: Burkholder, William " 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 a fda.hhs.gov >; Hartogensis, Martine < Martine Hartogensis a fda.hhs.gov >; Jones,

Jennifer L < Jennifer Jones a fda.hhs.gov> Cc: Burkholder, William Surkholder a fda.hhs.gov>; Carey, Lauren < Lauren, Carey a 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 **B**5 From: Rotstein, David Sent: Friday, May 11, 2018 4:14 PM To: Palmer, Lee Anne <Lee Anne Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine Hartogensis@fda.hhs.gov>; Jones, Jennifer L < Jennifer Jones a fda.hhs.gov> Cc: Burkholder, William Surkholder a fda.hhs.gov>; Carey, Lauren < Lauren Carey a fda.hhs.gov>; Norris, Anne ; DeLancey, Siobhan ; Lovell, Randall A <Randall.Lovell@fda.hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets Lee Anne. **B5** This is fantastic. From: Palmer, Lee Anne < Lee Anne. 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 Surkholder@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** Hi there - i **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 ; Hartogensis, Martine ;

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

Cc: Burkholder, William Surkholder a fda.hhs.gov >: Carey, Lauren < Lauren, Carey a 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 < Lee Anne 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 Surkholder@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>

<a href="mailto: 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 a fda. hhs.gov >; Jones, Jennifer L < Jennifer. Jones a fda. hhs.gov >; Palmer,

Lee Anne <Lee Anne. Palmer a fda.hhs.gov>

Cc: Burkholder, William < William Burkholder a fda.hhs.gov >; Carey, Lauren < Lauren Carey a fda.hhs.gov >; Norris, Anne

; DeLancey, Siobhan

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with B6 a 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.

B5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

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













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From: Hartogensis. Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L < Jennifer. Jones a fda.hhs.gov >; Rotstein, David < David. Rotstein a fda.hhs.gov >; Palmer, Lee Anne

<Lee Anne. Palmer a fda.hhs.gov>

Subject: RE: DCM

| B6 | |
|---|--|
| keep us posted! | |
| Thanks again! | |
| Martine | |
| li Martine. | |
| | |
| | B5 |
| | |
| | |
| m happy to share more info as needed. | |
| en | |
| ennifer Jones, DVM leterinary Medical Officer let: 240-402-5421 | |
| U.S. FOOD & DRUN | |
| From: Rotstein, David | |
| Sent: Tuesday, May 08, 2018 9:45 AM So: Hartogensis, Martine < Martine, Hartogensis of ones, Jennifer L < Jennifer Jones of fda.hhs.gov > Subject: RE: DCM | ufda.hhs.gov>; Palmer, Lee Anne < Lee Anne Palmer a fda.hhs.gov>; |
| Martine, | |
| en and I spoke with cardiologists from NCSU ar | nd a few other institutions. That's how we were able to get the informat |
| | |
| | B5 |
| | |

Thanks for the update

dave

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











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From: Hartogensis, Martine

Sent: Tucsday, May 08, 2018 9:00 AM

To: Rotstein, David David Rotstein@fda.hhs.gov> Palmer, Lee Anne Lee Anne Lee Anne Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

| | B5 |
|----|----|
| B5 | |
| B5 | 1 |

Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogensis, Martine < Martine Hartogensis a 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: Hartogensis, 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

RE: 800.267-DCM and meeting with Cardiac Care for Pets Subject:

Excellent point!

Martine

From: Rotstein, David < David Rotstein@fda.hhs.gov>

Date: June 11, 2018 at 2:39:55 PM EDT

To: Hartogensis, Martine < Martine Hartogensis@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 240-506-6763 (BB)













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From: Hartogensis. Martine

Sent: Monday, June 11, 2018 2:37 PM

To: Reimschuessel, Renate < Renate Reimschuessel a fda.hhs.gov>, Jones, Jennifer L < Jennifer.Jones a fda.hhs.gov>

Cc: Rotstein, David \(David \text{Rotstein} \(\hat{a} \) 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-LIKN

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 a fda.hhs.gov >; Reimschuessel, Renate < Reimschuessel a fda.hhs.gov >

Cc: Rotstein, David < David Rotstein a 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 a fda.hhs.gov >; Palmer, Lee Anne < Lee Anne Palmer a fda.hhs.gov >; Rotstein, David

- < <u>David Rotstein a fda.hhs.gov</u>>, Reimschuessel, Renate < <u>Renate Reimschuessel a fda.hhs.gov</u>>, 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 a fda. hhs.gov >; Nemser, Sarah < Sarah Nemser a fda. hhs.gov >; Conway, Charlotte
- < <u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z < <u>Krisztina.Atkinson@fda.hhs.gov</u>>; 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,

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 < Lee Anne . Palmer@fda.hhs.gov >; Rotstein, David < David.Rotstein@fda.hhs.gov >; Jones, Jennifer

L < Jennifer Jones@fda.hhs.gov >; Reimschuessel, Renate < Reimschuessel@fda.hhs.gov >; Edwards, David

<<u>David Edwards@fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine Hartogensis@fda.hhs.gov</u>>; 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 a fda. hhs.gov >; Nemser, Sarah < Sarah. Nemser a 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/a/fda.hhs.gov >; Rotstein, David < David. Rotstein/a/fda.hhs.gov >; Jones, Jennifer L

<a href="Self-align: Align: Self-align: Align: Alig

<<u>David Edwards a fda.hhs.gov</u>>; Hartogensis, Martine <<u>Martine Hartogensis a fda.hhs.gov</u>>; 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 a 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 |
| ; DeLancey, Siobhan |
| 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 |
| < <u>Charlotte.Conway@fda.hhs.gov</u> >; Atkinson, Krisztina Z < <u>Krisztina.Atkinson@fda.hhs.gov</u> >; Hodges, April < <u>April.Hodges@fda.hhs.gov</u> > |
| Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets |
| |
| That should be fine 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</renate.reimschuessel@fda.hhs.gov></jennifer.jones@fda.hhs.gov> |
| <david.edwards @fda.hhs.gov="">; Hartogensis, Martine <martine.hartogensis@fda.hhs.gov>; Burkholder, William</martine.hartogensis@fda.hhs.gov></david.edwards> |
| < 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 |
| < <u>Olgica Ceric@fda.hhs.gov</u> >; Nemser, Sarah < <u>Sarah Nemser@fda.hhs.gov</u> >; Conway, Charlotte |
| ; Atkinson, Krisztina Z ; Hodges, April |
| < April Hodges a 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 |
| Palmer, Lee Anne (Martine:Hartogensis@fda.hhs.gov); Palmer, Lee Anne |
| < Lee Anne. Palmer@fda.hhs.gov >; De Lancey, Siobhan Siobhan Delancey@fda.hhs.gov > Con Const. Lancey Charles Const. Clarical Delancey & Fda.hhs.gov > Const. Clarical Delancey & |
| 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 |
| <a hre<="" td=""> |
| , Akkinson, Kriszuna 2 , Hodges, April-Hodges@fda.hhs.gov |
| Subject: RE: 800,267-DCM and meeting with Cardiac Care for Pets |
| |
| Anne, |
| Agreed. |
| |
| DE |
| B5 |
| |

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











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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L < Jennifer Jones a fda.hhs.gov>; Rotstein, David < David Rotstein a fda.hhs.gov>; Reimschuessel, Renate < Renate Reimschuessel a fda.hhs.gov>; Edwards, David < David Edwards a fda.hhs.gov>; Hartogensis, Martine <Martine Hartogensis@fda.hhs.gov>: Burkholder, William <William Burkholder@fda.hhs.gov>: Palmer, Lee Anne

<Lee Anne. Palmer@fda.hhs.gov>; De Lancey, 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 a fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:31 AM

To: Rotstein, David ; Reimschuessel, Renate ; Reimschuessel, Reimschue Edwards, David
 Hartogensis, Martine
 Burkholder.
 Burkholder. William <William Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne Palmer@fda.hhs.gov>; DeLancev, 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

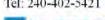
<<u>Sarah, Nemser@fda.hhs.gov</u>>; Conway, Charlotte <<u>Charlotte.Conway@fda.hhs.gov</u>>; Atkinson, Krisztina Z

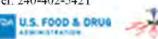
< Krisztina. Atkinson@fda.hhs.gov>; Hodges, April < April. Hodges@fda.hhs.gov>

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.Delancev@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

< Randall Lovell a fda.hhs.gov >; Ceric, Olgica < Olgica Ceric a fda.hhs.gov >; Nemser, Sarah

Sarah Nemser a fda.hhs.gov>; Conway, Charlotte < Charlotte. Conway a fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina. Atkinson/a/fda.hhs.gov>; Hodges, April <April. Hodges/a/fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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





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From: Reimschuessel. Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David < David Edwards @fda.hhs.gov >; Rotstein, David < David Rotstein @fda.hhs.gov >; Hartogensis, Martine < Martine Hartogensis @fda.hhs.gov >; Burkholder, William < William Burkholder @fda.hhs.gov >; Palmer, Lee Anne < Lee Anne Palmer @fda.hhs.gov >; Jones, Jennifer L < Jennifer Jones @fda.hhs.gov >; De Lancey, 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 a fda.hhs.gov>; Conway, Charlotte <Charlotte Conway a 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 a fda.hhs.gov>; DeLancey, Siobhan <Siobhan Delancey a 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 < Lee Anne 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 a fda.hhs.gov>; Reimschuessel, Renate < Renate Reimschuessel a fda.hhs.gov>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina Atkinson@fda.hhs.gov>: Hodges, April <April Hodges@fda.hhs.gov>

Subject: RE: 800,267-DCM and meetign with Cardiac Care for Pets

B5

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













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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William < William Burkholder a fda.hhs.gov >; Palmer, Lee Anne < Lee Anne Palmer a fda.hhs.gov >; Jones, Jennifer L Sennifer Jones afda hhs.gov >; DeLancey, Siobhan Siobhan Delancey afda hhs.gov >; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren < Lauren, Carey a fda.hhs.gov>; Norris, Anne < Anne Norris a 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!



Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William Sent: Friday, May 18, 2018 5:04 PM To: Palmer, Lee Anne <Lee Anne 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 afda.hhs.gov>: Norris, Anne < Anne Norris afda.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 a fda.hhs.gov>; Hartogensis, Martine < Martine Hartogensis a fda.hhs.gov>; DeLancey, Siobhan Siobhan Delancey a fda.hhs.gov>; Rotstein, David Sovid Rotstein a fda.hhs.gov> Cc: Burkholder, William < William Burkholder a fda.hhs.gov>; Carey, Lauren < Lauren Carey a 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

Thanks, Jen, very interesting issue!

FDA-CVM-FOIA-2019-1704-018105

B5

| I also cleaned up and | B5 | Thanks – hope we can figure this one |
|--|-------------------------------------|---|
| out! | | |
| Lee Anne | | |
| From: Jones, Jennifer L | | |
| Sent: Friday, May 18, 2018 1:54 I | M | |
| To: Hartogensis, Martine < Martin | e.Hartogensis@fda.hhs.gov>; DeL | ancey, Siobhan < Siobhan Delancey@fda.hhs.gov>; |
| Palmer, Lee Anne < Lee Anne Paln | ner@fda.hhs.gov>; Rotstein, David | d < David Rotstein a fda.hhs.gov> |
| Cc: Burkholder, William < William | n.Burkholder@fda.hhs.gov>; Care | y, Lauren < Lauren Carey@fda.hhs.gov>; Norris, Anne |
| <anne.norris@fda.hhs.gov>; Lov</anne.norris@fda.hhs.gov> | ell, Randall A < Randall. Lovella f | da.hhs.gov>; Reimschuessel, Renate |
| <renate.reimschuessel@fda.hhs.< td=""><td>gov>; Ceric, Olgica < Olgica.Ceric</td><td>@fda.hhs.gov>; Nemser, Sarah</td></renate.reimschuessel@fda.hhs.<> | gov>; Ceric, Olgica < Olgica.Ceric | @fda.hhs.gov>; Nemser, Sarah |

B5

Any other ideas or suggestions?

<Sarah.Nemser@fda.hhs.gov>

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 < Lee Anne 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

< <u>Anne.Norris@fda.hhs.gov</u>>; Lovell, Randall A < <u>Randall.Lovell@fda.hhs.gov</u>>; 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

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 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 a fda hhs.gov>; Carey, Lauren < Lauren Carey a fda hhs.gov>; Norris, Anne

< Anne. Norris a fda. hhs.gov >; Lovell, Randall A < Randall. Lovell a 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 afda.hhs.gov>; Palmer, Lee Anne LeeAnne Palmer afda.hhs.gov>; Jones,

Jennifer L < Jennifer Jones a fda hhs.gov>; Rotstein. David < David Rotstein a fda hhs.gov>

Cc: Burkholder, William : 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 a fda.hhs.gov>; Ceric, Olgica < Olgica Ceric a fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5 Yes, excellent work! **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 < Lee Anne. Palmer@fda.hhs.gov >, Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William < William Burkholder@fda.hhs.gov >, Carey, Lauren < Lauren.Carey@fda.hhs.gov >, Norris, Anne < Anne. Norris@fda.hhs.gov>, Lovell, Randall A < Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate < Renate Reimschuessel@fda.hhs.gov>, Ceric, Olgica < Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

From: Palmer, Lee Anne < Lee Anne 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 < Lee Anne Palmer a fda.hhs.gov>: Hartogensis. Martine < Martine. Hartogensis a fda.hhs.gov>: Jones, Jennifer L < Jennifer, Jones a fda.hhs.gov>; Rotstein. David < David.Rotstein a fda.hhs.gov> Cc: Burkholder, William < William Burkholder afda.hhs.gov>; Carey, Lauren < Lauren Carey afda.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 a 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 < Lee Anne 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 Lones@fda.hhs.gov) Rotstein, David < David Rotstein@fda.hhs.gov> Cc: Burkholder, William William Surkholder@fda.hhs.gov, Carey, Lauren Lauren Norris, Anne , DeLancey, Siobhan , 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 HI there **B5 B**5



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

<Lee Anne. Palmer@fda.hhs.gov>

Cc: Burkholder, William William.Burkholder@fda.hhs.gov; Carey, Lauren Lauren.Carey@fda.hhs.gov; Norris, Anne

; DeLancey. Siobhan ; 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

| ust a few questions. | B5 | |
|--|----|--|
| The state of the s | | |
| | B5 | |

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David , Hartogensis, Martine , Palmer, Pavid , Palmer, Pavid , Palmer, Pavid Rotstein@fda.hhs.gov

Lee Anne < Lee Anne. Palmer a fda.hhs.gov>

Cc: Burkholder, William < William Burkholder afda.hhs.gov>: Carey, Lauren < Lauren, Carey afda.hhs.gov>: Norris, Anne

<Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A

< Randall Lovell a fda.hhs.gov >; Reimschuessel, Renate < Renate Reimschuessel a 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 a fda.hhs.gov >; Palmer, Lee Anne < Lee Anne Palmer a fda.hhs.gov >;

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

Cc: Burkholder, William < William Burkholder a fda.hhs.gov >; Carey, Lauren < Lauren Carey a fda.hhs.gov >; Norris, Anne

< Anne Norris a fda.hhs.gov>; DeLancey, Siobhan < Siobhan Delancey a 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>

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 a fda.hhs.gov >; Hartogensis, Martine < Martine. Hartogensis a fda.hhs.gov >; Jones,

Jennifer L < Jennifer Jones a fda.hhs.gov>

Cc: Burkholder, William Surkholder a fda.hhs.gov >; Carey, Lauren Suren, Carey a fda.hhs.gov >; Norris, Anne

<a href="mailto: , Lovell, Randall A , 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 < Lee Anne Palmer a fda.hhs.gov >: Hartogensis. Martine < Martine Hartogensis a fda.hhs.gov >:

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

Cc: Burkholder, William Surkholder afda.hhs.gov>: Carey, Lauren Carey afda.hhs.gov>: Norris, Anne

<a href="mailto: . DeLancey, Siobhan . Lovell, Randall A

<Randall,Lovell@fda,hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

| This is fantastic | B5 | |
|-------------------|------------|--|
| | B 5 | |
| | | |

From: Palmer, Lee Anne < Lee Anne . 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 Surkholder@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 | |
| | | |
| | | |
| | B 5 | |
| | | |
| | | |

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne



From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <Lee Anne Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>;

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

Cc: Burkholder, William Surkholder afda.hhs.gov >; Carey, Lauren < Lauren Carey afda.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 < Lee Anne 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>

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 < <u>David Rotstein a fda.hhs.gov</u>>; Jones, Jennifer L < <u>Jennifer Jones a fda.hhs.gov</u>>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William < William Burkholder afda.hhs.gov >; Carey, Lauren < Lauren Carey afda.hhs.gov >: Norris, Anne

<a href="mailto: Anne.Norris@fda.hhs.gov Delancev@fda.hhs.gov Delancev@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 Martine Martine.Hartogensis@fda.hhs.gov; Palmer, Lee Anne <Lee Anne. Palmer a fda.hhs.gov> Cc: Burkholder, William William Surkholder@fda.hhs.gov; Carey, Lauren Lauren.Carey@fda.hhs.gov; Norris, Anne <Anne Norris a fda hhs.gov>; DeLancey, Siobhan Siobhan Delancey a fda hhs.gov> Subject: RE: DCM and meetign with Cardiac Care for Pets Good Afternoon. Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we I spoke with **B6** can set the meeting up from that point. As a side note, there is a facebook page dedicated to this issue: https://www.facebook.com/groups/1952593284998859/about/ David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place 240-506-6763 (BB) S. FOOD & DRUG 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 a fda.hhs.gov. From: Hartogensis, Martine Sent: Tuesday, May 08, 2018 10:58 AM To: Jones, Jennifer L < Jennifer Jones a fda.hhs.gov>; Rotstein, David < David Rotstein a 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

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 a fda.hhs.gov >; Palmer. Lee Anne < Lee Anne Palmer a fda.hhs.gov >;

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

Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

dave

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











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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David David Rotstein a fda.hhs.gov; Palmer, Lee Anne Lee Anne Palmer a fda.hhs.gov

Subject: RE: DCM

Thank you Dave! We did not go around vesterday because the Vet-LIRN folks came in for their routine presentation.

| B5 | | | |
|--|--------------------------------------|------|--|
| | B5 | | |
| Martine | | | |
| rom: Rotstein, David ent: Monday, May 07, 20 | | | |
| Co: Hartogensis, Martine Subject: Re: DCM Martine | Martine Hartogensis@fda.hhs.gov> | | |
| ubject: Re: DCM | Martine, Hartogensis(a) tda.hhs.gov> | | |
| ubject: Re: DCM | | | |
| ubject: Re: DCM | B5 | | |

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 |