

Commentary

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

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Diet-associated DCM first came to light in cats in the late 1980s¹ and in dogs in the mid-1990s.² The association between diet and DCM in dogs has generally not been much in the news since the early 2000s, but over the past few years, an increasing number of DCM cases involving dogs appear to have been related to diet. The extent of this issue is not clear, not all cases have been confirmed to be linked to diet, and a true association has not been proven to exist. However, when one of the authors (RF) recently surveyed veterinary cardiologists about cases of possible diet-associated DCM in dogs examined in the past 2 years, information for > 240 cases was obtained, with responses received from the United States, United Kingdom, Canada, Israel, and Austria (unpublished data). Dogs for which breed was specified consisted of mixed-breed dogs (n = 134), Golden Retrievers (23), Labrador Retrievers (9), German Shepherd Dogs (8), Cocker Spaniels (7), and between 1 and 5 dogs each of 25 other breeds. Further, possible diet-associated DCM represented 16% of all cases of DCM diagnosed by the respondents during this period.

The recent announcement from the US FDA³ alerting pet owners and veterinarians about reports of DCM in dogs eating pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients has raised concerns among the pet-owning public. Therefore, we wanted to increase awareness of this issue among veterinarians, review what is currently known about the possible association between certain diets and DCM in dogs, and discuss what veterinarians can do to help identify underlying causes.

DCM and Diet in Dogs and Cats

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

ABBREVIATIONS

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

ever, Pion et al¹ published a landmark paper reporting that DCM in cats was associated with taurine deficiency and could be reversed by providing supplemental taurine. On the basis of that report and substantial subsequent research, the requirement for taurine in cat foods was increased, and taurine deficiency-related DCM is now uncommon in cats. However, it can still be seen in cats eating home-prepared diets or commercial diets prepared with inadequate nutritional expertise or quality control.

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

Current Concerns About Diet and DCM in Dogs

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

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

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

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

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

diet, compared with a chicken-based diet, and can be affected by the amount and types of fiber in the diet.^{14,15}

Diet-associated DCM in dogs with taurine deficiency

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

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

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

Diet-associated DCM in dogs without taurine deficiency

Preliminary results of a study⁸ performed by one of the authors (DBA) found that dogs with DCM that had been eating grain-free diets had more advanced cardiomyopathic changes than did dogs with DCM that had been eating grain-based diets. Unreported results of the study indicated that a subset of dogs

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

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

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

Researchers are also exploring whether diet-associated DCM in dogs without taurine deficiency may be related to inclusion of a cardiotoxic ingredient in the diet. This could be an adulterated ingredient, as with ingredients containing melamine-cyanuric acid that affected pet foods in 2007, resulting in extensive recalls²¹; a heavy metal; a chemical sprayed on 1 of the ingredients; or even a natural chemical compound in 1 of the ingredients that has toxic effects when fed in large amounts.

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

Diet History

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

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

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

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

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

Of course, pet food is often just the tip of the iceberg. The diet history should also include all treats; table food; rawhides, bully sticks, and other chews; dietary supplements; and foods used to administer medications. These other components of the diet can contribute large amounts of sodium and other nutrients to a patient's overall intake or unbalance the overall diet. In addition, these other components may contribute to adverse effects. For example, a Fanconi-like syndrome associated with jerky treats has been reported²⁸ but may not have been identified if complete diet histories had not been obtained for affected dogs. In addition, although diet-associated DCM is most likely related to pet food, it may possibly be a result of another dietary

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

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

Recommendations

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

We also recommend that all other dogs in the household that are eating the same diet be screened for DCM. Further, we recommend that owners of dogs with possible diet-associated DCM be instructed to save samples of all dietary components they are currently feeding, including not only the main food itself but also all treats, chews, and supplements. Ideally, this would include not just samples of the dietary components but also product bags or labels. With complete diet information in hand, the veterinarian or owner should report the case to the FDA, which can be done either online or by telephone²⁹ because this will help the agency identify possible underlying causes as quickly as possible. A recently published article³⁰ provides an excellent summary of information for veterinarians on reporting suspected animal food issues. If the dog is a Golden Retriever, the veterinarian or owner may also consider reporting the case to the Josh Stern Cardiac Genetics Laboratory,³¹ which

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

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

We also provide supplemental taurine for all dogs with possible diet-associated DCM. In dogs with a taurine deficiency, taurine supplementation is critical. In dogs with taurine concentrations within reference limits, it is unclear whether taurine supplementation is needed, and some patients have recovered with only a diet change. However, taurine supplementation may still have some benefits owing to other effects of taurine (eg, antioxidant and positive inotropic effects). Taurine supplements from manufacturers with a history of good quality control should be used. A 2009 study³³ identified certain brands with good quality control. In addition, ConsumerLab is expected to release a report in late 2018 on independent quality control testing of taurine supplements.

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

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

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

Summary

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

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

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Footnotes

- a. Adin D. Echocardiographic phenotype of canine dilated cardiomyopathy differs based on diet (abstr), in *Proceedings*. American College of Veterinary Internal Medicine Forum, 2018. Available at: events.scribeme.com/2018/ACVIM/fsPopUp.asp?Mode=PresInfo&PresentationID=393940. Accessed Aug 29, 2018.
- b. Amino Acid Laboratory. University of California-Davis School of Veterinary Medicine. Available at: www.vetmed.ucdavis.edu/labs/amino-acid-laboratory. Accessed Aug 21, 2018.

References

1. Pion PD, Kittleson MD, Rogers QR, et al. Myocardial failure in cats associated with low plasma taurine: a reversible cardiomyopathy. *Science* 1987;237:764-768.
2. Kramer GA, Kittleson MD, Fox PR, et al. Plasma taurine concentrations in normal dogs and in dogs with heart disease. *J Vet Intern Med* 1995;9:253-258.
3. USFDA. FDA investigating potential connections between diet and cases of canine heart disease. Jul 12, 2018. Available at: www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm. Accessed Jul 21, 2018.
4. Kittleson MD, Keene B, Pion PD, et al. Results of the multicenter spaniel trial (MUST): taurine- and carnitine-responsive dilated cardiomyopathy in American Cocker Spaniels with decreased plasma taurine concentration. *J Vet Intern Med* 1997;11:204-211.
5. Freeman LM, Rush JE, Brown DJ, et al. Relationship between circulating and dietary taurine concentrations in dogs with dilated cardiomyopathy. *Vet Ther* 2001;2:370-378.
6. Backus RC, Cohen G, Pion PD, et al. Taurine deficiency in Newfoundland dogs fed commercially available complete and balanced diets. *J Am Vet Med Assoc* 2003;223:1130-1136.
7. Fascetti AJ, Reed JR, Rogers QR, et al. Taurine deficiency in dogs with dilated cardiomyopathy: 12 cases (1997-2001). *J Am Vet Med Assoc* 2003;223:1137-1141.
8. Bélanger MC, Ouellet M, Queney G, et al. Taurine-deficient dilated cardiomyopathy in a family of Golden Retrievers. *J Am Anim Hosp Assoc* 2005;41:284-291.
9. Backus RC, Ko KS, Fascetti AJ, et al. Low plasma taurine concentration in Newfoundland dogs is associated with low plasma methionine and cyst(e)ine concentrations and low taurine synthesis. *J Nutr* 2006;136:2525-2533.
10. Vollmar AC, Fox PR, Servet E, et al. Determination of the prevalence of whole blood taurine in Irish Wolfhound dogs with and without echocardiographic evidence of dilated cardiomyopathy. *J Vet Cardiol* 2013;15:189-196.
11. Sanderson SL, Gross KL, Ogburn PN, et al. Effects of dietary fat and L-carnitine on plasma and whole blood taurine con-

- centrations and cardiac function in healthy dogs fed protein-restricted diets. *Am J Vet Res* 2001;62:1616-1623.
12. Delaney SJ, Kass PH, Rogers QR, et al. Plasma and whole blood taurine in normal dogs of varying size fed commercially prepared food. *J Anim Physiol Anim Nutr (Berl)* 2003;87:236-244.
13. Spitze AR, Wong DL, Rogers QR, et al. Taurine concentrations in animal feed ingredients; cooking influences taurine content. *J Anim Physiol Anim Nutr (Berl)* 2003;87:251-262.
14. Törres CL, Backus RC, Fascetti AJ, et al. Taurine status in normal dogs fed a commercial diet associated with taurine deficiency and dilated cardiomyopathy. *J Anim Physiol Anim Nutr (Berl)* 2003;87:359-372.
15. Ko KS, Fascetti AJ. Dietary beet pulp decreases taurine status in dogs fed low protein diet. *J Anim Sci Technol* 2016;58:29.
16. Ko KS, Backus RC, Berg JR, et al. Differences in taurine synthesis rate among dogs relate to differences in their maintenance energy requirement. *J Nutr* 2007;137:1171-1175.
17. Freeman LM. A broken heart: risk of heart disease in boutique or grain-free diets and exotic ingredients. Jun 4, 2018. Available at: vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/. Accessed Jul 21, 2018.
18. Lawler DF, Templeton AJ, Monti KL. Evidence for genetic involvement in feline dilated cardiomyopathy. *J Vet Intern Med* 1993;7:383-387.
19. Van Vleet JF, Ferrans VJ. Myocardial diseases of animals. *Am J Pathol* 1986;124:98-178.
20. Markovich JE, Freeman LM, Heinze CR. Analysis of thiamine concentrations in commercial canned foods formulated for cats. *J Am Vet Med Assoc* 2014;244:175-179.
21. Puschner B, Reimschuessel R. Toxicosis caused by melamine and cyanuric acid in dogs and cats: uncovering the mystery and subsequent global implications. *Clin Lab Med* 2011;31:181-199.
22. Tang WHW, Hazen SL. The gut microbiome and its role in cardiovascular diseases. *Circulation* 2017;135:1008-1010.
23. Baldwin K, Bartges J, Buffington T, et al. AAHA nutritional assessment guidelines for dogs and cats. *J Am Anim Hosp Assoc* 2010;46:285-296.
24. Freeman L. WSAVA Nutritional Assessment Guidelines Task Force. WSAVA nutritional assessment guidelines. *J Small Anim Pract* 2011;52:385-396.
25. Freeman LM. Cachexia and sarcopenia: emerging syndromes of importance in dogs and cats. *J Vet Intern Med* 2012;26:3-17.
26. World Small Animal Veterinary Association. Global nutrition guidelines. Available at: www.wsava.org/Guidelines/Global-Nutrition-Guidelines. Accessed Aug 30, 2018.
27. Petfoodology. What's your pet's score? Assessing muscle condition. Available at: vetnutrition.tufts.edu/2017/11/mcs/. Accessed Aug 30, 2018.
28. US FDA. FDA provides update on jerky pet treat investigation. May 16, 2016. Available at: www.fda.gov/animalveterinary/newsupdates/ucm500776.htm. Accessed Jul 21, 2018.
29. USFDA. How to report a pet food complaint. Available at: www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm. Accessed Jul 21, 2018.
30. Jones JL, Rotstein DS, Cerio O, et al. Information for veterinarians on reporting suspected animal food issues. *J Am Vet Med Assoc* 2018;253:550-553.
31. University of California-Davis School of Veterinary Medicine. Josh Stern Cardiac Genetics Laboratory. Available at: www2.vetmed.ucdavis.edu/ccah/areas-study/genetics/stern-lab.cfm. Accessed Jul 21, 2018.
32. Cummings Veterinary Medical Center. Reduced sodium diet and treat lists for pets with heart disease. Available at: vetmed.tufts.edu/heartsmart/diet/reduced-sodium-diet-and-treat-lists-for-pets-with-heart-disease/. Accessed Jul 21, 2018.
33. Bragg RR, Freeman LM, Fascetti AJ, et al. Composition, disintegrative properties, and labeling compliance of commercially available taurine and carnitine dietary products. *J Am Vet Med Assoc* 2009;234:209-213.

For all commentaries, views expressed are those of the authors and do not necessarily reflect the official policy of the AVMA.



Determination of the prevalence of whole blood taurine in Irish wolfhound dogs with and without echocardiographic evidence of dilated cardiomyopathy[☆]

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Nutrition;
Cardiomyopathy

Abstract Objectives: Taurine plays an important role in maintaining myocardial function. Irish wolfhound dogs (IW) are at risk for dilated cardiomyopathy (DCM), but a relationship between whole blood taurine (WBT) deficiency and DCM has not been established. Our aim was to determine prevalence of WBT deficiency in IW with and without DCM and assess its association with diet.

Animals: 115 privately owned IW.

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

Results: Forty-nine (42.6%) had DCM; 66 (57.4%) had no DCM. Dogs with DCM were older ([median; inter-quartile range or IQR] 5.3; 4.3, 6.2 years) than dogs without heart disease (3; 2, 4 years; $P < 0.001$). There was no significant relationship between WBT concentration and age ($P = 0.64$). Whole blood taurine was severely reduced (<130 nmol/mL) in 8 dogs (4 with and 4 without DCM) and moderately reduced (130–179.9 nmol/mL) in 32 dogs (12 with DCM and 20 without DCM). Follow

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up of dogs without DCM revealed that a higher proportion of dogs with any degree of WBT deficiency developed DCM later compared to dogs with normal WBT ($P < 0.001$).

Conclusions: Whole blood taurine deficiency occurred in IW with and without DCM. Based on taurine measurement on a single occasion, there was no clear relationship between low WBT and presence of DCM in this population. Regardless of WBT, DCM affected predominantly older dogs, suggesting a relatively late onset disease in the IW.

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From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Carey, Lauren; Rotstein, David; Jones, Jennifer L; Palmer, Lee Anne
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:49:14 PM
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Lauren and Dave! We'll keep the comms moving in clearance, but will update them as needed with any further info from Lee Anne upon her return.

Anne

From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Date: July 2, 2018 at 4:30:57 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Norris, Anne <Anne.Norris@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>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Anne,

I'm in today, just with intermittent network connectivity at the moment. B5
B5 so I'm not any help even though I'm here. Lee Anne will be back on Thursday and should be able to help then, but I'm not sure if that decision was on her end or not.

Thanks,
Lauren

From: Rotstein, David
Sent: Monday, July 02, 2018 4:07 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

B5

Others may have differing thoughts.

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

7519 Standish Place

B6

(BB)



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From: Norris, Anne
Sent: Monday, July 02, 2018 4:05 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave

B5

B5

From: Rotstein, David
Sent: Monday, July 02, 2018 3:58 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that

B5

Dave

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

B6

(BB)



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the sender immediately at david.rotstein@fda.hhs.gov.

From: Norris, Anne

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

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

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

Subject: FW: Redacted complaint file for the DCM webposting

Importance: High

Hi Jen and Dave,

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

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne

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

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

Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Norris, Anne; Carey, Lauren; Jones, Jennifer L; Palmer, Lee Anne
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:53:12 PM
Subject: RE: Redacted complaint file for the DCM webposting

The list was provided to me, but not sure who provided it to me.

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

B6 **BB)**



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From: Norris, Anne
Sent: Monday, July 02, 2018 4:49 PM
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>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Lauren and Dave! We'll keep the comms moving in clearance, but will update them as needed with any further info from Lee Anne upon her return.

Anne

From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Date: July 2, 2018 at 4:30:57 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Norris, Anne <Anne.Norris@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>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Anne,

I'm in today, just with intermittent network connectivity at the moment

B5

B5

so I'm not any help even though I'm here. Lee Anne will be back on Thursday and should be able to help then, but I'm not sure if that decision was on her end or not.

Thanks,
Lauren

From: Rotstein, David

Sent: Monday, July 02, 2018 4:07 PM

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

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

Subject: RE: Redacted complaint file for the DCM webposting

Anne,

B5

Others may have differing thoughts.

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CVM Vet-LIRN Liaison
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B6

BB)



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From: Norris, Anne

Sent: Monday, July 02, 2018 4:05 PM

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

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

Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave

B5

B5

From: Rotstein, David

Sent: Monday, July 02, 2018 3:58 PM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that

B5

Dave

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

B6

BB)



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

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point...

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Norris, Anne; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan
Sent: 7/2/2018 9:27:52 PM
Subject: RE: Redacted complaint file for the DCM webposting

I am confused.

B5

B5

Martine

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

Hi Jen and Dave,

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

B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

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Thanks!

Lee Anne

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Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov





From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Hartogenesis, Martine; Norris, Anne; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 7/2/2018 9:59:03 PM
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

I just double checked our database and these are all complaints that came directly to FDA through our reporting portals, [REDACTED]

B5

Thanks,
Lauren

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

I am confused, [REDACTED]

B5

[REDACTED]
B5

Martine

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

Hi Jen and Dave,

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B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

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Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine

OSC, Division of Veterinary Product Safety

U.S. Food and Drug Administration

Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



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

Hi all,

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

Anne

Anne Norris

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



From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Hartogensis, Martine; McDermott, Patrick; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Edwards, David; Conway, Charlotte
CC: DeLancey, Siobhan
Sent: 7/12/2018 6:07:27 PM
Subject: RE: DCM Comms going live today at 2:00 pm

The [CVM Update](#) and [FDA In Brief](#) are now live!

From: Norris, Anne
Sent: Thursday, July 12, 2018 9:14 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; McDermott, Patrick <Patrick.McDermott@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: DCM Comms going live today at 2:00 pm

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Anne

Anne Norris

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



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Hartogensis, Martine; Putnam, Juli; Carey, Lauren; Palmer, Lee Anne; DeLancey, Siobhan; Norris, Anne; Forfa, Tracey; Rotstein, David
Sent: 7/13/2018 5:42:02 PM
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

I have approximately

B5

B5

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



From: Hartogensis, Martine

Sent: Friday, July 13, 2018 9:47 AM

To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

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

Looks good!

B5

Martine

From: Putnam, Juli

Sent: Friday, July 13, 2018 9:45 AM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

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

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

B5

B5

Proposed response:

B5

From: Carey, Lauren

Sent: Friday, July 13, 2018 9:37 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

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

I think Martine's example is good.

B5

B5

From: Hartogensis, Martine

Sent: Friday, July 13, 2018 9:33 AM

To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

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

Hi Juli,

You could also say something like:

B5

Looping in Jen as well...

Martine

From: Putnam, Juli

Sent: Friday, July 13, 2018 9:29 AM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

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

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

B5

Proposed response:

B5

From: Carey, Lauren

Sent: Friday, July 13, 2018 9:18 AM

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

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

Hi,

B5

Thanks,
Lauren

From: Putnam, Juli

Sent: Friday, July 13, 2018 9:04 AM

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

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

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

Thanks, everyone

B5

B5

See the draft proposed response below for your review.

B5

Proposed response:

B5

From: Hartogensis, Martine

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

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

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

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

Thanks Lee Anne!

B6

From: Palmer, Lee Anne

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

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: July 12, 2018 at 6:16:01 PM EDT
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi about **B5** dog reports to date . Can't see whole steam - will send them read all

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: July 12, 2018 at 5:28:58 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Yes, me too.

As of right now, I believe we have about **B5** ports that have been sent to us.

Lee Anne or Lauren, can you confirm?

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: July 12, 2018 at 4:54:18 PM EDT
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

That works for me!

Siobhan DeLancey, RVT, MPH

O: 240-402-9973

M: **B6**

From: Putnam, Juli
Sent: Thursday, July 12, 2018 4:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

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

B5

From: DeLancey, Siobhan
Sent: Thursday, July 12, 2018 4:47 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

B5

Siobhan DeLancey, RVT, MPH

O: 240-402-9973

M: B6

From: Putnam, Juli
Sent: Thursday, July 12, 2018 4:44 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP
Importance: High

Hi again - just following on this. Bloomberg is pinging me again. They want the list of brands/products. Can we provide this? OCC has cleared it.

B5

B5

From: Putnam, Juli

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

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

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

Importance: High

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

Best,
Juli

Reporter: Aziza Kasumov

Outlet: Bloomberg

Deadline: asap

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

Questions and proposed responses:

B5

CVM, please advise.

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Palmer, Lee Anne; Carey, Lauren; Rotstein, David; Jones, Jennifer L; Peloquin, Sarah; Reimschuessel, Renate; Hartogensis, Martine; Burkholder, William; DeLancey, Siobhan
Sent: 2/21/2019 5:11:55 PM
Subject: RE: DCM paper - Darcy Adin, 2019 Vet Cardiology
Attachments: sky488.pdf

I've lost track of whether we circulated this paper internally, but sharing because it caught the eye of Phyllis Entis from Food Safety News. She hasn't written about it (at least not yet). One of the authors is Greg Aldrich.

From: Norris, Anne
Sent: Tuesday, February 19, 2019 9:09 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: DCM paper - Darcy Adin, 2019 Vet Cardiology

Thanks!

From: Palmer, Lee Anne
Sent: Tuesday, February 19, 2019 9:05 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: DCM paper - Darcy Adin, 2019 Vet Cardiology

Hi – please forgive me if we have this already, but I think this just came out.

I haven't read it yet.

Thanks, lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
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Special topic: The association between pulse ingredients and canine dilated cardiomyopathy: addressing the knowledge gaps before establishing causation¹

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ABSTRACT: In July 2018, the Food and Drug Administration warned about a possible relationship between dilated cardiomyopathy (DCM) in dogs and the consumption of dog food formulated with potatoes and pulse ingredients. This issue may impede utilization of pulse ingredients in dog food or consideration of alternative proteins. Pulse ingredients have been used in the pet food industry for over 2 decades and represent a valuable source of protein to compliment animal-based ingredients. Moreover, individual ingredients used in commercial foods do not represent the final nutrient concentration of the complete diet. Thus, nutritionists formulating dog food must balance complementary ingredients to fulfill the animal's nutrient needs in the final diet. There are multiple factors that should be considered, including differences in nutrient digestibility and overall bioavailability, the fermentability and quantity of fiber, and interactions among food constituents that can increase the risk of DCM development.

Taurine is a dispensable amino acid that has been linked to DCM in dogs. As such, adequate supply of taurine and/or precursors for taurine synthesis plays an important role in preventing DCM. However, requirements of amino acids in dogs are not well investigated and are presented in total dietary content basis which does not account for bioavailability or digestibility. Similarly, any nutrient (e.g., soluble and fermentable fiber) or physiological condition (e.g., size of the dog, sex, and age) that increases the requirement for taurine will also augment the possibility for DCM development. Dog food formulators should have a deep knowledge of processing methodologies and nutrient interactions beyond meeting the Association of American Feed Control Officials nutrient profiles and should not carelessly follow unsubstantiated market trends. Vegetable ingredients, including pulses, are nutritious and can be used in combination with complementary ingredients to meet the nutritional needs of the dog.

Key words: dilated cardiomyopathy, dogs, feed formulation, grain-free, nutrition, pulse ingredients

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like to acknowledge the contribution of James Templeman, Sarah Dodd, and Emma Thornton.

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INTRODUCTION

In July 2018, the Food and Drug Administration (FDA) issued a statement relating dilated cardiomyopathy (DCM) in dogs to the consumption of foods that have potatoes and/or pulse ingredients, such as peas and lentils or their coproducts, as main ingredients (FDA, 2018). The FDA's statement, as well as media attention, has raised concern in some pet owners, veterinarians, nutritionists, and the pet food manufacturing and retail industry. The underlying cause for concern with pet food and DCM is that there is a link between nutrition that was previously tied to DCM and insufficient circulating taurine (Fascetti et al., 2003; Backus et al., 2006). The result was an increased need for dietary taurine or its precursor methionine due to higher fermentation of taurine and greater fecal excretion with dietary fermentable fiber (Kim et al., 1996a, 1996b). Whether this has any link to dietary pulses or the greater inclusion of pulses in grain-free dog food has yet to be directly demonstrated and mechanistic research is warranted.

Pulses are a subset of legumes, harvested as a dry crop, with low concentrations of lipid. They include peas, lentils, chickpeas, and dry beans (Marinangeli et al. 2017) which have been used as ingredients in dog food for their protein and fiber for more than 2 decades (Butterwick et al., 1994; Rice and Ihle, 1994). As a source of protein, the amino acid (AA) profile in peas, lentils, chickpeas, and beans is generally high in lysine and low in methionine (NRC, 2006) and serves as a complementary protein to both animal and plant-derived ingredients. As an example, soybean meal is derived from defatted soybeans and has an AA profile similar to pulses. In a 24-wk study that evaluated graded concentrations of soybean meal up to 17% (as-fed basis) in dog foods, soybean meal inclusion did not affect the nutrient status of dogs as indicated by serum biochemistry analysis (Menniti et al., 2014). However, Yamka et al. (2003) demonstrated that using soybean meal at more than 15% inclusion on a dry matter basis decreased crude protein digestibility. Based on the authors assessment of current formulas in the market, there is a high likelihood that legume seed use in some foods may be greater

than 40%. This inclusion exceeds concentration of legumes previously investigated in dogs. When used to complement the nutritional profile of other ingredients, pulses can be used as nutrient-rich vehicles to meet the nutritional requirements of dogs and other companion animals. Given that companion animals most often consume static diets for long periods of time, overuse of any ingredient could facilitate higher risk of certain nutrient deficiencies if nutrient balance is not considered in the formulation. Thus, the formulation of static diets that use significant concentrations of a single ingredient, relative to other ingredients in the formulation, requires an in-depth knowledge of nutrient interactions, animal physiology, and effects of processing, beyond that of simply meeting minimum nutrient profiles stipulated in the Official Publication of The Association of American Feed Control Officials (AAFCO, 2018).

The present commentary discusses the following: 1) The limited data being used to support linkages between DCM and pulse ingredients; 2) The nutritional factors and physiological mechanisms that should be explored to establish causation between nutritional deficiencies and incidence of DCM; 3) The factors that nutritionists should consider when formulating complete diets destined for long-term consumption; and 4) The disadvantages of formulating protein and minimal AA recommendations rather than a balanced indispensable AA profile.

The Development of Canine DCM, Historical Linkages to Taurine Deficiency, and Pulses

Dilated cardiomyopathy is a disease of the myocardium that results in both mechanical dysfunction (enlarged heart cavities and congestion) and/or electrical dysfunction (arrhythmias and sudden death) (Sisson et al., 2000; Maron et al., 2006; Dutton and López-Alvarez, 2018). Development of DCM is slow and few clinical signs manifest over time. As DCM progresses, signs include lethargy, anorexia, shallow breathing, sudden fainting, and potential death. In some cases, animals may die from irregular heart rhythm without previous signs of the disease. In dogs, DCM can be

caused by various factors. Genetic predisposition is thought to play the most important role in the development of DCM in several dog breeds, mostly large and giant breeds. Genetic mutations associated with DCM have been discovered in American lines of Doberman and Boxer dogs (Meurs et al., 2012; Meurs et al., 2013). However, the Doberman variant's association was not upheld in a European population of Dobermans (Owczarek-Lipska et al., 2013). Similarly, a United Kingdom population of Boxers did not uphold their published DCM-associated variant (Cattanach et al., 2015). It is becoming increasingly clear that the genetic basis for DCM in dogs is not monogenic, but complex and polygenic. Breeds with the highest prevalence of DCM include Dobermans, Boxers, Great Danes, Newfoundlands, Irish Wolfhounds, English Cocker Spaniels, and Portuguese Water Dogs (Monnet et al., 1995; Borgarelli et al., 2006; Werner et al., 2008; Martin et al., 2009), and the genetic basis of DCM in each of these breeds has been investigated (Dutton and López-Alvarez, 2018). In addition, Golden Retrievers and American Cocker Spaniels appear to have breed predispositions to taurine deficiency (Kramer et al., 1995; Bélanger et al., 2005). When dogs are not genetically predisposed for developing DCM, diet and physiology are other factors that may be associated with the disease.

The first link between taurine deficiency and DCM was demonstrated in cats in 1987. Cats diagnosed with DCM recovered after taurine supplementation (Pion et al., 1987). Similarly, an inverse association between dietary taurine and the incidence of DCM in a population of foxes was documented by Moise et al. (1991) and

established the importance of taurine in the family Canidae. In dogs, DCM diagnoses related to low whole blood taurine concentrations have been reported in Cocker Spaniels, Dalmatians, Boxers, Newfoundlands, Portuguese Water Dogs, English Setters, Alaskan Malamutes, and Scottish Terriers (Freeman et al., 1996; Kittleston et al., 1997; Pion et al., 1998; Alroy et al., 2000; Fascetti et al., 2003; Backus et al., 2006). In all these cases, taurine supplementation improved cardiac function. However, dogs, in contrast to cats, can endogenously synthesize taurine from methionine and cysteine (Figure 1). Therefore, the above-mentioned data do not unequivocally establish taurine intake as the underlying mechanism for the development of DCM in dogs, whether they are genetically predisposed. Dietary supply of precursor AAs necessary for taurine synthesis (i.e., methionine and cysteine), metabolic intermediates, and cofactors (such as methyl donors) cannot be ruled out as factors that contribute to the susceptibility of dogs to developing genetic and diet-related DCM. When DCM is diet-related, the formulation and the provision of all nutrients, including indispensable AAs, to facilitate optimum health and wellbeing of dogs should be considered.

Recent reports, including the statement by the FDA (2018), have implicated that lentils, peas, and other legumes seeds could be responsible for the development of DCM in dogs not genetically predisposed to this disease. Such statements and associations between pulse ingredients and incidence of DCM are, at the present time, premature. Animals, including dogs, have no minimum or maximum requirements for ingredients. Ingredients serve

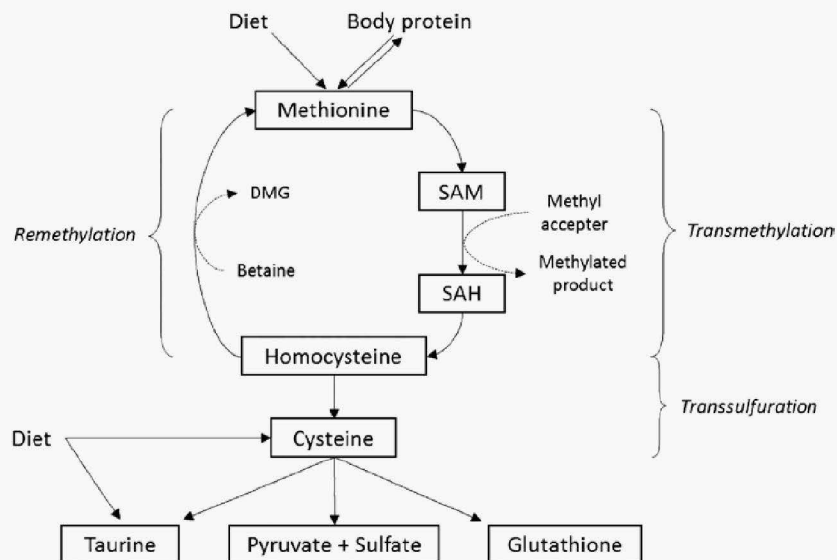


Figure 1. Metabolism of sulfur amino acids. DMG = dimethylglycine; SAH = S-adenosylhomocysteine; SAM = S-adenosylmethionine.

as the vehicle to providing nutrients to animals. As such, animals have nutrient requirements, not ingredient requirements. In diets that have nutrient deficits, imbalances, or exceed maximums, the final nutrient composition of the diet, not the ingredients, should be critiqued. In addition, animal nutritionists should consider that the nutrient concentration of ingredients can vary, nutrient availability is not 100%, and diets formulated to marginally meet requirements could actually be deficient. Overall, it is the responsibility of nutritionists to use different ingredients to formulate diets that can be produced and safely meet the nutritional needs of animals.

Taurine Deficiency and the Development of Canine DCM

For dogs, taurine is a dispensable AA synthesized from methionine and cysteine primarily in the liver (Figure 1). Taurine is not incorporated into proteins. Instead, it is used as a mediator for various biological processes and is the most abundant free AA intracellularly (Huxtable, 1992). In the heart, taurine represents ~60% of the total AA free pool (Huxtable, 1992). The high concentration of taurine in cardiac cells may explain the role of a taurine deficiency in the development of DCM. It has been speculated that taurine contributes to the reabsorption of calcium by the sarcoplasmic reticulum and increases the sensitivity of the myofilaments to calcium (Bakker and Berg, 2002). Thus, low dietary taurine intake and/or reduced synthesis of taurine from methionine and cysteine can deplete calcium pools in the cardiac cells and impede proper contraction of the cardiac muscle tissue, resulting in DCM in dogs.

For diagnosing DCM in dogs and cats, among other diagnostic methods including electrocardiograms and echocardiography, it is common to measure taurine concentration in whole blood. Whole blood samples, and not plasma samples, should be used to assess circulating taurine concentrations. In plasma, free taurine concentrations are much lower compared with intracellular taurine. This suggests that the plasma pool is not representative of taurine in other pools (Schaffer et al., 2010). In platelets, taurine concentration is high and is considered a marker of taurine status. Taurine concentration in platelets is captured when whole blood is analyzed (Huxtable, 1992). However, platelet count can vary depending on the immune status of the animal and whole blood taurine concentration can be affected. In this scenario, whole blood taurine may not represent concentrations of

taurine in muscle cells, including cardiac muscle. These additional variables related to the measurement of taurine status may explain why some dogs diagnosed with DCM have normal whole blood taurine concentrations.

As taurine can be synthesized endogenously in dogs, taurine is not considered an indispensable AA for the species Canidae. Thus, there are no recommendations on minimum dietary concentrations of taurine for dogs reported by the National Research Council (NRC, 2006) or AAFCO (2018). The lack of regulation on minimum taurine concentrations in commercial dog foods suggests that endogenous synthesis of taurine can meet the metabolic needs in all dogs and at all life stages. This assumption may not be accurate as studies have determined that synthesis of taurine is related to the size of dog (Ko et al., 2007), and some dietary factors can increase the physiological need for taurine (Story, 1978). Nutritional factors that increase the dietary requirement, reduce the supply, or increase the excretion of taurine in dogs are discussed in subsequent sections of this review and should be considered to avoid taurine deficiency in dogs and the risk of DCM.

Physiological factors can increase taurine utilization in dogs, and endogenous synthesis of taurine could be insufficient for meeting taurine requirements. For example, compared with smaller size dogs, synthesis of taurine in large dog breeds is up to 50% lower per unit of metabolic body weight (Ko et al., 2007). These results demonstrate that larger dogs are at higher risk for insufficient endogenous taurine synthesis, and dietary supplementation or fortification may be required, even when there is no minimum dietary taurine concentration according to current recommendations (AAFCO, 2018). Obesity and diabetes have also been related to lower concentrations of taurine in blood in humans and rats, respectively (Merheb et al., 2007; Nardelli et al., 2011; Ito et al., 2012), and may increase the requirement for sulfur AAs necessary for endogenous taurine synthesis. This is of importance given that approximately half of dogs in North America are obese (Linder and Mueller, 2014). Data from rats and cats suggest that age and sex could also affect whole body taurine status. Hepatic activity of cysteine sulfonate decarboxylase, the enzyme responsible for taurine synthesis, was shown to be 16 times higher in adult male rats vs. female rats. In the same study, the activity of cysteine sulfonate decarboxylase was higher in 5- to 6-wk-old kittens compared with 15-mo-old cats and in 8-wk-old mice compared with 16-wk-old mice; changes of

the enzyme activity in dogs have not been tested (Worden and Stipanuk, 1985). Overall, these studies suggest that, despite some capacity for endogenous synthesis, physiological need of taurine can be heavily dependent on breed, age, sex, and physiological status. These physiological factors could help us to predict the risk for developing DCM when genotypic and environmental factors, such as diet, are simultaneously considered to ensure that dogs maintain adequate concentrations of taurine and other sulfur AAs.

Given that there are no recommendations for the minimum concentration of taurine in dog food, the concentration of taurine in dog foods can vary substantially depending on the ingredients used. Taurine is very low in plant-based ingredients (Table 1) but is higher in some algae and fungi species and is ubiquitously found in animal tissues, especially in the heart, brain, and white blood cells (Huxtable, 1992). This is relevant, as many grain-free and/or high legume dog foods attempt to limit the use of animal byproducts, which can substantially decrease the levels of dietary taurine. In the context of providing adequate and preventive nutrition, dog foods should include organ meat

or animal byproducts or be fortified with taurine and/or its precursors (methionine and/or cysteine) to ensure the delivery of sufficient levels of taurine.

Effect of Dietary Fiber on Taurine Status and Risk of Canine DCM

Dietary fiber has been shown to affect the taurine status in dogs. For example, commercial diets formulated with lamb meal and rice bran were shown to cause taurine deficiency in part because of low bioavailable cysteine from lamb meal and possibly more importantly due to the effects of rice bran fiber on gastrointestinal metabolism of taurine (Johnson et al., 1998; Tôrres et al., 2003). It has been hypothesized that high-fiber diets can increase susceptibility to taurine deficiency by 2 mechanisms of action linked to obligatory bile acid conjugation with taurine in dogs (O'Mádille et al., 1965) and reliance on enterohepatic circulation for the reabsorption of bile acids and taurine. First, high-fiber diets may increase fecal output and losses of taurine-conjugated bile. This would require higher synthesis rates of bile in the liver, and consequently, higher utilization of taurine

Table 1. Crude protein (CP), fiber, selected amino acids, and carnitine contents in the principal legumes, cereals, and animal-derived ingredients used in dog food formulation

Ingredients	CP, %	Crude fiber, ¹ %	α -amino acids, mg/g protein ¹			Tau, mg/kg ²	Carnitine, mg/kg ³	
			Lys	Met	Cys			
Legumes	Fava beans	27.2	8.55	23.9	7.0	12.5	–	–
	Phaseolus beans	22.9	NR	72.9	12.7	12.7	–	–
	Kidney beans	20.0	6.40	26.5	14.0	12.0	–	–
	Lentils	26.0	NR	65.8	6.9	10.4	–	–
	Lupins	32.4	14.25	48.7	6.5	14.2	–	–
	Chick peas	20.3	6.16	69.4	14.8	21.6	–	–
	Soybean meal	47.7	3.89	62.0	13.8	14.7	–	–
Grains	Barley	11.3	3.90	35.3	17.7	22.9	–	–
	Corn, yellow dent	8.2	1.98	30.3	21.8	23.1	–	–
	Oats	11.2	2.20	43.9	60.9	32.3	–	–
	Rice	7.9	0.52	44.5	31.8	22.9	–	–
	Rye	11.7	2.71	36.9	13.7	16.3	–	–
	Sorghum	9.4	2.14	21.4	17.1	19.2	–	–
	Wheat hard, red	14.5	2.57	27.0	15.2	22.8	–	–
Animal-derived ingredients	Beef, meat	15.0	–	77.3	28.7	15.3	296	150
	Chicken, meat and skin	17.6	–	81.3	26.7	13.1	159	57
	Chicken, by product	59.0	–	48.1	17.3	16.8	3049	120
	Lamb, ground	16.6	–	88.0	25.9	12.0	473	282.3
	Rendered meat	54.1	2.50	53.8	14.2	11.3	NR	NR

Cys = cysteine; Lys = lysine; Met = methionine; NR = not reported; Tau = taurine.

Values are presented on as-fed basis.

¹NRC, 2006; NRC, 2012.

²Spitze et al. 2003.

³Arslan, 2006.

(Story, 1978). Second, high consumption of fermentable fibers may increase the abundance of microbial populations that degrade taurine in the intestinal lumen (Kim et al., 1996a, 1996b). Either alone or together, increased excretion or degradation of taurine from high-fiber diets may decrease enterohepatic circulation and recycling of taurine. Given that taurine is the only AA used for bile acid conjugation in dogs, over time, high-fiber diets could increase the risk of taurine insufficiency in dogs and lead to DCM.

This should not be interpreted as dietary fiber being deleterious to the health of dogs. However, there may be a limit to the benefit for soluble fibers. Legume seeds contain an appreciable quantity of oligosaccharides which are known to be fermentable (Tosh and Yada, 2010). Thus, by a similar mechanism as described above, high levels of legume seed oligosaccharides could ostensibly contribute to taurine depletion via excretion in the feces as bile conjugation and degradation by colonic bacteria. In addition to the physiological benefits of high-fiber diets in certain dogs, formulators should also be cognizant of possible nutritional risks associated with high concentrations of fiber in dog foods. Consequently, dog foods with high concentrations of dietary fiber should be accompanied by higher supplies of taurine or sulfur AAs for endogenous taurine synthesis. Overall, the digestibility and bioavailability of taurine in ingredients used and the effect of other nutrients in taurine metabolism should be considered to avoid taurine deficiency and the development of DCM.

Carnitine Deficiency and Risk of Canine DCM

Carnitine is not nutritionally indispensable since it is endogenously produced in the liver and kidneys from lysine and methionine; it can also be attained exogenously from animal-based products. Carnitine is highly abundant in skeletal and cardiac muscles. Together, these represent >95% of the total carnitine in the body. Carnitine is essential for metabolism of fatty acids used for energy production (Hoppel, 2003). In the heart, where 60% of the energy is derived from fatty acid oxidation, carnitine facilitates the uptake of free fatty acids into the mitochondria to produce ATP (Hoppel, 2003). Plant-based ingredients do not contain carnitine (Table 1). Therefore, in commercial dog foods with reduced inclusion of animal-based ingredients, intakes of carnitine could be decreased if diets are not fortified. Reduced dietary carnitine intake

translates into increased reliance on endogenous synthesis to meet physiological requirements.

Given that carnitine is required for sufficient energy production in cardiac muscle, it is not surprising that carnitine deficiency is associated with DCM. In 1991, a family of Boxers diagnosed with DCM were also diagnosed with carnitine deficiency (Keene et al., 1991). In dogs, carnitine deficiency can occur with aberrations of carnitine regulation in disorders such as cardiomyopathy (including DCM), diabetes, sepsis, and malnutrition (Flanagan et al., 2010). However, carnitine deficiency as a causative factor in the development of DCM or a consequence of cardiac malfunction remains as a subject of debate (Freeman and Rush, 2006). Despite the interest in this metabolite, little progress has been made on determining the effect of carnitine supplementation on alleviating risk of DCM. However, both taurine and carnitine are often supplemented in suprphysiological concentrations once DCM is diagnosed. This practice is supported by positive clinical outcomes, albeit without comparison groups (Kittleson et al., 1997; Sanderson et al., 2001). Concentrations of carnitine in the plasma are relatively insensitive to dietary carnitine, and more invasive techniques (biopsies) are required to determine the concentration of carnitine in muscle tissue (Flanagan et al., 2010; Rășanu et al., 2012). The invasive nature of testing for carnitine status is likely the reason why carnitine is rarely explored when investigating possible causes of canine DCM.

Preventing Diet-Mediated DCM in Dogs by Providing Adequate Sulfur AAs and Maximizing Endogenous Taurine Synthesis

Although taurine is considered a dispensable AA in dogs, endogenous taurine synthesis requires an adequate supply of bioavailable sulfur AA precursors cysteine or methionine (Figure 1). Thus, providing marginal concentrations of these 2 sulfur AAs, or providing sources with lower bioavailability, could increase the risk of taurine deficiency and facilitate the development of DCM. Contrary to taurine, methionine cannot be synthesized endogenously in dogs (NRC, 2006). Therefore, dogs depend on the provision of dietary methionine to meet daily sulfur AA requirements, which includes production of taurine. From an ingredient perspective, methionine and lysine are usually the first or second limiting AAs in dog diets formulated with soybean meal and rendered meats (NRC, 2006). In addition, methionine is particularly susceptible to damage, and subsequent reduction in bioavailability,

secondary to heat processing (Marshall et al. 1982; Hurrell et al., 1983). This suggests that the risk of methionine deficiency is more likely than any other indispensable AA in commercial dog diets. Although the primary role for methionine is protein synthesis, in pigs at least 50% of absorbed methionine acts as a methyl donor and a precursor in the production of cysteine, taurine, sulfate, and pyruvate (Robinson et al., 2016a; Figure 1). These functions of methionine become more crucial when dietary intake of cysteine, taurine, and/or dietary methyl donors (e.g., folate, betaine, and their precursors) is limited (Robinson et al., 2016b), and they need to be considered when nutritionists set criteria for delivery of sulfur AAs in pet foods.

Methionine and cysteine both contribute to the total sulfur AA requirements for humans and animals. For adult dogs at maintenance, the latest guidelines from the NRC (2006) recommend that adult dog foods contain 0.33% (on dry matter basis) methionine when cysteine is provided in excess, and 0.65% for methionine + cysteine. These NRC (2006) recommendations are not based on dose–response studies, but on a 4-yr study where adult dogs were fed low-crude protein diets (Sanderson et al., 2001). In that study, the lowest concentration of methionine in the diet that reported no observable deficiencies was used as the recommended requirement. As companion animals are typically fed a single static diet during adulthood, and for most of their lifespan, it is necessary that AA requirements of dogs should be measured empirically (Baker, 1986). In addition to the lack of empirical data corresponding to the AA requirements of dogs, it is equally important to understand how other dietary (e.g., dietary fiber), environmental, other physiological variables, and breed/genotype may alter AA requirements. The lack of recommendations for taurine in commercial dog food puts a higher stress on accurately meeting requirements for sulfur AAs, not only for protein synthesis, but also for the endogenous synthesis of taurine, for support of optimal methyl status, and for the synthesis of secondary metabolites.

Rethinking Indispensable AA Targets in Commercial Dog Foods

Currently, the ingredients permitted in pet foods and the corresponding nutrient targets are guided by recommendations made by AAFCO (2018). These recommendations are based on the peer-reviewed scientific literature and represented in the Nutrient Requirement of Dogs and Cats

(NRC, 2006). However, AA recommendations made by AAFCO correspond to total AA content within the formulation and do not consider the true ileal digestibility of ingredients. True ileal digestibility of AAs is more representative of nutrient absorption capacity and bioavailability compared with fecal digestibility or total AA content in the diet (Columbus and de Lange, 2012). To account for the reduced digestibility and bioavailability of protein-bound AAs in food ingredients, AAFCO arbitrarily increases AA recommendations relative to those from the NRC to ensure that an adequate supply of AAs is provided, regardless of the ingredients and effects of processing (Table 2). However, this increment is only applied to lysine, threonine, and tryptophan and not applied to other indispensable AAs, including methionine (AAFCO, 2018). For example, the recommended allowance for lysine reported in NRC (2006) is 0.35% for adult dogs at maintenance, whereas the minimum content of lysine to meet AAFCO (2018) recommendations is 0.63%. Nonruminant animals, including dogs, absorb AAs from the duodenum to the terminal ileum (Columbus and de Lange, 2012). Hence, feeding diets with lower ileal digestibility coefficients could decrease actual concentrations of available indispensable AAs, even when meeting AAFCO recommendations. This is of special concern for dietary taurine and other sulfur AAs, considering that there is no regulated minimum threshold for taurine in dog foods and that AAFCO (2018) recommendations for sulfur AAs are not increased compared with NRC (2006) recommendations to account for potential ileal digestibility coefficients. There is a dearth of data in this area to justify empirical adjustments based on different dietary variables. As such, future research should pursue how AA requirements change under different dietary variables that can affect small intestinal digestibility and whole body availability.

It is worthwhile to note that minimum dietary nutrient contents for dog foods, as reported in AAFCO (2018), only consider differences between growth/reproduction and adult life stages. This lack of data places the pregnant bitch in the same group as growing animals. Moreover, most studies on nutrient requirements in dogs have been established using Beagles as a proxy for all dogs. Using a single breed creates a homogenous sample and likely does not account for nutritional variability across pure and mixed breeds, or those of different sizes. Unpublished data from Shoveller et al. investigated the minimum methionine (with excess cysteine) requirements of

Table 2. Recommended allowance (RA) and minimum dietary content suggested by AAFCO for crude protein and essential amino acids in dog food, and their physiological roles and potential interactions

Nutrient	NRC RA ¹ , % DM	AAFCO ² , % DM	Important physiological roles and potential interactions
Crude protein	10	18	Necessary for synthesis of nonessential amino acids
Arginine	0.35	–	Competes with lysine absorption, arginine should be increased when high lysine concentrations in the diet
Histidine	0.19	–	
Lysine	0.35	0.63	Highly reactive to reducing sugars during heating (Maillard reaction), reducing bioavailability
Methionine	0.33	0.33	Requirement increases when methyl donors/acceptors and cysteine are reduced in the diet
Methionine + cystine	0.65	0.65	Requirement is increased with low supply of taurine and during immune challenge
Phenylalanine	0.45	0.45	
Phenylalanine + tyrosine	0.74	0.74	
Threonine	0.43	0.48	Abundant in mucosal proteins (mucin), requirement increases when feeding high fermentable fibers
Tryptophan	0.14	0.16	Precursor for serotonin synthesis. Ratio of Trp:LNAA should be considered; lower ratios may deprive appetite
Valine	0.49	0.49	Abnormal Increment of valine, leucine, or isoleucine (BCAA) will cause catabolism of the other BCAA in the muscle
Isoleucine	0.38	–	
Leucine	0.68	0.68	

AAFCO = The Association of American Feed Control Officials; BCAA = branched chain amino acids; DM = dry matter; NRC = National Research Council; RA = recommended allowance; Trp:LNAA = tryptophan to large neutral amino acid ratio.

¹Recommended Allowance requirements for adult dogs at maintenance, Nutrient Requirements of Dogs and Cats (NRC, 2006).

²Minimum dietary content, AAFCO (2018).

Miniature Dachshunds, Beagles, and Labrador Retrievers as proxies for small, medium, and large dog breeds and found that methionine requirements may differ across breeds or size of dogs and be greater than previously estimated. Thus, given the methods of derivation, single indispensable AA requirements for all dog populations, as presented in AAFCO (2018), may not consider variable AA requirements across dog phenotypes. Moreover, it is widely assumed that endogenous synthesis of dispensable AAs, such as taurine in the dog, is sufficient for meeting metabolic demands. However, recent studies suggest that under some metabolic conditions, dispensable AAs may also be required in diets (Hou et al., 2015). Taurine, as described in this commentary, is a clear example of this paradigm shift. Dietary taurine or the capacity for its adequate endogenous synthesis, especially in circumstances where excessive losses might occur, should be considered in the final formulation of dog foods to decrease the risk of canine DCM.

Nutritionists and regulatory agencies should be aware that, in the spectrum of nutrient requirements, dog populations with higher AA requirements relative to energy intake and other factors could be at a higher risk for a taurine deficiency. More precise categorization of requirements among different canine populations would help us to optimize nutritional

adequacy and decrease risk of diseases, such as DCM, that are possibly linked to nutrient deficiencies.

Effect of Processing on Antinutritional Factors in Plant-Based Ingredients

Just as understanding the inherent nutritional characteristics and the interaction between ingredients is important for preventing nutritional imbalances in pet foods, the effects of processing on these factors are equally important. Raw cereals and legumes contain antinutritional factors such as trypsin inhibitors, phytates, hemagglutinins, and polyphenols that can decrease protein digestion, nutrient absorption, and/or cause illness. Some of these antinutritional factors are thermolabile and, under the right conditions, can be effectively destroyed during the extrusion process improving the overall quality of plant-based ingredients and the final diet (Patterson et al., 2017). Recent reviews across a variety of legumes and legume-derived ingredients show that the activities of trypsin inhibitor, chymotrypsin inhibitor, and hemagglutinating activity were decreased by up to 95% across a variety of thermal treatment conditions, including extrusion (Patterson et al., 2017; Avilés-Gaxiola et al., 2018). Extrusion had modest effects on levels of phytate with reductions ranging from 7% to 26% and varied by legume and extrusion conditions (Patterson

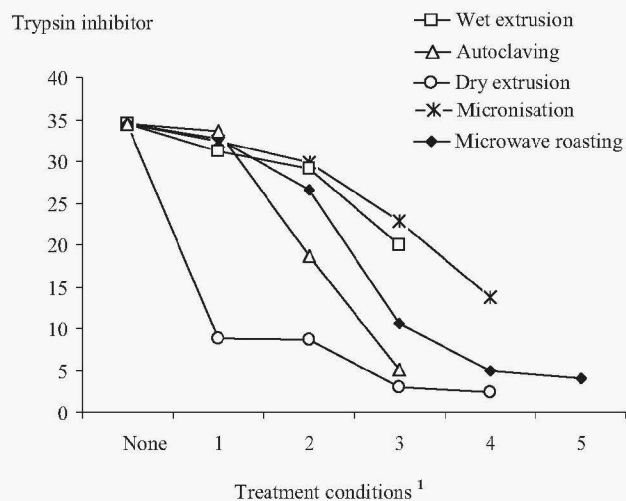


Figure 2. Effect of thermal processing methods on trypsin inhibitor levels (mg/g) soybean kernel. ¹Treatment conditions: None = no treatment; dry extrusion for 25 to 30 sec (1 = 100 °C; 2 = 125 °C; 3 = 140 °C; 4 = 150 °C); wet extrusion for 25 to 30 s with 6% to 8% added moisture (1 = 100 °C; 2 = 125 °C; 3 = 140 °C); micronization with near-infrared rays wavelength of 1.8 to 3.4 μ m for 90 s (1 = 100 °C; 2 = 125 °C; 3 = 140 °C; 4 = 150 °C); microwave roasting at 800 W and 2450 MHz (1 = 1 min [kernel temp = 57 °C], 2 = 2 min [kernel temp = 88 °C], 3 = 3 min [kernel temp = 108 °C], 4 = 4 min [kernel temp = 121 °C], 5 = 5 min [kernel temp = 132 °C]); Autoclaving at 120 °C and 1.2 bars (1 = 10 min, 2 = 20 min, 3 = 30 min). Reprinted with permission from Žilić et al. (2012).

et al., 2017). Figure 2 highlights the variability between processing methods and thermic conditions for decreasing antinutritional factors. For example, when soybeans were subjected to extrusion at increasing temperatures that ranged from 100 to 150 °C, trypsin inhibitor levels were incrementally decreased. At 140 °C, dry extrusion was considerably more effective at decreasing trypsin inhibitors (−91%) compared with wet extrusion (−44%). When the dry extrusion temperature was increased to 150 °C, reductions in trypsin inhibitors were further decreased by 94% (Žilić et al., 2012). Other thermal treatments, such as micronisation, microwave roasting, and autoclaving, also facilitated incremental reductions in trypsin inhibitors with increasing temperatures (Žilić et al., 2012). When formulating foods with higher concentrations of plant-based ingredients, consideration should also be given to the processing methods and the parameters used to effectively optimize the nutritional density and decrease antinutritional factors.

It is important to mention that, while temperature and pressure processing can greatly decrease antinutritional factors, they can also negatively affect bioavailability of AAs. The Maillard reaction is a well-known example of heat-damaged protein (Teodorowicz et al., 2017). In this reaction, lysine interacts with reducing sugars present in the diets forming the Maillard product. The

complex formed can be digested and absorbed by the animal but cannot be utilized for metabolic processes (e.g., protein synthesis). Thus, in heat-damaged proteins, digestibility of AAs can greatly overestimate bioavailability (Moehn et al., 2005). Other products of heat damage on proteins include racemization of AAs (alteration from L to D form) and the formation of cross-linked AAs. Such components can decrease bioavailability of AAs and digestibility of proteins, and their effects on protein quality cannot usually be determined using conventional methods of AA analysis. Pet foods with higher levels of plant-based ingredients may also require optimization of processing methods to maximize their nutritional density and nutrient bioavailability.

Recommendations for Formulating Dog Food With Novel Ingredients

Considering the AA profile of dog foods. Feed formulation for agricultural and companion animals should be based on the ideal protein concept (Baker, 1991; Swanson et al., 2013). The ideal protein is defined as that in which all AAs are in perfect balance compared with the animal's AA requirements (mg/g protein). Hence, all indispensable AAs are equally limiting. However, this is impossible to achieve in practical animal feed formulation, and diets should be formulated considering the first limiting indispensable AA. The first limiting indispensable AA refers to the indispensable AA that is present in the lowest proportion compared with the animal's requirement. By meeting the first indispensable limiting AA requirement, requirements for all other indispensable AAs are also inherently satisfied. Moreover, to avoid the formulation of diets with excessive protein concentration or an excess of indispensable AAs relative to the requirements of dogs, animal nutritionists combine multiple ingredients that are complementary in their AA profiles. Commonly, dog foods are formulated with a higher proportion of animal-derived ingredients, and a lower proportion of plant-based ingredients to meet nutrient recommendations. More recently, however, cereal grains have been removed in some diet formulations or the proportion of animal-based ingredients has been reduced. The production of these types of formulations is often driven by consumer perception, rather than scientific evidence. Allowing consumers to direct the ingredient composition of dog foods, or other pet foods, could perpetuate nutrient deficits that affect the health of animals in the long term.

In the formulation of grain-free pet foods, cereal grains are replaced with alternative ingredient(s). Animal-derived ingredients are expensive relative to plant-based ingredients. Thus, pulses, a subset of legumes, are often used as the replacement. In addition to containing substantial fiber, pulses also contain significant concentrations of protein and are used to partly meet indispensable AA requirements. Of interest, soybean meal and pulses contain 48% and 25% crude protein, respectively, which is substantially greater than the average protein concentration for grains (11%; Table 1). Although the high-protein content in soybean meal and pulses is indicative of higher concentration of AAs compared with grains, it does not imply AA balance. Soybean meal and pulses are high in lysine (mg/g protein) but low in sulfur AAs (mg/g protein), whereas the reverse is true for cereals. Plant-based ingredients tend to have lower ileal digestibility coefficients for protein compared with protein from animal sources (FAO and WHO, 1991). Thus, dog foods that contain substantial amounts of pulses, lower proportions of animal-based ingredients, and do not address AA imbalances through the addition of alternate ingredients or fortification, may risk AA deficiencies. To mitigate this risk across the pet food industry and ensure the final pet diets are nutritionally adequate and balanced, it is prudent that the digestibility coefficients of all final pet food products be calculated.

Considering the addition of high-fiber ingredients to dog foods. By definition, dietary fiber is carbohydrates that are resistant to digestion by endogenous enzymes in the gastrointestinal tract (NRC, 2006). Typical fibers include arabinoxylan, raffinose, inulin, β -glucan, cellulose, and pectin (NRC, 2006). Common ingredients to increase fiber content in companion animal diets include beet pulp, corn fiber, rice bran, whole grains, and pulse fibers (de Godoy et al., 2013). Achieving an optimal fiber concentration in canine diets has diverse positive physiological effects in the gastrointestinal tract; for example, higher fermentable fiber intake has been shown to slow the transit time of digesta, increasing satiety of the animal (Haber et al., 1977). Moreover, high-fiber diets generally have lower energy density making them an important nutritional strategy for controlling body weight (Johnson et al., 2008) and reducing the incidence of diarrhea (Homann et al., 1994). Gut health is also improved with higher consumption of fiber; fermentable fiber can act as a prebiotic and increase the population of health-promoting microbiota including lactobacilli and

bifidobacteria (Roberfroid, 2005). Although not required by AAFCO to fulfill the criteria of “complete and balanced,” fiber is an important component of the diet, and depending on the type of fiber and the amount consumed, fiber can increase the gut health status. Adding the necessary amount and type of fiber in the diet is crucial for optimal dog nutrition.

Despite the benefits of fiber in the diet, fiber can also affect enterohepatic recycling of taurine (discussed above). In monogastric species, including humans, high dietary fermentable fiber may also decrease digestibility and availability of dietary AAs (Blackburn and Southgate, 1981; Degen et al., 2007) and, in some cases, increase the risk of DCM in dogs fed diets that marginally meet requirements for sulfur AAs. Moreover, higher concentrations of dietary fiber increase the size of the gastrointestinal tract in pigs and poultry (Nyachoti et al., 2000), increasing nutrient utilization in this organ. It has been determined in pigs that on average the gastrointestinal tract catabolizes 30% of dietary indispensable AAs during absorption, and this utilization represents ~50% for sulfur AAs (Stoll et al., 1998; Mansilla et al., 2018), further reducing precursor availability for taurine synthesis and increasing the risk for taurine deficiency. For some high-fiber diets, fortification of specific nutrients, including taurine and other sulfur AAs, might be beneficial to avoid nutrient deficiencies.

Compared with the pet food industry, in other industries where high-fiber ingredients (coproducts) are routinely used (e.g., swine industry), the effects of fiber on the absorption of nutrients have been given more attention when formulating diets (NRC, 2012). For example, highly fermentable fiber in swine diets increases the threonine requirement to compensate for the increase in mucus (mucin protein) production in the intestinal cell lining (Lien et al., 1997; Mathai et al., 2016). This has underpinned the development of “requirement models” (NRC, 2012) to tailor nutrient requirements for pigs while accounting for the different nutrient interactions. In contrast, in the pet food industry, the only concentrations of nutrients used for comparison are those recommended by AAFCO (2018). Such recommendations are static and may not encompass all the effects of the different nutrient combinations in the final diet. There is a clear need in companion animal nutrition to improve the understanding of the interactions of different ingredients and how these alter nutrient requirements for different breeds, age, and physiological status of dogs.

Other recent publications highlight the need for careful nutrient formulation. Several recent papers, both original research and reviews, likewise highlight the unknowns surrounding grain-free diets (typically legume or pulse-based, but sometimes also with “exotic” ingredients such as kangaroo, bison, or wild boar) and DCM. For example, Adin et al. (2019) examined 48 dogs of many breeds with diagnosed DCM and having a known diet history. Among grain-free diets being consumed in this study, 1 dog was particularly associated with DCM, possibly underscoring the importance of specific diet formulation. Furthermore, 2 dogs switched from that diet to other grain-free diets showed improvement in their DCM; it is unclear if those dogs were taurine deficient or if they also received taurine and/or carnitine supplementation. This suggests that grain-free composition per se may not be the root cause of DCM. Another recently published case series of 24 Golden Retrievers with DCM and known diet histories were evaluated, and an association between grain-free diets and DCM was suggested (Kaplan et al., 2018). Most dogs (15 of 24) were fed a single diet which was significantly associated with low blood taurine concentrations, again suggesting that specific diet formulation may play an important role. However, as in the previous study, soluble vs. insoluble fiber concentrations were not available for the diets, nor were taurine, methionine, or cysteine concentrations, meaning that the true nutrient profiles of the diets could not be assessed and reinforcing the point that diet formulation for nutrients—not ingredients—is essential. It also suggests that nutrient requirements may vary widely based on breed, diet, and other phenotypic data. Indeed, most of the dogs with DCM in the previously described study were consuming less energy compared with their predicted requirements (Kaplan et al., 2018). It also bears pointing out that the numbers in both studies were very low (representing less than 100 DCM-affected dogs between them), which surely represents a fraction of the dogs consuming grain-free, pulse-based diets. A recent thoughtful review supports these conclusions by reiterating the crucial need for plant-based diets for dogs to be formulated with sufficient quantities of bioavailable methionine and cysteine to support adequate taurine synthesis (Dodd et al., 2018). This can be achieved with the addition of purified AAs and other sources that are readily available (Gloaguen et al., 2014). Finally, a recent commentary carefully concludes that a true cause-and-effect relationship

between grain-free diets and DCM has not been proven, and other factors may ultimately be more important (Freeman et al., 2018). Taken together, these recent publications may point to faulty nutrient formulation in some, but not all, grain-free diets.

CONCLUSIONS

Recently, it has been suggested that pulse ingredients in commercial dog foods are associated with a limited number of cases of DCM. Although pulse ingredients have been implicated for having negative effects on the taurine status in dogs (deficiency of which is a known cause of canine DCM) based on the available evidence, the relationship between pulses and canine DCM remains undefined. However, the FDA statement may harm consideration of protein alternatives, such as pulses, as quality ingredients in pet foods and undermine attempts to diversify ingredients used across the food chain as the global population continues to grow. Ingredients do not represent the nutritional composition of the diet, and therefore, nutrient deficiencies should not be attributed to individual ingredients. The authors of this commentary recognize the important role of endogenous, and perhaps exogenous, taurine in the prevention of DCM in some dogs. The assurance of appropriate concentrations of all indispensable sulfur AAs, including methionine and cysteine, is crucial for ensuring adequate endogenous synthesis of taurine and to meet the metabolic demands of dogs. Additional dietary factors, such as methyl donors required for sulfur AA metabolism, carnitine for energy production in muscle, and dietary fiber, as well as animal factors, such as breed, size, and health status, should also be investigated when nutrient deficiency-related DCM is suspected.

It is the responsibility of animal nutritionists to formulate balanced diets for dogs, and other animals, by looking beyond the goal of meeting AAFCO recommendations or satisfying unsubstantiated market trends. Pulses and other plant-based ingredients can be used to formulate nutritionally adequate dog foods, and final product formulations should be assessed for nutrient balance and bioavailability, especially when using a limited number of ingredients. Although dietary factors are important in the prevention of sulfur AA deficiency and development of DCM, empirical data and mechanistic studies are required to better understand the indispensable AA requirements of dogs and preventing DCM. In diets that contain high concentrations of dietary fiber, compensative inclusion

of dietary indispensable sulfur AAs, including exogenous taurine, might be required to offset the possibility of increased fecal excretion or microbial assimilation of taurine in the large intestine. Processing conditions may also require adjustments to ensure the presence or effects of antinutritional factors are minimized and nutrient bioavailability is not compromised. Greater awareness of AA balance is crucial for ensuring that AA requirements are met for dogs consuming static diets.

LITERATURE CITED

- AAFCO. 2018. Association of American feed control officials. Official Publication Association of American Feed Control Inc., Oxford.
- Adin, D., T. C. DeFrancesco, B. Keene, S. Tou, K. Meurs, C. Atkins, B. Aona, K. Kurtz, L. Barron, and K. Saker. 2019. Echocardiographic phenotype of canine dilated cardiomyopathy differs based on diet type. *J. Vet. Card.* 21:1–9. doi: 10.1016/j.jvc.2018.11.002.
- Alroy, J., J. E. Rush, L. Freeman, M. S. Amarendhra Kumar, A. Karuri, K. Chase, and S. Sarkar. 2000. Inherited infantile dilated cardiomyopathy in dogs: genetic, clinical, biochemical, and morphologic findings. *Am. J. Med. Genet.* 95:57–66. doi:10.1002/1096-8628(20001106)95:1<57::AID-AJMG12>3.0.CO;2-O
- Arslan, C. 2006. L-Carnitine and its use as a feed additive in poultry feeding a review. *Revue Med Vet.* 157:134–142.
- Avilés-Gaxiola, S., C. Chuck-Hernández, and S. O. Serna Saldivar. 2018. Inactivation methods of trypsin inhibitor in legumes: a review. *J. Food Sci.* 83:17–29. doi: 10.1111/1750-3841.13985
- Backus, R. C., K. S. Ko, A. J. Fascetti, M. D. Kittleson, K. A. Macdonald, D. J. Maggs, J. R. Berg, and Q. R. Rogers. 2006. Low plasma taurine concentration in newfoundland dogs is associated with low plasma methionine and cyst(e)ine concentrations and low taurine synthesis. *J. Nutr.* 136:2525–2533. doi: 10.1093/jn/136.10.2525
- Baker, D. H. 1986. Problems and pitfalls in animal experiments designed to establish dietary requirements for essential nutrients. *J. Nutr.* 116:2339–2349. doi: 10.1093/jn/116.12.2339
- Baker, D. H. 1991. Comparative nutrition of cats and dogs. *Annu. Rev. Nutr.* 11:239–263. doi: 10.1146/annurev.nu.11.070191.001323
- Bakker, A. J., and H. M. Berg. 2002. Effect of taurine on sarcoplasmic reticulum function and force in skinned fast-twitch skeletal muscle fibres of the rat. *J. Physiol.* 538:185–194. doi: 10.1113/jphysiol.2001.012872
- Bélanger, M. C., M. Ouellet, G. Queney, and M. Moreau. 2005. Taurine-deficient dilated cardiomyopathy in a family of golden retrievers. *J. Am. Anim. Hosp. Assoc.* 41:284–291. doi: 10.5326/0410284
- Blackburn, N. A., and Southgate D. A. T. 1981. Protein digestibility and absorption: effects of fibre and the extent of individual variation. Joint FAO/WHO/UNU Expert Consultation on Energy and Protein Requirements Rome; October 5–17.
- Borgarelli, M., R. A. Santilli, D. Chiavegato, G. D'Agnolo, R. Zanatta, A. Mannelli, and A. Tarducci. 2006. Prognostic indicators for dogs with dilated cardiomyopathy. *J. Vet. Intern. Med.* 20:104–110. doi: 10.1111/j.1939-1676.2006.tb02829.x
- Butterwick, R. F., P. J. Markwell, and C. J. Thorne. 1994. Effect of level and source of dietary fiber on food intake in the dog. *J. Nutr.* 124(12 Suppl):2695S–2700S. doi: 10.1093/jn/124.suppl_12.2695S.
- Cattanach, B. M., J. Dukes-McEwan, P. R. Wotton, H. M. Stephenson, and R. M. Hamilton. 2015. A pedigree-based genetic appraisal of boxer ARVC and the role of the striatin mutation. *Vet. Rec.* 176:492. doi: 10.1136/vr.102821.
- Columbus, D., and C. F. de Lange. 2012. Evidence for validity of ileal digestibility coefficients in monogastrics. *Br. J. Nutr.* 108 (Suppl 2):S264–S272. doi: 10.1017/S0007114512002334.
- Degen, L., V. Halas, and L. Babinszky. 2007. Effect of dietary fibre on protein and fat digestibility and its consequences on diet formulation for growing and fattening pigs: a review. *Act. Agr. Scand. A-AN.* 57:1–9. doi: 10.1080/09064700701372038
- Dodd, S. A. S., J. L. Adolphe, and A. Verbrugghe. 2018. Plant-based diets for dogs. *J. Am. Vet. Med. Assoc.* 253:1425–1432. doi: 10.2460/javma.253.11.1425
- Dutton, E., and J. López-Alvarez. 2018. An update on canine cardiomyopathies – is it all in the genes? *J. Small. Anim. Pract.* 59:455–464. doi: 10.1111/jsap.12841
- FAO. 1991. Food and agriculture organization of the United Nations. Protein quality evaluation. Report of Joint FAO/WHO, Expert Consultation, Rome, Italy.
- Fascetti, A. J., J. R. Reed, Q. R. Rogers, and R. C. Backus. 2003. Taurine deficiency in dogs with dilated cardiomyopathy: 12 cases (1997–2001). *J. Am. Vet. Med. Assoc.* 223:1137–1141. doi: 10.2460/javma.2003.223.1137
- FDA, Center for Veterinary Medicine. 2018. FDA investigating potential connection between diet and cases of canine heart disease. <https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm613305.htm> (Accessed 12 July 2018.)
- Flanagan, J. L., P. A. Simmons, J. Vehige, M. D. Willcox, and Q. Garrett. 2010. Role of carnitine in disease. *Nutr. Metab. (Lond).* 7:30. doi: 10.1186/1743-7075-7-30
- Freeman, L. M., and J. E. Rush. 2006. Cardiovascular diseases: nutritional modulation. In: P. Pibot, V. Biourge, and D. Elliott, editors, *Encyclopedia of canine clinical nutrition*. Aniwa SAS, Aimargues. p. 316–347.
- Freeman, L. M., K. E. Michel, D. J. Brown, P. M. Kaplan, M. E. Stamoulis, S. L. Rosenthal, B. W. Keene, and J. E. Rush. 1996. Idiopathic dilated cardiomyopathy in dalmatians: nine cases (1990–1995). *J. Am. Vet. Med. Assoc.* 209:1592–1596.
- Freeman, L. M., J. A. Stern, R. Fries, D. B. Adin, and J. E. Rush. 2018. Diet-associated dilated cardiomyopathy in dogs: what do we know? *J. Am. Vet. Med. Assoc.* 253:1390–1394. doi: 10.2460/javma.253.11.1390
- Gloaguen, M., N. Le Floc'h, E. Corrent, Y. Primot, and J. van Milgen. 2014. The use of free amino acids allows formulating very low crude protein diets for piglets. *J. Anim. Sci.* 92:637–644. doi: 10.2527/jas.2013-6514
- de Godoy, M. R., K. R. Kerr, and G. C. Fahey, Jr. 2013. Alternative dietary fiber sources in companion animal nutrition. *Nutrients* 5:3099–3117. doi: 10.3390/nu5083099.

- Haber, G. B., K. W. Heaton, D. Murphy, and L. F. Burroughs. 1977. Depletion and disruption of dietary fibre. Effects on satiety, plasma-glucose, and serum-insulin. *Lancet* 2:679–682. doi: 10.1016/S0140-6736(77)90494-9
- Homann, H. H., M. Kemen, C. Fuessenich, M. Senkal, and V. Zumtobel. 1994. Reduction in diarrhea incidence by soluble fiber in patients receiving total or supplemental enteral nutrition. *JPEN. J Parenter. Enteral Nutr.* 18:486–490. doi: 10.1177/0148607194018006486
- Hoppel, C. 2003. The role of carnitine in normal and altered fatty acid metabolism. *Am. J. Kidney Dis.* 41:S4–12. doi: 10.1016/S0272-6386(03)00112-4
- Hou, Y., Y. Yin, and G. Wu. 2015. Dietary essentiality of “nutritionally non-essential amino acids” for animals and humans. *Exp. Biol. Med. (Maywood).* 240:997–1007. doi: 10.1177/1535370215587913
- Hurrell, R. F., P. A. Finot, and J. E. Ford. 1983. Storage of milk powders under adverse conditions. I. Losses of lysine and of other essential amino acids as determined by chemical and microbiological methods. *Br. J. Nutr.* 49:343–354. doi: 10.1079/BJN19830043
- Huxtable, R. J. 1992. Physiological actions of taurine. *Physiol. Rev.* 72:101–163. doi: 10.1152/physrev.1992.72.1.101
- Ito, T., S. W. Schaffer, and J. Azuma. 2012. The potential usefulness of taurine on diabetes mellitus and its complications. *Amino Acids* 42:1529–1539. doi: 10.1007/s00726-011-0883-5
- Johnson, L., A. P. Mander, L. R. Jones, P. M. Emmett, and S. A. Jebb. 2008. Energy-dense, low-fiber, high-fat dietary pattern is associated with increased fatness in childhood. *Am. J. Clin. Nutr.* 87:846–854. doi: 10.1093/ajcn/87.4.846
- Johnson, M. L., C. M. Parsons, G. C. Fahey, Jr, N. R. Merchen, and C. G. Aldrich. 1998. Effects of species raw material source, ash content, and processing temperature on amino acid digestibility of animal by-product meals by cecectomized roosters and ileally cannulated dogs. *J. Anim. Sci.* 76:1112–1122. doi: 10.2527/1998.7641112x
- Kaplan, J. L., J. A. Stern, A. J. Fascetti, J. A. Larsen, H. Skolnik, G. D. Peddle, R. D. Kienle, A. Waxman, M. Cocchiario, C. T. Gunther-Harrington, et al. 2018. Taurine deficiency and dilated cardiomyopathy in golden retrievers fed commercial diets. *PLoS One* 13:e0209112. doi: 10.1371/journal.pone.0209112
- Keene, B. W., D. P. Panciera, C. E. Atkins, V. Regitz, M. J. Schmidt, and A. L. Shug. 1991. Myocardial L-carnitine deficiency in a family of dogs with dilated cardiomyopathy. *J. Am. Vet. Med. Assoc.* 198:647–650.
- Kim, S. W., Q. R. Rogers, and J. G. Morris. 1996a. Dietary antibiotics decrease taurine loss in cats fed a canned heat-processed diet. *J. Nutr.* 126:509–515. doi: 10.1093/jn/126.2.509
- Kim, S. W., Q. R. Rogers, and J. G. Morris. 1996b. Maillard reaction products in purified diets induce taurine depletion in cats which is reversed by antibiotics. *J. Nutr.* 126:195–201. doi: 10.1093/jn/126.1.195
- Kittleson, M. D., B. Keene, P. D. Pion, and C. G. Loyer. 1997. Results of the multicenter spaniel trial (MUST): taurine- and carnitine-responsive dilated cardiomyopathy in american cocker spaniels with decreased plasma taurine concentration. *J. Vet. Intern. Med.* 11:204–211. doi: 10.1111/j.1939-1676.1997.tb00092.x
- Ko, K. S., R. C. Backus, J. R. Berg, M. W. Lame, and Q. R. Rogers. 2007. Differences in taurine synthesis rate among dogs relate to differences in their maintenance energy requirement. *J. Nutr.* 137:1171–1175. doi: 10.1093/jn/137.5.1171
- Kramer, G. A., M. D. Kittleson, P. R. Fox, J. Lewis, and P. D. Pion. 1995. Plasma taurine concentrations in normal dogs and in dogs with heart disease. *J. Vet. Intern. Med.* 9:253–258. doi: 10.1111/j.1939-1676.1995.tb01076.x
- Lien, K. A., W. C. Sauer, and M. Fenton. 1997. Mucin output in ileal digesta of pigs fed a protein-free diet. *Z. Ernährungswiss.* 36:182–190. doi: 10.1007/BF01611398
- Linder, D., and M. Mueller. 2014. Pet obesity management: beyond nutrition. *Vet. Clin. North Am. Small Anim. Pract.* 44:789–806, vii. doi: 10.1016/j.cvsm.2014.03.004
- Mansilla, W. D., K. E. Silva, C. Zhu, C. M. Nyachoti, J. K. Htoo, J. P. Cant, and C. F. M. de Lange. 2018. Ammonia-nitrogen added to low-crude-protein diets deficient in dispensable amino acid-nitrogen increases the net release of alanine, citrulline, and glutamate post-splanchnic organ metabolism in growing pigs. *J. Nutr.* 148:1081–1087. doi: 10.1093/jn/nxy076
- Marinangeli, C. P. F., J. Curran, S. I. Barr, J. Slavin, S. Puri, S. Swaminathan, L. Tapsell, and C. A. Patterson. 2017. Enhancing nutrition with pulses: defining a recommended serving size for adults. *Nutr. Rev.* 75:990–1006. doi: 10.1093/nutrit/nux058
- Maron, B. J., J. A. Towbin, G. Thiene, C. Antzelevitch, D. Corrado, D. Arnett, A. J. Moss, C. E. Seidman, J. B. Young. 2006. Contemporary definitions and classification of the cardiomyopathies: an American Heart Association Scientific Statement from the Council on Clinical Cardiology, Heart Failure and Transplantation Committee; Quality of Care and Outcomes Research and Functional Genomics and Translational Biology Interdisciplinary Working Groups; and Council on Epidemiology and Prevention. *Circulation.* 113:1807–1816. doi: 10.1161/CIRCULATIONAHA.106.174287
- Marshall, H. F., K. C. Chang, K. S. Miller, and L. D. Satterlee. 1982. Sulfur amino acid stability: effects of processing on legume proteins. *J. Food Sci.* 47:1170–4. doi: 10.1111/j.1365-2621.1982.tb07642.x
- Martin, M. W., M. J. Stafford Johnson, and B. Celona. 2009. Canine dilated cardiomyopathy: a retrospective study of signalment, presentation and clinical findings in 369 cases. *J. Small Anim. Pract.* 50:23–29. doi: 10.1111/j.1748-5827.2008.00659.x
- Mathai, J. K., J. K. Htoo, J. E. Thomson, K. J. Touchette, and H. H. Stein. 2016. Effects of dietary fiber on the ideal standardized ileal digestible threonine:lysine ratio for twenty-five to fifty kilogram growing gilts. *J. Anim. Sci.* 94:4217–4230. doi: 10.2527/jas.2016-0680
- Menniti, M. F., G. M. Davenport, A. K. Shoveller, J. P. Cant, and V. R. Osborne. 2014. Effect of graded inclusion of dietary soybean meal on nutrient digestibility, health, and metabolic indices of adult dogs. *J. Anim. Sci.* 92:2094–2104. doi: 10.2527/jas.2013-7226
- Merheb, M., R. T. Daher, M. Nasrallah, R. Sabra, F. N. Ziyadeh, and K. Barada. 2007. Taurine intestinal absorption and renal excretion test in diabetic patients: a pilot study. *Diabetes Care* 30:2652–2654. doi: 10.2337/dc07-0872
- Meurs, K. M., S. Lahmers, B. W. Keene, S. N. White, M. A. Oyama, E. Mauceli, and K. Lindblad-Toh. 2012. A splice site mutation in a gene encoding for PDK4, a mitochondrial protein, is associated with

- the development of dilated cardiomyopathy in the doberman pinscher. *Hum. Genet.* 131:1319–1325. doi: 10.1007/s00439-012-1158-2
- Meurs, K. M., J. A. Stern, D. D. Sisson, M. D. Kittleson, S. M. Cunningham, M. K. Ames, C. E. Atkins, T. DeFrancesco, T. E. Hodge, B. W. Keene, et al. 2013. Association of dilated cardiomyopathy with the striatin mutation genotype in boxer dogs. *J. Vet. Intern. Med.* 27:1437–1440. doi: 10.1111/jvim.12163
- Moehn, S., R. F. Bertolo, P. B. Pencharz, and R. O. Ball. 2005. Development of the indicator amino acid oxidation technique to determine the availability of amino acids from dietary protein in pigs. *J. Nutr.* 135:2866–2870. doi: 10.1093/jn/135.12.2866
- Moise, N. S., L. M. Pacioretty, F. A. Kallfelz, M. H. Stipanuk, J. M. King, and R. F. Gilmour, Jr. 1991. Dietary taurine deficiency and dilated cardiomyopathy in the fox. *Am. Heart J.* 121:541–547. doi: 10.1016/0002-8703(91)90724-V
- Monnet, E., E. C. Orton, M. Salman, and J. Boon. 1995. Idiopathic dilated cardiomyopathy in dogs: survival and prognostic indicators. *J. Vet. Intern. Med.* 9:12–17. doi: 10.1111/j.1939-1676.1995.tb03266.x
- Nardelli, T. R., R. A. Ribeiro, S. L. Balbo, E. C. Vanzela, E. M. Carneiro, A. C. Boschero, and M. L. Bonfleur. 2011. Taurine prevents fat deposition and ameliorates plasma lipid profile in monosodium glutamate-obese rats. *Amino Acids* 41:901–908. doi: 10.1007/s00726-010-0789-7
- NRC, National Research Council. 2006. Nutrient requirements of dogs and cats. 10th ed. Natl. Acad. Press, Washington, DC.
- NRC, National Research Council. 2012. Nutrient requirements of swine. 11th ed. Natl. Acad. Press, Washington, DC.
- Nyachoti, C. M., C. F. M. de Lange, B. W. McBride, S. Leeson, and H. Schulze. 2000. Dietary influence on organ size and in vitro oxygen consumption by visceral organs of growing pigs. *Livest Prod Sci.* 65:229–237. doi: 10.1016/S0301-6226(00)00157-3
- O'Máille, E. R., T. G. Richards, and A. H. Short. 1965. Acute taurine depletion and maximal rates of hepatic conjugation and secretion of cholic acid in the dog. *J. Physiol.* 180:67–79.
- Owczarek-Lipska, M., T. B. Mausberg, H. Stephenson, J. Dukes-McEwan, G. Wess, and T. Leeb. 2013. A 16-bp deletion in the canine PDK4 gene is not associated with dilated cardiomyopathy in a European cohort of doberman pinschers. *Anim. Genet.* 44:239. doi: 10.1111/j.1365-2052.2012.02396.x
- Patterson, C. A., J. Curran, and T. Der. 2017. Effect of processing on antinutrient compounds in pulses. *Cereal Chemistry.* 94:2–10. doi: 10.1094/CCHEM-05-16-0144-FI
- Pion, P. D., M. D. Kittleson, Q. R. Rogers, and J. G. Morris. 1987. Myocardial failure in cats associated with low plasma taurine: a reversible cardiomyopathy. *Science* 237:764–768. doi: 10.1126/science.3616607
- Pion, P. D., S. L. Sanderson, and M. D. Kittleson. 1998. The effectiveness of taurine and levocarnitine in dogs with heart disease. *Vet. Clin. North Am. Small Anim. Pract.* 28:1495–514, ix. doi: 10.1016/S0195-5616(98)50134-9
- Rășanu, T., M. Mehedinti-Hâncu, M. Alexianu, T. Mehedinti, E. Gheorghe, and I. Damian. 2012. Carnitine deficiency. *Rom. J. Morphol. Embryol.* 53:203–206.
- Rice, J. E., and S. L. Ihle. 1994. Effects of diet on fecal occult blood testing in healthy dogs. *Can. J. Vet. Res.* 58:134–137.
- Roberfroid, M. B. 2005. Introducing inulin-type fructans. *Br. J. Nutr.* 93 (Suppl 1):S13–S25. doi: 10.1079/BJN20041350
- Robinson, J. L., S. V. Harding, J. A. Brunton, and R. F. Bertolo. 2016a. Dietary methyl donors contribute to whole-body protein turnover and protein synthesis in skeletal muscle and the jejunum in neonatal piglets. *J. Nutr.* 146:2007–2012. doi: 10.3945/jn.115.226035
- Robinson, J. L., L. E. McBreaity, E. W. Randell, J. A. Brunton, and R. F. Bertolo. 2016b. Restriction of dietary methyl donors limits methionine availability and affects the partitioning of dietary methionine for creatine and phosphatidylcholine synthesis in the neonatal piglet. *J. Nutr. Biochem.* 35:81–86. doi: 10.1016/j.jnutbio.2016.07.001
- Sanderson, S. L., K. L. Gross, P. N. Ogburn, C. Calvert, G. Jacobs, S. R. Lowry, K. A. Bird, L. A. Koehler, and L. L. Swanson. 2001. Effects of dietary fat and L-carnitine on plasma and whole blood taurine concentrations and cardiac function in healthy dogs fed protein-restricted diets. *Am. J. Vet. Res.* 62:1616–1623. doi:10.2460/ajvr.2001.62.1616
- Schaffer, S. W., C. J. Jong, K. C. Ramila, and J. Azuma. 2010. Physiological roles of taurine in heart and muscle. *J. Biomed. Sci.* 17 (Suppl 1):S2. doi: 10.1186/1423-0127-17-S1-S2
- Sisson, D. D., W. P. Thomas, and B. W. Keene. 2000. Primary myocardial disease in the dog. In: S. J. Ettinger, and E. C. Feldman, editors, *Textbook of veterinary internal medicine. Diseases of the dog and cat.* 5th ed. WB Saunders Co., Philadelphia. p. 874–895.
- Spitze, A. R., D. L. Wong, Q. R. Rogers, and A. J. Fascetti. 2003. Taurine concentrations in animal feed ingredients; cooking influences taurine content. *J. Anim. Physiol. Anim. Nutr. (Berl).* 87:251–262. doi: 10.1046/j.1439-0396.2003.00434.x
- Stoll, B., J. Henry, P. J. Reeds, H. Yu, F. Jahoor, and D. G. Burrin. 1998. Catabolism dominates the first-pass intestinal metabolism of dietary essential amino acids in milk protein-fed piglets. *J. Nutr.* 128:606–614. doi: 10.1093/jn/128.3.606
- Story, J. A., and D. Kritchevsky. 1978. Bile acid metabolism and fiber. *Am. J. Clin. Nutr.* 31 (10 Suppl):S199–S202. doi: 10.1093/ajcn/31.10.S199
- Swanson, K. S., R. A. Carter, T. P. Yount, J. Aretz, and P. R. Buff. 2013. Nutritional sustainability of pet foods. *Adv. Nutr.* 4:141–150. doi: 10.3945/an.112.003335
- Teodorowicz, M., J. van Neerven, and H. Savelkoul. 2017. Food processing: the influence of the Maillard reaction on immunogenicity and allergenicity of food proteins. *Nutrition* 9:835. doi: 10.3390/nu9080835
- Tôrres, C. L., R. C. Backus, A. J. Fascetti, and Q. R. Rogers. 2003. Taurine status in normal dogs fed a commercial diet associated with taurine deficiency and dilated cardiomyopathy. *J. Anim. Physiol. Anim. Nutr. (Berl).* 87:359–372. doi:10.1046/j.1439-0396.2003.00446.x
- Tosh, S.M., and S. Yada. 2010. Dietary fibres in pulse seeds and fractions: characterization, functional attributes, and applications. *Food Res. Int.* 43:450–460. doi: 10.1016/j.foodres.2009.09.005
- Werner, P., M. G. Raducha, U. Prociuk, M. M. Sleeper, T. J. Van Winkle, and P. S. Henthorn. 2008. A novel locus for dilated cardiomyopathy maps to canine

- chromosome 8. *Genomics* 91:517–521. doi: 10.1016/j.ygeno.2008.03.007
- Worden, J. A., and M. H. Stipanuk. 1985. A comparison by species, age and sex of cysteinesulfinatase activity and taurine concentration in liver and brain of animals. *Comp. Biochem. Physiol.* 82B:233–239. doi: 10.1016/0305-0491(85)90232-9
- Yamka, R. M., U. Jamikorn, A. D. True, and D. L. Harmon. 2003. Evaluation of soybean meal as a protein source in canine foods. *Anim. Feed Sci. Technol.* 109:121–132. doi: 10.1016/S0377-8401(03)00203-7
- Žilić, S., I. Božović, and V. H. T. Šukalović. 2012. Thermal inactivation of soybean bioactive proteins. *Int. J. Food Eng.* 8:1556–3758. doi:10.1515/1556-3758.2521

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogenesis, Martine; Putnam, Juli; DeLancey, Siobhan; Jones, Jennifer L; Reimschuessel, Renate; Carey, Lauren; Norris, Anne
CC: Forfa, Tracey; Rotstein, David; Eisenman, Theresa; Nemser, Sarah
Sent: 7/24/2018 1:32:11 PM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Lee Anne

From: Hartogenesis, Martine
Sent: Tuesday, July 24, 2018 9:09 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

B5

Martine

From: Putnam, Juli
Sent: Tuesday, July 24, 2018 8:41 AM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: DeLancey, Siobhan

Sent: Monday, July 23, 2018 12:56 PM

To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Siobhan DeLancey, RVT, MPH

O: 240-402-9973

M: B6

Siobhan.DeLancey@fda.hhs.gov

From: Putnam, Juli

Sent: Monday, July 23, 2018 12:45 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Thanks for your guidance.

Best,
Juli

From: Jones, Jennifer L

Sent: Monday, July 23, 2018 6:48 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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



From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:27 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Renate!

Martine

From: Reimschuessel, Renate
Sent: Friday, July 20, 2018 11:26 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:14 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Ok, thanks Juli! I am looping in Sarah Nemser and Renate in case they know, but no worries if not.

Thanks again!

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 11:02 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks, Martine. I got an out of office that Jen is out until Monday. However, if we are able to confirm this number before then, please send to my colleague Theresa Eisenman (copied on this email) and she will provide it to the NYT reporter. I am on leave the rest of today so Theresa will be able to help on any other follow-up we may have with NYT or Washington Post on DCM today.

Thanks, and hope everyone has a good weekend!

Best,
Juli

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 10:21 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

It sounds like there may be about B5 Jen, can you confirm?

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 10:19 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Carey, Lauren
Sent: Friday, July 20, 2018 9:50 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne

<Anne.Norris@fda.hhs.gov>

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

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Hartogenesisis, Martine

Sent: Friday, July 20, 2018 8:02 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

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

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Jen.

B5

Martine

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

Date: July 20, 2018 at 6:47:01 AM EDT

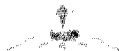
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogenesisis, Martine <Martine.Hartogenesisis@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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



From: Carey, Lauren

Sent: Thursday, July 19, 2018 4:12 PM

To: Hartogenesisis, Martine <Martine.Hartogenesisis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>;
Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Jen should have an answer for you on that.

From: Hartogenesis, Martine

Sent: Thursday, July 19, 2018 4:02 PM

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

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@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: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

Just looping in the dream team again. Do any of you know if our

B5

TIA!

Martine

From: Putnam, Juli

Sent: Thursday, July 19, 2018 3:58 PM

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

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

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Hartogenesis, Martine

Sent: Thursday, July 19, 2018 3:43 PM

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

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

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Great points, thank you Anne!

From: Norris, Anne

Sent: Thursday, July 19, 2018 3:42 PM

To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

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

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

I know you haven't accepted yet, Martine, but wanted to throw these points out for you and Juli to consider for future interviews. We keep getting variations on the same questions over and over again from consumers, so it might be helpful to mention a variation of the information provided below to allay some of the consumer anxiety out there.

B5

Thanks,
Anne

From: Putnam, Juli
Sent: Thursday, July 19, 2018 3:33 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Martine,
Are you willing to do another interview on DCM tomorrow morning? Washington Post is now writing too.
Please advise.
Thanks!
Juli

Reporter: Kate Furby
Outlet: Washington Post
Deadline: 7/20

Background: Kate would like to write a story on FDA's alert regarding DCM and its potential link to dog food. This would be for the Health, Environment, Science section of the Post. She is contacting a few vets at universities now as well.

Questions:

She said her questions would just be standard ones about the FDA alert on dog food and canine heart health.

- Questions about DCM – what is it, what are symptoms, how is it detected, how common is it, etc.
- Questions about legumes and potatoes in dog diets.

Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-0537 / B6
Juli.Putnam@fda.hhs.gov



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Carey, Lauren; Hartogensis, Martine; Putnam, Juli; Norris, Anne
CC: DeLancey, Siobhan; Forfa, Tracey; Rotstein, David
Sent: 7/20/2018 10:46:55 AM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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



From: Carey, Lauren
Sent: Thursday, July 19, 2018 4:12 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
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Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
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Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-0537

B6

Juli.Putnam@fda.hhs.gov



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Hartogensis, Martine; Carey, Lauren; Putnam, Juli; Norris, Anne
CC: DeLancey, Siobhan; Forfa, Tracey; Rotstein, David
Sent: 7/20/2018 12:07:18 PM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thank you for clarifying.

B5

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



From: Hartogensis, Martine

Sent: Friday, July 20, 2018 8:02 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Jen.

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Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
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Outlet: Washington Post
Deadline: 7/20
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Juli Putnam

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration

Tel: 240-402-0537

B6

Juli.Putnam@fda.hhs.gov



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Hartogenesis, Martine; Reimschuessel, Renate; Putnam, Juli; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Forfa, Tracey; Rotstein, David; Eisenman, Theresa; Nemser, Sarah
Sent: 7/23/2018 10:47:31 AM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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



From: Hartogenesis, Martine
Sent: Friday, July 20, 2018 11:27 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Renate!

Martine

From: Reimschuessel, Renate
Sent: Friday, July 20, 2018 11:26 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:14 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Ok, thanks Juli! I am looping in Sarah Nemser and Renate in case they know, but no worries if not.

Thanks again!

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 11:02 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks, Martine. I got an out of office that Jen is out until Monday. However, if we are able to confirm this number before then, please send to my colleague Theresa Eisenman (copied on this email) and she will provide it to the NYT reporter. I am on leave the rest of today so Theresa will be able to help on any other follow-up we may have with NYT or Washington Post on DCM today.

Thanks, and hope everyone has a good weekend!

Best,
Juli

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 10:21 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Hi Juli,

It sounds like there may be about B5 Jen, can you confirm?

Martine

From: Putnam, Juli
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To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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From: Carey, Lauren
Sent: Friday, July 20, 2018 9:50 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Thanks Jen.

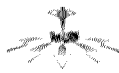
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Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

Just looping in the dream team again. Do any of you know if our

B5

TIA!

Martine

From: Putnam, Juli
Sent: Thursday, July 19, 2018 3:58 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

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From: Hartogensis, Martine
Sent: Thursday, July 19, 2018 3:43 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Great points, thank you Anne!

From: Norris, Anne
Sent: Thursday, July 19, 2018 3:42 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

I know you haven't accepted yet, Martine, but wanted to throw these points out for you and Juli to consider for

future interviews. We keep getting variations on the same questions over and over again from consumers, so it might be helpful to mention a variation of the information provided below to allay some of the consumer anxiety out there.

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Anne

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Subject: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Martine,
Are you willing to do another interview on DCM tomorrow morning? Washington Post is now writing too.
Please advise.
Thanks!
Juli

Reporter: Kate Furby
Outlet: Washington Post
Deadline: 7/20

Background: Kate would like to write a story on FDA's alert regarding DCM and its potential link to dog food. This would be for the Health, Environment, Science section of the Post. She is contacting a few vets at universities now as well.

Questions:

She said her questions would just be standard ones about the FDA alert on dog food and canine heart health.

- Questions about DCM – what is it, what are symptoms, how is it detected, how common is it, etc.
- Questions about legumes and potatoes in dog diets.

Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-0537 **B6**
Juli.Putnam@fda.hhs.gov



From: Putnam, Juli </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45A45E85E6E94413A4BD2C9FDBB3DE1B-JULIANN.PUT>
To: Hartogensis, Martine; DeLancey, Siobhan; Jones, Jennifer L; Reimschuessel, Renate; Carey, Lauren; Norris, Anne; Palmer, Lee Anne
CC: Forfa, Tracey; Rotstein, David; Eisenman, Theresa; Nemser, Sarah
Sent: 7/27/2018 1:25:59 PM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Hi all,
The Washington Post story got delayed and now the reporter (Kate Furby) is asking us for an updated case count for dogs without the genetic predisposition falling ill. She also wants an updated number on the dogs who may have passed away as a result. She saw that The New York Times mentioned that the FDA had reported three deaths. She is wondering if these deaths were just since the report came out, or if this is total number. (I know those were the # from our initial warning but not sure if more deaths have been reported to us since).

Are we able to provide an updated case count between now and next Tuesday? I will, of course, remind her that the numbers are constantly changing so they only represent a single point in time.

Best,
Juli

From: Hartogensis, Martine
Sent: Tuesday, July 24, 2018 9:09 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

B5

Martine

From: Putnam, Juli
Sent: Tuesday, July 24, 2018 8:41 AM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: DeLancey, Siobhan

Sent: Monday, July 23, 2018 12:56 PM

To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Siobhan DeLancey, RVT, MPH

O: 240-402-9973

B6

Siobhan.DeLancey@fda.hhs.gov

From: Putnam, Juli

Sent: Monday, July 23, 2018 12:45 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Thanks for your guidance.

Best,

Juli

From: Jones, Jennifer L

Sent: Monday, July 23, 2018 6:48 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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



From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:27 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Renate!

Martine

From: Reimschuessel, Renate
Sent: Friday, July 20, 2018 11:26 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

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: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:14 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Ok, thanks Juli! I am looping in Sarah Nemser and Renate in case they know, but no worries if not.

Thanks again!

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 11:02 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks, Martine. I got an out of office that Jen is out until Monday. However, if we are able to confirm this number before then, please send to my colleague Theresa Eisenman (copied on this email) and she will provide it to the NYT reporter. I am on leave the rest of today so Theresa will be able to help on any other follow-up we may have with NYT or Washington Post on DCM today.

Thanks, and hope everyone has a good weekend!

Best,
Juli

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 10:21 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

It sounds like there may be about B5 Jen, can you confirm?

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 10:19 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

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From: Carey, Lauren
Sent: Friday, July 20, 2018 9:50 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne

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Thanks Jen.

B5

Martine

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

Date: July 20, 2018 at 6:47:01 AM EDT

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>

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



From: Carey, Lauren

Sent: Thursday, July 19, 2018 4:12 PM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>

Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Jen should have an answer for you on that.

From: Hartogenesis, Martine

Sent: Thursday, July 19, 2018 4:02 PM

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

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

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

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

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

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Outlet: Washington Post
Deadline: 7/20

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- Questions about DCM – what is it, what are symptoms, how is it detected, how common is it, etc.
- Questions about legumes and potatoes in dog diets.

Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-0537 / B6
Juli.Putnam@fda.hhs.gov





Montréal, Quebec Canada
June 3 - 6, 2009

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MAIN : [AAVN/ACVN \(Small Animal\)](#) : Taurine Supplementation

BACK TO AAVN/ACVN (Small Animal) NEXT >>

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Could Dietary Taurine Supplementation in Dogs Be Masking a Problem?

Robert C. Backus, MS, DVM, PhD, DACVN
Columbia, MO, USA

18689779

INTRODUCTION

The need for dietary protein relates to its constituent amino acids. Perhaps the most recognized need for dietary protein is for provision of amino acids used in the synthesis of body proteins, which constantly turnover, and the synthesis of non-protein substances, such as signaling molecules, pigments, antioxidants. Perhaps less well recognized about the need for dietary protein is for the provision of amino acids for support of metabolic pathways and products of amino acid catabolism, such amino nitrogen, methyl carbon, reduced sulfur, and the carbon- and nitrogen-containing skeletal elements of amino acids. The basis of the need for dietary protein is in essence reflective of needs for amino acids in a great variety of functions. Determining dietary adequacy in providing amino acids is then complicated by there being so many different functions that depend on the supply of amino acids. Hence, at times the dietary amino acid content needed to meet one function may not be great enough to meet the need for another function. For this reason, dietary protein and amino acid adequacies are evaluated from outcomes of a few different variables. Nitrogen balance and optimal growth rate and nitrogen retention are the most commonly evaluated variables. In some cases, other additional variables are evaluated because a physiological or metabolic function with a recognized health consequence requires a greater dietary concentration for optimization. One example used in dogs is urinary excretion of orotic acid. When dietary arginine is adequately provided, urinary excretion of orotic acid is minimized. Another variable that has come to light recent years is blood taurine concentration in dogs. Dietary protein provision that supports a minimal concentration of taurine in the blood of dogs is targeted to prevent development of cardiomyopathy. In the information presented below, the basis for evaluation of blood taurine in dogs will be described and the practice of taurine supplementation of diets for normal healthy dogs will be discussed.

TAURINE DEFICIENCY

Taurine is unique among dietary amino acids in that it is structurally a β -sulfonic amino acid and not bound in protein. Body needs for taurine may be met from dietary sources replete with taurine and by synthesis from sulfur-containing amino acids that are variably abundant in dietary protein, i.e., methionine and cyst(e)ine. Body needs for taurine have been realized from metabolic aberrations, dysfunction, and disease observed in experimental and natural depletions of body taurine caused by inadequate intake of methionine, cyst(e)ine, and or taurine. Body taurine reserves affect many functions, including fetal development, growth, reproduction, neuromodulation, vision, hearing, immunity, and cardiac performance.

Nutritional research that determined the cause of taurine deficiency in cats led to recognition that the synthesis of taurine from dietary methionine and cyst(e)ine is limited in strict carnivores. The limitation is so great that taurine must be included in the diets of cats and other carnivores to prevent deficiency disease. Low activity of a liver enzyme in the taurine biosynthetic pathway (cysteine dioxygenase and cysteine cysteinesulfinate decarboxylase) is among suggested causes for limited production of taurine in cats¹ (Figure 1). Most herbivores and omnivores, among which dogs are included, appear capable of meeting body taurine through *de novo* synthesis of taurine when dietary methionine and cyst(e)ine are adequately provided. It is for this reason that taurine is not considered to be an essential nutrient in dogs.

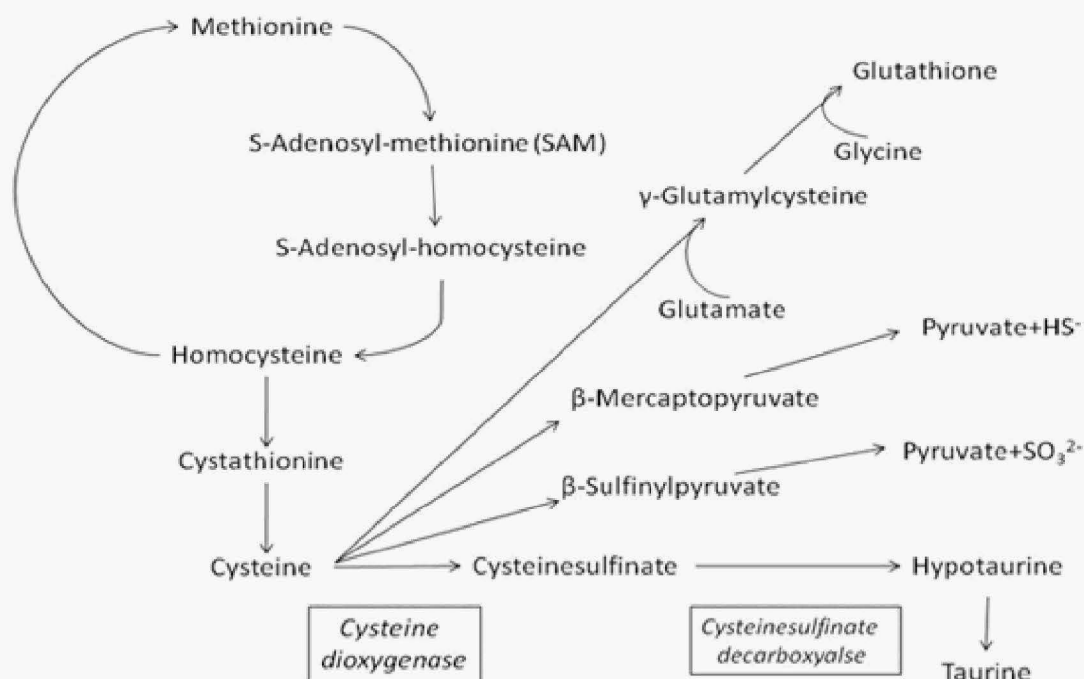
Nonetheless, taurine deficiency has been observed in dogs given diets apparently adequate in methionine and cyst(e)ine. At this time, taurine deficiency appears most clearly to affect heart function in dogs, seen clinically as a reversible dilated cardiomyopathy^{2,3}. Retinal degeneration as indicated from fundic exams has been described in few dogs⁴. Poor reproduction, small litters, and short-statured puppies have been anecdotally reported³. Correlation with low activity, health problems, and need for medications are also described⁵. Some of the taurine deficiency disease may be breed-specific. A dilated cardiomyopathy that appears to respond to taurine supplementation has been described in American Cocker Spaniels with low blood taurine concentration⁶. Low blood taurine concentration has been described in Newfoundlands with cystinuria⁷. In this case, urinary loss of biosynthetic precursor of taurine is surmised to explain the taurine deficiency. A

defect in renal tubular reabsorption of cystine from an inherited mutation of an amino acid transporter appears to underlie Newfoundland cystinuria⁸.

During the last 10 years, a taurine deficiency of nutritional origin has been described in dogs. One case in research Beagles clearly could be attributed to long-term feeding of a low protein diet⁹. Methionine and cyst(e)ine in the experimental diet were evidently inadequate because blood taurine concentrations among the dogs were low, and two dogs showed signs consistent with dilated cardiomyopathy that was improved by taurine supplementation. In other cases, clinically presented dogs of a variety of breeds are reported to have low blood taurine concentration and varying degrees of myocardial failure^{2,3,10,11}. Many of these dogs were of large body size and maintained on commercial diets in which lamb-meal and rice were the principal protein sources. The cause for the taurine deficiency among the dogs was initially unclear. Breed differences in protein digestibility have been reported but the differences did not seem consistent with body size¹². Chemical analyses of suspect diets revealed more than adequate dietary protein, methionine, and cyst(e)ine, and varying amounts of dietary taurine. However, taurine status could be improved by oral methionine or dietary change³. It seemed that bioavailabilities of either dietary protein, methionine, and or cyst(e)in were low.

The cause for the susceptibility of large-breed dogs to taurine deficiency has been investigated in recent years. The approach for this has involved comparisons between Beagles and larger dogs, about 3 times or greater in body weight. This research has produced several important findings. Gastrointestinal and not urinary taurine loss was found to be greater in large compared to small dogs given the same diet¹³. The cause for the size-difference was not clear but as indicated from fecal bile acid analysis it may have been related to differences in efficiency of bile acid reabsorption. Like cats, dogs conjugate their bile acids with taurine. Comparisons of taurine synthesis between large and small dogs revealed an impact of food intake and energy requirement of maintenance^{13,14}. Unlike that which is observed in cats, taurine status in dogs was found to increase with food intake and energy needed to maintain a healthy body weight^{15,16}. Together these findings indicated a greater need for taurine biosynthesis and precursor to support the biosynthesis in large compared to small dogs, especially in large dogs with a low maintenance energy requirement. This conclusion meant that a greater risk for taurine deficiency may be expected in large- than small-breed dogs if fed diets that are marginal protein content and or sulfur-containing amino bioavailability.

Figure 1. Metabolic pathways to taurine synthesis.



DIETARY SUPPLEMENTATION

As a result of finding causes for taurine deficiency in dogs, taurine was recognized to be a dispensable nutrient for dogs when inadequate quantities of sulfur-containing amino acids are provided¹⁷. An adequate intake of taurine for dogs was recommended for diets low in protein or known to be low in sulfur-containing amino acids. For other diets, the sulfur-containing amino acid allowance for dogs was substantially increased by the

NRC^{17,18}. Based on the extent of the increase in the allowance, it would seem that much of the sulfur-containing amino acid requirement in dogs is devoted to taurine synthesis. This condition can be appreciated by comparing recommendations for dogs with those for cats. The recommended allowance for methionine + cystine in diets for dogs (1.65 g/1000 kcal) in the maintenance state are now about twice that of cats (0.85 g/1000 kcal), a species in which taurine needs cannot be met by biosynthesis. Recommended allowances for most other amino acids in dogs are lower than those in cats.

In apparently responding to reports of taurine deficiency in dogs, pet food manufacturers have been supplementing some diets for dogs with taurine. The taurine supplementation is not limited to diets low in protein. This practice unfortunately eliminates application of a very useful means for evaluation of sulfur-containing amino acid bioavailability. As pointed out by Odle *et al.* over 15 years ago¹⁹, the monitoring of taurine status is potentially useful for determining the adequacy dietary sulfur-containing amino acid content in animals that synthesize taurine, such as dogs. The adequacy of dietary provision of methionine and cystine is not sensitively indicated by changes in plasma concentrations of methionine and cyst(e)ine. This appears to be a beneficial consequence of homeostatic regulation of the amino acids by liver. When in excess, methionine and cysteine compared to other dietary amino acids have a greater potential to be toxic. In contrast, taurine has low toxicity and its concentrations in plasma are observed to vary substantially with dietary sulfur amino acid concentration. End products of methionine and cysteine metabolism other than taurine could be monitored; however, they may not be as sensitive or as desirable to measure as taurine. Glutathione is a good example for comparison because glutathione synthesis utilizes methionine and cyst(e)ine. Glutathione, like taurine, occurs in high concentrations in many cell types, serves as an antioxidant, circulates in plasma, and has many vital functions. Low glutathione concentrations in tissues are believed to compromise cell function, to promote tissue damage, and increase morbidity under various disease conditions²⁰. Though glutathione is arguably important to consider in suspected dietary deficiency of sulfur-containing amino acids, taurine is a more sensitive indicator to monitor than glutathione for a least two reasons. First, the liver regulates concentrations of circulating glutathione like that observed for methionine and cyst(e)ine. And, second, the synthesis of taurine appears to have a lower priority than synthesis of glutathione. The Michaelis constant (K_m) for the rate controlling enzyme of glutathione synthesis is less than that of taurine synthesis¹.

The relative sensitivity of taurine as an indicator of adequacy of dietary sulfur-containing amino acids is evident from measurements in large dogs given commercial dog foods believed to have low sulfur-containing amino acid bioavailability^{15,16}. Plasma concentration of taurine was found to be significantly depressed while plasma glutathione concentration appeared unaffected and whole blood glutathione appeared only mildly depressed.

MONITORING ADEQUACY OF SULFUR-CONTAINING AMINO ACIDS

Commercial dog foods that have produced taurine deficiency appear to adequately support protein synthesis. Labeling claims for some diets indicate that the diet passed a feeding protocol in which acceptable changes in body weight, albumin, and hemoglobin concentration were observed. Evidence that protein synthesis is supported by such diets is still consistent with a low level of sulfur-containing amino acid intake. Under such a condition, catabolism of methionine and cysteine as with taurine synthesis is restricted while remethylation of homocysteine back to methionine and incorporation of cysteine into protein and glutathione given high priorities¹ (Figure 1). Hence, the monitoring of taurine status is tool that may be used to specifically assess sulfur-containing amino acid adequacy beyond that needed to achieve nitrogen balance. Such monitoring would seem worthwhile given the potential for producing diets deficient in sulfur-containing amino acids.

Methionine is often the first or second limiting amino acid in diets for dogs¹⁷ and cystine is usually present in diets in a limited range of proportions (~ 1:1 to 1:2) relative to methionine¹. Thus, because typical amino acid analyses of diets do not indicate bioavailability²¹, unrecognized, less than optimal amounts of methionine and cystine may occur in dog foods. This has been substantiated by studies of diets and ingredients in ileal-cannulated animals, where variable and low digestibilities of cystine are reported^{22,23}. The heat processing of diets and including the rendering process used in producing meat-meals is suggested to especially affect the cystine bioavailability. It should be noted that though heat processing has this effect, a few factors are mitigating. Digestibility effects of heat processing vary considerably with the temperature, time, and nature of the food matrix [e.g., 24]. Also, heat processing can increase digestibility of some proteins that contain sulfur-amino acids, such as protein from soybeans¹⁷.

For non-invasive convenient monitoring of taurine status, taurine concentrations in urine, blood, and plasma are useful. Of these concentrations, taurine to creatine ratio in free-catch urine samples appears to change most acutely with a dietary change¹³. Unfortunately, reference ranges are not reported for urine taurine to creatine ratio, and urine creatinine concentration varies with muscle mass and may scale differently with body size than taurine excretion. With daily urine collections over 5 days, taurine synthesis rate in dogs may be estimated after a single oral administration of stable isotopic taurine^{15,16}. Determination of taurine synthesis

rate is useful for distinguishing the cause of low taurine status. High loss of taurine could reduce taurine status, but so could low synthesis, as would occur with low intake or bioavailability of sulfur-containing amino acids. Low values thought to be indicative of taurine deficiency have been reported for blood and plasma taurine concentrations^{2,5,6}. These values are based on prevention of dilated cardiomyopathy. Greater values than these may be needed to optimize other functions dependant on taurine and other sulfur-containing amino acids. In the maintenance state, dietary amino acids concentrations that optimize variables like the immune response, wound healing, and health in old age have not been determined¹⁷.

CORRECTING DEFICIENCY

For diets that are not made intentional low in protein, as with some therapeutic diets, it seems inappropriate to add taurine to correct low taurine status induced by a diet. Correction by increasing methionine and cysteine bioavailability seems most appropriate. In making such a correction, monitoring of taurine status as described above may be used assess sulfur-containing amino acid bioavailabilities. Increasing the concentration of dietary protein with low sulfur-containing amino acid bioavailability is also not a desirable means of correction. This manipulation may increase fermentable residue if the protein is not well digested. Of relevance here is a report of many years ago demonstrating distal small intestinal fermentation in dogs given a high protein diet²⁵. The health significance of such fermentation is not known. Better options than increasing dietary protein would be to substitution of higher quality protein or supplementation with DL-methionine. It is interesting that the latter measure may especially support taurine synthesis while filling other needs for sulfur-containing amino acids. Research in rats show higher taurine formation and excretion in animals fed excess methionine than in those fed excess protein²⁶. With methionine compared to protein supplementation, the switch to formation of taurine more than sulfate is suggested to have the advantage of less perturbation of acid-base balance¹.

References

1. Stipanuk M, et al. *Annu Rev Nutr* 2004;24:539.
2. Fascetti A, et al. *J Am Vet Med Assoc* 2003;223(8):1137.
3. Backus R, et al. *J Am Vet Med Assoc* 2003;223(8):1130.
4. Pion P, et al. *Vet Clin North Am Small Anim Pract* 1998;28(6):1495.
5. Backus R, et al. *J Nutr* 2006;136(10):2525.
6. Gavaghan B, et al. *Aust Vet J* 1997;75(12):862.
7. Sanderson S, et al. *J Vet Intern Med* 2001;15(2):94.
8. Henthron P, et al. *Hum Genet* 2000;107(4):295.
9. Sanderson S, et al. *Am J Vet Res* 2001;62(10):1616.
10. Bélanger M, et al. *J Am Anim Hosp Assoc* 2005;41(5):284.
11. Dukes-McEwan J, et al. *BSAVA proceedings*, 2001.
12. Hannah S, et al. *Vet Clin Nutr* 1995;2:145.
13. Torres C. PhD Thesis, Univ. Calif. Davis 2004.
14. Tôrres C. *J Anim Physiol Anim Nutr* 2003;87(9-10):359.
15. Backus R. *J Nutr* 2006;136(10):2525.
16. Ko K. *J Nutr* 2007;137(5):1171.
17. NRC. *Nutrient Requirements of Dogs and Cats* 2006.
18. NRC. *Nutrient Requirements of Dogs* 1985.
19. Odle J. *Adv Exp Med Biol* 1992;315:55.
20. Lyons J, et al. *PNAS* 2000;97(10),5071.
21. Rutherford S, Moughan P. *J AOAC Int* 2008;91(4):907.
22. Johnson M, et al. *J Anim Sci* 1998;76:1112.
23. Gajda E. *J Anim Sci* 2005;83:160.
24. Piva G. *Ani Feed Sci Tech* 2001;89(1-2);59.
25. Banta C. *J Nutr* 1979;109(9):1592.
26. Bella D, Stipanuk M. *Am J Physiol* 1995;269:E910.

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MAIN : AAVN/ACVN (Small Animal) : Taurine Supplementation

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Plasma and whole blood taurine in normal dogs of varying size fed commercially prepared food

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Summary

The objective of the present study was to examine the effect of signalment, body size and diet on plasma taurine and whole blood taurine concentrations. A total of 131 normal dogs consuming commercially prepared dog food had blood drawn 3–5 h post-prandially to be analysed for plasma amino acids and whole blood taurine. Body weight and morphometric measurements of each dog were taken. Plasma and whole blood taurine concentrations were 77 ± 2.1 nmol/ml (mean \pm SEM) and 266 ± 5.1 nmol/ml (mean \pm SEM), respectively. No effect of age, sex, body weight, body size, or diet was seen on plasma and whole blood taurine concentrations. Mean whole blood taurine concentrations were lower in dogs fed diets containing whole grain rice, rice bran or barley. The lowest whole blood concentrations were seen in dogs fed lamb or lamb meal and rice diets. Plasma methionine and cysteine concentrations were lower in dogs fed diets with animal meals or turkey, and whole grain rice, rice bran or barley. Fifteen of 131 dogs had plasma taurine concentrations lower than, or equal, to the previously reported lowest mean food-deprived plasma taurine concentration in normal dogs of 49 ± 5 nmol/ml (mean \pm SEM) (ELLIOTT et al., 2000). These findings support the theory that taurine deficiency in dogs may be related to the consumption of certain dietary ingredients. Scientific and clinical evidence supports the hypothesis that dilated cardiomyopathy is associated with low blood taurine concentration in dogs; therefore, further work is indicated to determine the mechanism by which diet can affect taurine status in dogs.

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Kinetics of taurine depletion and repletion in plasma, serum, whole blood and skeletal muscle in cats*

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Summary. The relationship between taurine concentrations of plasma, whole blood, serum and skeletal muscle during taurine depletion and repletion was investigated in cats, to identify the most useful indicators of taurine status. Sixteen cats were fed a purified diet containing either 0 or 0.15 g/kg taurine for 5 months. Treatments were then reversed and the taurine concentration was measured during repletion and depletion phases. Plasma taurine exhibited the fastest rate (slow component) of depletion ($t_{1/2} = 4.8$ wk), followed by serum (5.3 wk), whole blood (6.2 wk), and skeletal muscle (11.2 wk). Whole blood taurine was the first to replete at a rate of 0.74 wk to $1/2$ maximal repletion, followed by serum (2.1 wk), skeletal muscle (3.5 wk), and plasma (3.5 wk). Whole blood more closely reflected skeletal muscle taurine concentrations than plasma during depletion, while plasma taurine concentrations appear to be the most valuable predictor of skeletal muscle taurine concentrations during repletion. This study suggests that the best clinical method to evaluate the taurine status of the cat is the determination and interpretation of both plasma and whole blood taurine concentrations.

Keywords: Amino acids – Taurine – Taurine depletion – Taurine repletion – Cats – Feline

Introduction

Taurine deficiency is associated with a number of specific pathological conditions in cats, including feline central retinal degeneration (Hayes et al., 1975;

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Schmidt et al., 1976), reproductive failure in queens with associated congenital abnormalities in kittens (Sturman et al., 1986; Sturman and Messing, 1991) and dilated cardiomyopathy (Pion et al., 1987). Studies in normal humans have shown that plasma taurine concentration is subject to wide variation (Trautwein and Hayes, 1990; Vinton et al., 1986) and that sampling technique can have a marked affect on resulting values (Laidlaw et al., 1987; Trautwein and Hayes, 1990). Sampling discrepancies occur from contamination of plasma with taurine from intracellular blood sources, including platelets or granulocytes, which can have 300–400 fold greater taurine concentrations. In addition, the relatively small plasma taurine pool rapidly exchanges with the larger tissue taurine pools, which can lead to marked fluctuations in plasma taurine concentration (Sturman et al., 1975; Matsubara et al., 1985). Whole blood, an easily obtainable tissue to sample, has been investigated as an index of taurine status (Laidlaw et al., 1987; Trautwein and Hayes, 1990) and may prove to be a superior indicator of the taurine status of an animal than plasma taurine. However, the correlation between plasma, whole blood and other tissue taurine pools has not been thoroughly investigated.

Kinetic studies examining taurine metabolism and turnover in humans (Sturman et al., 1975), rats (Sturman, 1973), and the rhesus monkey (Matsubara et al., 1985), demonstrate the existence of at least two pools of whole body taurine, a relatively small pool that has a rapid turnover rate and a much larger pool with a slow turnover rate. Tissues that comprise the rapidly exchanging pool include the liver, kidney, intestine, spleen and lung, while the slower pool is comprised of brain, heart and skeletal muscle. The differences in taurine kinetics between tissues complicate the determination of whole body taurine status in an individual animal. This study was conducted to determine the relationship between taurine concentrations of plasma, whole blood, serum and skeletal muscle during taurine depletion and repletion in cats to identify the most useful indicators of taurine status. Previous studies have measured the concentrations of taurine in plasma and various tissues of taurine depleted kittens (Sturman et al., 1978), but no studies have investigated the time-course of taurine concentration changes during depletion and none have evaluated changes during taurine repletion. Preliminary studies in our laboratory (unpublished) suggest that taurine kinetics during repletion and depletion are not the same in all taurine pools. Because cats may be fed diets varying widely in taurine content, an individual animal may be undergoing taurine depletion or repletion at the time taurine status is evaluated. This study examined pools of taurine that may be clinically assayed with the objective of defining the most appropriate indicator of taurine status for an individual cat.

Materials and methods

Animals

Sixteen, 9-wk old cats (1,050–1,180 g), from the Nutrition and Pet Care Center, University of California at Davis, were used as experimental animals. Cats were housed in individual

stainless steel cages with food and water available at all times, in a light-controlled (14h light: 10h dark) room at $21 \pm 3^\circ\text{C}$. Care throughout the study was in compliance with the "Guide for The Use and Care of Laboratory Animals" developed by the Institute of Laboratory Animal Resources of the National Research Council. The experimental protocol was approved by the University of California at Davis, Animal Use and Care Administrative Advisory Committee, utilizing the guidelines provided by the American Association for Laboratory Animal Care.

Diets

Cats were fed two purified diets that were identical except for the taurine concentrations, 1,500 or 0 mg taurine/kg (Table 1). In the 0 mg taurine/kg diet, taurine was replaced by an equal weight of cornstarch. Food intake was measured daily.

Design

Cats were randomly assigned to two groups, with equal representation of males and females, and fed either the 1,500 or 0 mg taurine/kg purified diet for 5 mo. The dietary treatments were then reversed and the cats then fed the taurine-free diet were designated the depletion group and those fed the 1,500 mg taurine/kg diet were designated the repletion group. Changes in the concentration of taurine in plasma, whole blood, serum and skeletal muscle were then measured for 25 wk. Prior to the dietary change, 2 samples were taken from each cat at 4 day intervals with subsequent samples taken on d 1, 3, 6 and 13, and wk 5, 11, 17 and 25. Lean body mass was estimated at wk 24 by whole body counting of ^{40}K as previously described (Peacock et al., 1987).

Blood samples

Food was withheld from cats for 12h and then 3 mL blood samples were collected by jugular puncture in a heparin-coated plastic syringe and in a non-heparinized plastic syringe. Each heparinized blood sample was divided into 2 sub-samples, one was centrifuged at room temperature (15 min at $3,900 \times g$), and the other remained as whole blood.

Table 1. Composition of diets

Dietary component	g/kg
High nitrogen casein ¹	340
Corn oil ²	250
Cornstarch ³	195
Glucose monohydrate ⁴	150
Mineral Mix ⁵	50
Vitamin Mix ⁶	10
Choline chloride	3
Taurine	1.5

¹U.S. Biochemical Corp., Cleveland, OH. ²Mazola, CPC International Inc., Englewood Cliffs, NJ. ³Melojel, Bridgewater, NJ. ⁴International Corp., Englewood Cliffs, NJ. ^{5,6}For composition see Williams et al., 1987.

The non-heparinized sample remained at room temperature for 1 h to allow clot formation (in plastic tubes) and was then centrifuged (20 min at $3,900 \times g$) to separate the serum. All samples were stored at -20°C until analysis.

Muscle samples

Skeletal muscle samples were obtained under light anesthesia. The average length of anesthesia prior to sample collection was 5 minutes, a length of time unlikely to cause changes in taurine pools. Cats were pre-medicated with 0.5 mg acetylpromazine (Acepromazine, Tech America, Elwood, Kansas) and 0.12 mg atropine (Elkins-Sinn, Inc., Cherry Hill, New Jersey), subcutaneously, and anesthetized with 40 mg of intravenous ketamine hydrochloride (Vetalar, Parke-Davis, Morris Plains, New Jersey). Using aseptic technique, a 5 to 24 mg (mean 11.4 mg) sample of semitendinosus muscle was obtained percutaneously using a biopsy needle (Tru-Cut, Travenol Inc., Deerfield, IL). Biopsies were taken alternately from the left and right muscles and the sampling site located approximately 5 mm proximally with each sampling to avoid previous biopsy sites.

Sample analysis

Taurine concentration was determined in all samples by amino acid analysis (Beckman models 121MB or 7300, Fullerton, CA) after deproteinization with an equal volume of aqueous sulfosalicylic acid (60 g/L). Before deproteinization, whole blood was lysed by freezing and thawing twice and an equal volume of distilled water was mixed with each sample resulting in a 1:1 dilution. Muscle samples were weighed and diluted with 400–750 μL of distilled water, depending on sample size, and homogenized with a glass homogenizer (Duell 20, Kontes, Vineland, New Jersey). Following homogenization, each sample was sonicated for three seconds (Biosonik IV sonicator, Bronwill Scientific) to ensure total cell disruption. Samples were then deproteinized by the same procedure as for plasma, serum and whole blood.

Statistical analysis

Differences in weekly body weight and food intake over time were assessed using a repeated measures analysis of variance for unbalanced data (SAS – General Linear Model, Version 6, SAS Institute, Cary, NC). Taurine depletion data were analyzed using a least squares curve fitting and decision making program (Brown and Manno, 1978). A nonlinear least squares analysis was used to assess taurine repletion kinetics (IMTEC, 1983, Bowie, Maryland). In order to assess the relationship of taurine concentrations in whole blood, plasma and serum to muscle, a simple linear regression was performed with muscle taurine concentration as the dependent variable. Correlation coefficients were used as an index of association for each of the three independent variables with muscle taurine. The statistical procedures used to determine linear regressions were as described (Snedecor and Cochran, 1980). Values in the text are means \pm SEM, $n = 8$. Differences between means were considered statistically significant at $p < 0.05$.

Results

The mean body weight of cats in the repletion group increased from 2.5 to 2.9 kg, while the mean body weight of cats in the depletion group remained unchanged at 2.7 kg. Maximum body weight was attained at 17 weeks for the repletion group. Despite the small difference between groups in mean body

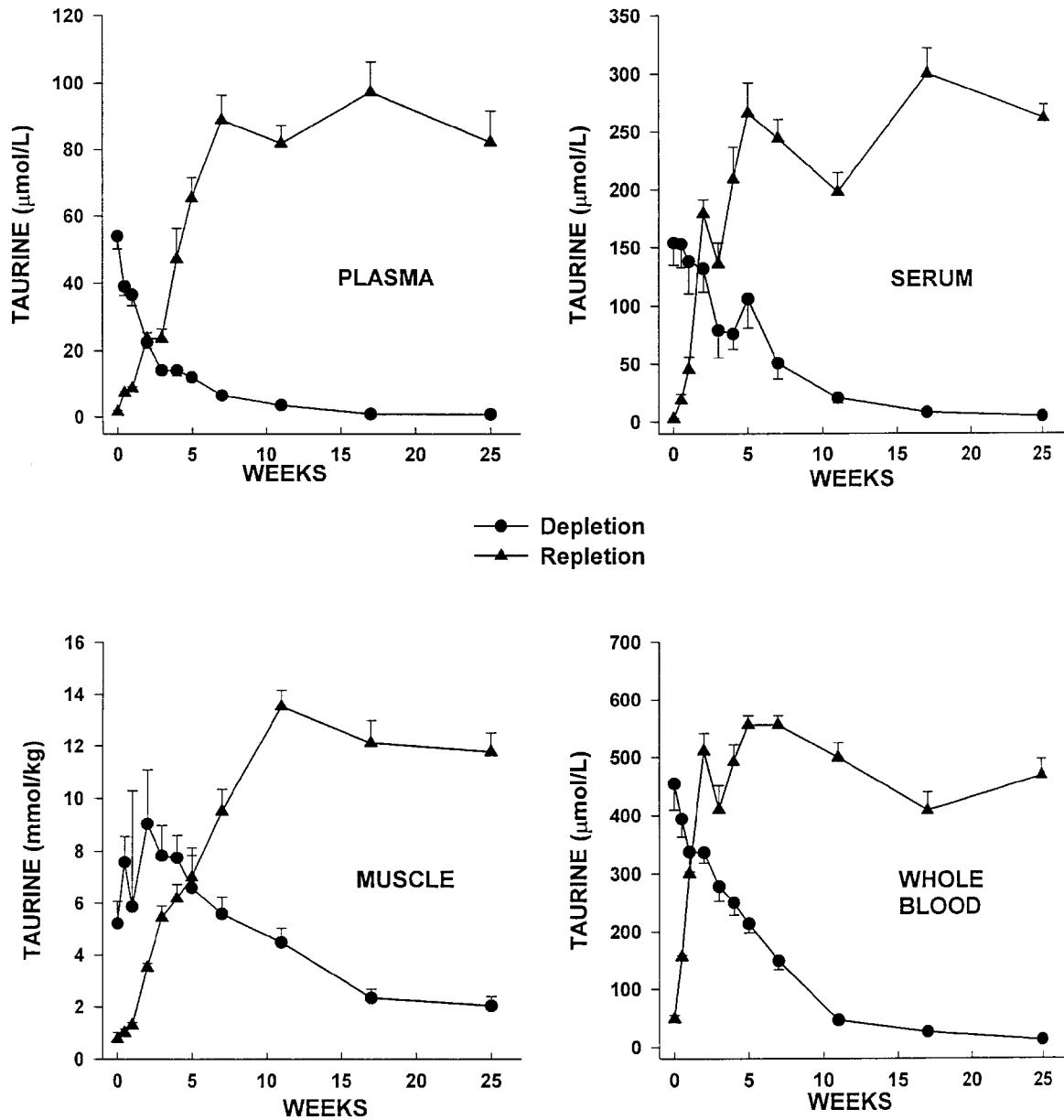


Fig. 1. Time course of taurine concentrations in plasma, serum, whole blood and skeletal muscle of cats during taurine depletion or taurine repletion. Values are means \pm SEM of 8 cats

weight, there was no difference in lean body mass as determined by percentage body potassium (taurine-repleted cats, $0.19 \pm 0.01\%$ compared to $0.18 \pm 0.005\%$ for the taurine-depleted cats). Food intakes were not different between the two groups following the dietary switch, nor did food intake change over the course of the experiment.

Kinetics of taurine depletion in plasma, serum and whole blood exhibited two components (Fig. 1). The rapid component of plasma taurine depletion had a half-life of 0.76 wk, depleting at a rate of $1.26 \mu\text{mol/L/wk}$ from an initial

Table 2. Taurine concentration, depletion rate and half-life in plasma, serum, whole blood and skeletal muscle of kittens¹

Tissue	Initial taurine	Rapid component		Slow component	
		Depletion rate	t _{1/2}	Depletion rate	t _{1/2}
	μmol/L, *μmol/kg (wet weight)	μmol/L/wk	wk	μmol/L/wk	wk
Plasma	59.3 ± 4.6 ^b	1.26 ± 0.31	0.876 ± 0.15 ^a	0.15 ± 0.01 ^b	4.77 ± 0.43 ^a
Serum	172 ± 18 ^c	1.11 ± 0.60	1.98 ± 0.41 ^{ab}	0.13 ± 0.01 ^b	5.3 ± 0.41 ^a
Whole blood	477 ± 84 ^d	1.53 ± 1.18	2.97 ± 0.69 ^b	0.12 ± 0.01 ^b	6.16 ± 0.58 ^a
Skeletal muscle*	9,800 ± 1,300 ^a			73 ± 10 ^a	11.2 ± 1.78 ^b

¹All values are mean ± SEM, n = 8. Means within each column not sharing a common superscript letter are significantly different at p < 0.05.

concentration of 59.3 μmol/L (Table 2). The rapid components of serum and whole blood taurine depletion had half-lives of 1.98 and 2.97 wk, respectively and the rates of depletion for these two pools were not different from plasma. Although the rates (μmol/L/wk) of taurine depletion did not differ, the half-life of the rapid component of plasma depletion was less than the half-life observed in whole blood taurine. No significant difference was observed between the half-life of the rapid component of plasma and serum, or serum and whole blood (p > 0.05).

Skeletal muscle taurine concentration exhibited only one component of depletion and actually appeared to increase early in the depletion period (Fig. 1). The rate of depletion and the half-life of skeletal muscle taurine was, therefore, determined from the last five samples, beginning 5 wk into the depletion period. The mean half-life for this period was 11.2 wk, with a depletion rate of 73 μmol/wk/kg (wet weight) from an initial concentration of 9,800 μmol/kg wet weight. During depletion the quantity of taurine lost from the muscle pool was greater than the other pools, because of the total size of the muscle pool. However, the half-life of the muscle pool was longer than the half-lives of the slow components of taurine depletion of the plasma, serum and whole blood pools.

The time for plasma taurine to replete to half-maximal concentration was 3.72 wk (Table 3), which was longer than the time for both serum and whole blood to reach half-maximal concentrations. The time to achieve half maximal repletion in skeletal muscle (3.49 wk), was similar to plasma (3.72 wk), but the maximum taurine concentration was much higher, 12,600 μmol/kg wet weight in muscle compared to 96.4 μmol/L in plasma. In addition, muscle size has several fold the volume of plasma.

The depletion characteristics of skeletal muscle (beginning 2 weeks into the depletion period) were significantly correlated with those of whole blood (r = 0.95), serum (r = 0.88) and plasma (r = 0.91) as illustrated in Fig. 2. While the depletion characteristics of skeletal muscle were highly correlated with those of whole blood, serum and plasma, the repletion characteristics of skeletal muscle most closely resembled plasma (r = 0.94). The relationship between the repletion of serum and skeletal muscle taurine, and between

Table 3. Taurine repletion variables in plasma, serum, whole blood and skeletal muscle in kittens¹

Tissue	Estimated maximal taurine concentration	Repletion rate	Time of half maximal repletion
	$\mu\text{mol/L}$, * $\mu\text{mol/kg wet wt}$	$\mu\text{mol/L/wk}$	wk
Plasma	96.4 ± 10.2^b	0.39 ± 0.10^a	3.72 ± 0.2^c
Serum	273 ± 9.9^c	0.70 ± 0.08^b	2.06 ± 0.1^b
Whole blood	512 ± 21^d	1.95 ± 0.06^c	0.74 ± 0.1^a
Skeletal muscle*	$12,560 \pm 800^a$	410 ± 10^a	3.49 ± 0.2^c

¹ All values of mean \pm SEM, n = 8. Means in a column not sharing a common superscript letter are significantly different at $p < 0.05$.

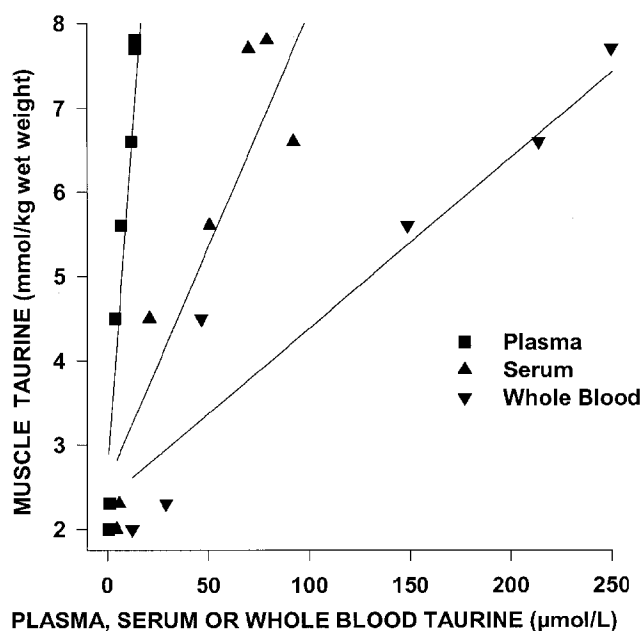


Fig. 2. Relationship between taurine concentrations of plasma ($r = 0.91$, $P < 0.001$), serum ($r = 0.88$, $P < 0.01$), whole blood ($r = 0.95$, $P < 0.001$) and taurine concentration of skeletal muscle during taurine depletion in cats. Each point represents mean data from 8 cats at each time point during depletion (from 2–25 weeks)

whole blood and skeletal muscle taurine were not as highly correlated, $r = 0.80$ and $r = 0.59$, respectively (Fig. 3). The low correlation between whole blood and skeletal muscle appears to be due to the rapid repletion of whole blood taurine compared to skeletal muscle.

Discussion

The major objective of this study was to compare the rates of taurine depletion and repletion and correlate the taurine concentrations of plasma, serum,

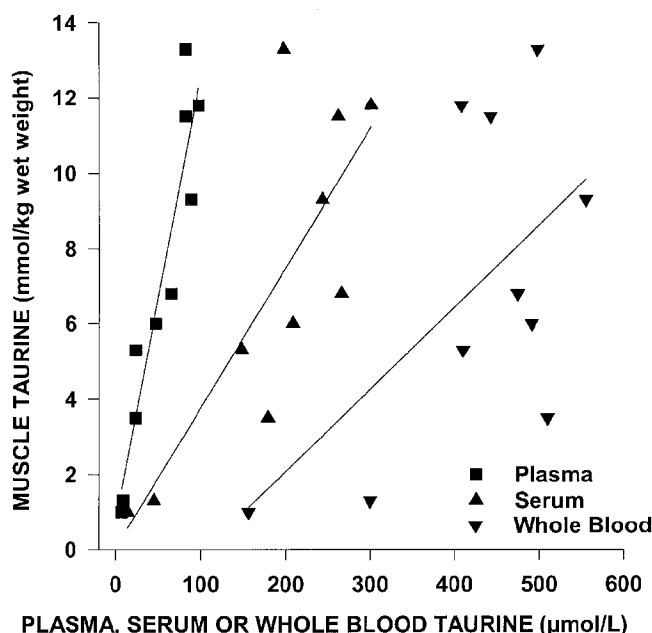


Fig. 3. Relationship between taurine concentrations of plasma ($r = 0.94$, $P < 0.001$), serum ($r = 0.80$, $P < 0.01$), whole blood ($r = 0.59$, $P < 0.1$) and taurine concentration of skeletal muscle during taurine repletion in cats. Each point represents mean data from 8 cats at each time point during repletion (from 0–25 weeks)

whole blood and skeletal muscle in order to identify the most useful clinical index of taurine status. The kinetics of depletion appear to be similar for plasma, serum and whole blood taurine concentrations with a more rapid decrease initially, followed by a slower phase of decline. In contrast, skeletal muscle taurine concentrations increased for the first 5 weeks of depletion and then demonstrated only a slow decrease. This is consistent with the findings of Sturman et al. (1978), who reported a greater half-life of taurine in feline gastrocnemius muscle than plasma, 10d compared to 2.5d, respectively. They also found that during taurine depletion, the half-life of taurine in gastrocnemius muscle remained unchanged while that of plasma increased to 10d, similar to the half-life observed in gastrocnemius muscle.

A change in plasma half-life during depletion could explain the initial rapid and slow terminal components of plasma taurine depletion observed in this study, with the slow component of plasma taurine depletion reflecting the increased $t_{1/2}$ of taurine. It is not known if the half-life of taurine in serum and whole blood changes during depletion, however, both of these fluids exhibit two components of taurine depletion similar to plasma.

The physiological role of taurine in skeletal muscle is unknown, but undoubtedly muscle taurine serves as a large reserve pool and supplies taurine to other tissues during depletion. Skeletal muscle might also be expected to replete at a slower rate, after full repletion of tissues having a higher affinity for taurine. This pattern of repletion was observed in skeletal muscle, with

rates of repletion significantly lower than whole blood or serum. The physiological make-up of the semitendinosus muscle may also influence the results due to fiber type and innervation (Iwata et al., 1986). "Normal" taurine concentrations in the semitendinosus muscle as determined in this study are consistent with the taurine concentrations in gastrocnemius muscle reported in previous feline studies (Knopf et al., 1978; Sturman et al., 1978, 1986; Sturman and Messing, 1991).

Repletion characteristics of plasma taurine were similar to that of skeletal muscle and suggest that plasma may also replete only after taurine provision to other tissues. In contrast, whole blood repleted rapidly compared to plasma and skeletal muscle and depleted more slowly than plasma. This likely reflects differences in active transport systems for taurine (Ahtee et al., 1974; Jacobson et al., 1986) and may be related to the important functions of taurine demonstrated in blood cells such as leukocytes and platelets (Hayes et al., 1989; Schuller-Levis et al., 1990). Changes in whole blood taurine during repletion and depletion reflect changes in the taurine content of leukocytes and platelets and not in erythrocytes.

Serum taurine concentrations were more closely correlated with whole blood taurine concentrations during depletion than plasma, but serum may be of questionable clinical value because of the variation in the time of clotting and method of separation of serum at various times and in various laboratories. Taurine is extruded from platelets during platelet aggregation and a prolonged clotting time may allow for a greater extrusion by the platelets. The rate of clot formation is dependent on many factors including temperature and type of tube used, variables which were controlled in this study. In previous studies, the variability observed in serum taurine concentrations was greater than that in plasma taurine concentration (unpublished observations). Because of these limitations and since serum is not a true compartment, we do not recommend the use of serum taurine concentration as an index of the taurine status.

It can be concluded from the comparison of depletion and repletion rates that whole blood taurine concentrations more closely reflects skeletal muscle taurine concentrations than plasma during depletion. However, plasma taurine concentrations appear to be the better predictor of skeletal muscle taurine concentrations during repletion. These findings suggest that the cytoplasmic membranes of muscle, leukocytes and platelets have the ability to retain taurine against a concentration gradient in plasma, a common feature of many cells containing active transport systems. However, the mechanism whereby different tissues sense and maintain appropriate intracellular taurine concentrations is unclear. The differential ability of tissues to extract taurine from plasma and to retain taurine against a concentration gradient during depletion may be related to the affinities of the membrane transporters for taurine, differences in number of transporters or differential rates of passive diffusion of taurine out of cells.

The concentration of taurine in soft tissues, whole blood and organs is greater than that of plasma, and their depletion and repletion kinetics differ. These differences make it difficult to evaluate, using a single clinical sample,

the taurine status of the cat. However, this study suggests that the best clinical method to evaluate taurine status may be the determination and interpretation of both plasma and whole blood taurine concentrations. When cats are undergoing active repletion or depletion, a single sample may give misleading results, either overestimating or underestimating body taurine. Therefore, we recommend that clinicians submit both plasma and whole blood taurine samples for analysis to evaluate taurine status. In cases where either plasma or whole blood values are not normal, serial samples should be monitored to ensure that cats are maintaining adequate taurine status. Until both plasma and whole blood taurine concentrations are normalized, cats should be considered at risk for taurine deficiency related diseases.

References

- Ahte L, Boullin DJ, Paasonen MK (1974) Transport of taurine by normal human blood platelets. *Br J Pharmacol* 52: 245–251
- Brown RD, Manno JE (1978) ESTRIP, a BASIC computer program for obtaining initial polyexponential parameter estimates. *J Pharm Sci* 67: 1687–1691
- Hayes KC, Carey RE, Schmidt SY (1975) Retinal degeneration associated with taurine deficiency in the cat. *Science* 188: 949–951
- Hayes KC, Pronczuk A, Addesa AE, Stephan ZF (1989) Taurine modulates platelet aggregation in cats and humans. *Am J Clin Nutr* 49: 1211–1216
- Iwata H, Dolara T, Kim BK, Baba A (1986) Regulation of taurine transport in rat skeletal muscle. *J Neurochem* 47: 158–163
- Jacobson E, Kurzawski G, Tustanowski S (1986) Synthesis and uptake of taurine by isolated human granulocytes. *Folia Histochemica Et Cytobiologica* 24: 179–182
- Knopf K, Sturman JA, Armstrong M, Hayes KC (1978) Taurine: an essential nutrient for the cat. *J Nutr* 108: 773–778
- Laidlaw SA, Sturman JA, Kopple JD (1987) Effect of dietary taurine on plasma and blood cell taurine concentrations in cats. *J Nutr* 117: 1945–1949
- Matsubara Y, Lin YY, Sturman JA, Gaull GE, Marks LM, Irving CS (1985) Stable isotope study of plasma taurine kinetics in rhesus monkey. *Life Sci* 36: 1933–1940
- Peacock JL, Incelet RI, Corsey R, Ford DB, Rumble WF, Lawson D, Norton JA (1987) Resting energy expenditure and body cell mass alterations in noncachectic patients with sarcomas. *Surgery* 102: 465–472
- Pion PD, Kittleson MD, Rogers QR, Morris JG (1987) Myocardial failure in cats associated with low plasma taurine: a reversible cardiomyopathy. *Science* 237: 764–768
- Schmidt SY, Berson EL, Hayes KC (1976) Retinal degeneration in cats fed Casein. I. Taurine deficiency. *Invest Ophthalmol* 15: 47–52
- Schuller-Levis G, Mehta PD, Rudelle R, Sturman J (1990) Immunologic consequences of taurine deficiency in cats. *J Leukocyte Biol* 47: 321–331
- Snedecor GW, Cochran WG (1980) *Statistical methods*. The Iowa State University Press, Ames, pp 175–183
- Sturman JA (1973) Taurine pool sizes in the rat: effects of vitamin B₆ deficiency and high taurine diet. *J Nutr* 103: 1566–1580
- Sturman JA, Messing JM (1991) Dietary taurine content and feline reproduction and outcome. *J Nutr* 121: 1195–1203
- Sturman JA, Hepner GW, Hoffmann AF, Thomas PJ (1975) Metabolism of [³⁵S]taurine in man. *J Nutr* 105: 1206–1214
- Sturman JA, Rassin DK, Hayes KC, Gaull GE (1978) Taurine deficiency in the kitten: exchange and turnover of [³⁵S]taurine in brain, retina, and other tissues. *J Nutr* 108: 1462–1476

- Sturman JA, Gargano AD, Messing JM, Imaki H (1986) Feline maternal taurine deficiency: effect on mother and offspring. *J Nutr* 116: 655–667
- Trautwein EA, Hayes KC (1990) Taurine concentrations in plasma and whole blood in humans: estimation of error from intra- and interindividual variation and sampling technique. *Am J Clin Nutr* 52: 758–764
- Vinton NE, Laidlaw SA, Ament ME, Kopple JD (1986) Taurine concentrations in plasma and blood cells of patients undergoing long-term parenteral nutrition. *Am J Clin Nutr* 44: 398–404
- Williams JM, Morris JG, Rogers QR (1987) Phenylalanine requirement of kittens and the sparing effect of tyrosine. *J Nutr* 117: 1102–1107

Authors' address: Dr. Quinton R. Rogers, Department of Molecular Biosciences, School of Veterinary Medicine, University of California, One Shields Avenue, Davis, CA 95616-8741, U.S.A., Fax: (530) 750-4698, E-mail: qrrogers@ucdavis.edu

Received October 9, 2000

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

Jen,

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

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

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

B6



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

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

To: **B6**

Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; **B6** Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: diet related DCM - a couple forms

Hi all

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

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

B5

Thanks
Lisa

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

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

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

[REDACTED] **B5**

Thanks,
[REDACTED] **B6**

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

[REDACTED] **B5**

[REDACTED] **B5**

Thanks
Lisa

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

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

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

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

B6

B6

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

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

Importance: High

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

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



From: Jones, Jennifer L

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

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

B6

B6

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

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

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

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

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

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



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

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

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

B6

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

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

Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

B6

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

B6

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

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

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

Sincerely,
Darcy Adin

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

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

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

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

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

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--

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

B6

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 5/30/2018 10:00:32 AM
Subject: reporting diet/DCM dogs

Hi Jennifer

The dog eating **B4, B5** that I reported last Friday died **B6** How should I report that? Owners are holding food for analysis. We have new one on **B4** that I'll submit today

Also, did you have thoughts **B5** Especially when it's a situation in which **B5**

Thanks

Lisa

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

Hi Jennifer

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

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

Thanks
Lisa

6-3323-414-1493 147461134348

Safety Reporting Portal Safety Reporting Portal Safety Reporting Portal

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

Other Phone

Fax

Location of the Reportable Food

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

*** Organization Name** [B6]

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

Official Establishment Inventory (OEI) Development and Maintenance Procedures

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

*** Country**

*** Street Address Line 1**

Street Address Line 2

*** City/Town**

*** State**

*** ZIP/Postal Code**

Location of the Reportable Food - Contact Information

*** First Name**

*** Last Name**

*** Job Title**

*** Email**

*** Confirm Email**

*** Primary Phone**

Other Phone

Fax

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

Organization Type (select all that apply) : *Required

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


Hi Jennifer

The dog eating [B4] that I reported last Friday died [B6] How should I report that? Owners are holding food for analysis. We have new one of [B4] that I'll submit today Also, did you have thoughts on [B5] Especially when it's a situation in which [B5]

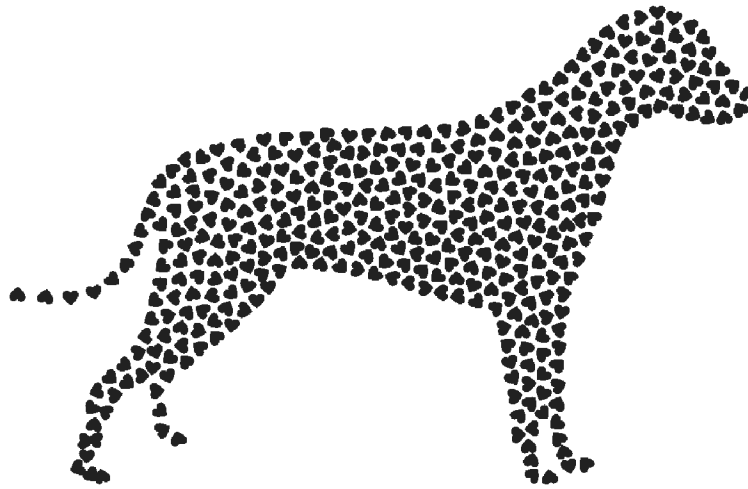
Thanks
Lisa

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A broken heart: Risk of heart disease in boutique or grain-free diets and exotic ingredients

 vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients

June 4, 2018



Earlier this year, Peanut, a 4-year-old male Beagle/Lab mix was diagnosed with a life-threatening heart disease at our hospital. Peanut had been lethargic, not eating well, and occasionally coughing. The veterinary cardiologist seeing him asked what he was eating and found that his owner, in a desire to do the best thing for Peanut, was feeding a boutique, grain-free diet containing kangaroo and chickpeas. Peanut required several medications to treat his heart failure but the owner also changed his diet. And today, now 5 months later, Peanut's heart is nearly normal!

Heart disease is common in our companion animals, affecting *10-15% of all dogs and cats*, with even higher rates in Cavalier King Charles Spaniels, Doberman Pinschers, and Boxer dogs. Most nutritional recommendations focus on treating dogs and cats with heart disease and there is much less information on the role of diet in causing heart disease. However, a recent increase in heart disease in dogs eating certain types of diets may shed light on the role of diet in causing heart disease. It appears that diet may be increasing dogs' risk for heart disease because owners have fallen victim to the many myths and misperceptions about pet food. If diet proves to be the cause, this truly is heart-breaking to me.

In my 20 years as a veterinary nutritionist, I've seen vast improvements in our knowledge about pet nutrition, in the quality of commercial pet foods, and in our pets' nutritional health (other than the unfortunate rise in obesity). However, in the last few years I've seen more

cases of nutritional deficiencies due to people feeding unconventional diets, such as unbalanced home-prepared diets, raw diets, vegetarian diets, and boutique commercial pet foods. The pet food industry is a competitive one, with more and more companies joining the market every year. Marketing is a powerful tool for selling pet foods and has initiated and expanded fads, that are unsupported by nutritional science, including grain-free and exotic ingredient diets. All this makes it difficult for pet owners to know what is truly the best food for their pet (as opposed to the one with the loudest or most attractive marketing). Because of the thousands of diet choices, the creative and persuasive advertising, and the vocal opinions on the internet, pet owners aren't able to know if the diets they're feeding have nutritional deficiencies or toxicities – or could potentially even cause heart disease.

Dilated cardiomyopathy

Dilated cardiomyopathy or DCM occurs in cats where it is associated with a nutritional deficiency (see below). DCM is a serious disease of the heart muscle which causes the heart to beat more weakly and to enlarge. DCM can result in abnormal heart rhythms, congestive heart failure (a build-up of fluid in the lungs or abdomen), or sudden death. In dogs, it typically occurs in large- and giant-breeds, such as Doberman pinschers, Boxers, Irish Wolfhounds, and Great Danes, where it is thought to have a genetic component. Recently, some veterinary cardiologists have been reporting increased rates of DCM in dogs – in both the typical breeds and in breeds not usually associated with DCM, such as Miniature Schnauzers or French Bulldogs. There is suspicion that the disease is associated with eating boutique or grain-free diets, with some of the dogs improving when their diets are changed. The US Food and Drug Administration (FDA) Center for Veterinary Medicine and veterinary cardiologists are currently investigating this issue.

Is diet the cause?

It's not yet clear if diet is causing this issue. The first thought was a deficiency of an amino acid called taurine. DCM used to be one of the most common heart diseases in cats but in 1987, it was discovered that feline DCM was caused by insufficient taurine in the diet. It was shown that DCM in cats could be reversed with taurine supplementation, and now all reputable commercial cat foods contain enough taurine to prevent the development of this lethal disease. We still occasionally see taurine deficiency-induced DCM in cats but it is usually when owners are feeding a vegetarian or home-prepared diet, supplemental diets, or a diet made by a manufacturer with inadequate nutritional expertise or quality control.

In dogs, Golden Retrievers and Cocker Spaniels were found to be at risk for DCM caused by taurine deficiency, and one study showed that Cocker Spaniels with DCM improved when given taurine supplementation. Since then, additional studies have shown associations between dietary factors and taurine deficiency in dogs, such as lamb, rice bran, high fiber diets, and very low protein diets. And certain other breeds were found to be at increased risk for taurine deficiency and DCM, including Newfoundlands, St. Bernards, English Setters, Irish Wolfhounds, and Portuguese Water Dogs. The reasons for taurine deficiency in dogs are not

completely understood but could be reduced production of taurine due to dietary deficiency or reduced bioavailability of taurine or its building blocks, increased losses of taurine in the feces, or altered metabolism of taurine in the body.

No matter what the reason, the number of dogs with taurine deficiency and DCM subjectively appeared to decrease since the early 2000's. However, recently, some astute cardiologists noticed higher rates of DCM including Golden retrievers and in some atypical dog breeds. They also noticed that both the typical and atypical breeds were more likely to be eating boutique or grain-free diets, and diets with exotic ingredients – kangaroo, lentils, duck, pea, fava bean, buffalo, tapioca, salmon, lamb, barley, bison, venison, and chickpeas. Even some vegan diets have been associated. It has even been seen in dogs eating raw or home-prepared diets.

So, is this latest rash of DCM caused by taurine deficiency? Most of these affected dogs were eating boutique, grain-free, or exotic ingredient diets. Some of the dogs had low taurine levels and improved with taurine supplementation. But even some of those dogs that were not taurine deficient improved with taurine supplementation and diet change. Fortunately, cardiologists reported the issue to the FDA which is currently investigating this issue. [Note: Dr. Joshua Stern from the University of California Davis is conducting research on taurine deficiency and DCM in Golden Retrievers.

It's not so simple

Currently, it seems that there may be two separate problems occurring – one related to taurine deficiency and a separate and yet unknown problem (with a third group of dogs likely having DCM completely unrelated to diet). Identifying the potential dietary factors contributing to DCM in the non-aurine deficient dogs is more difficult, but the FDA and cardiologists are hard at work trying to solve it. What seems to be consistent is that it does appear to be more likely to occur in dogs eating boutique, grain-free, or exotic ingredient diets.

Exotic ingredients are on the rise

Why are pet owners feeding these exotic ingredients? I think is it primarily because pet owners are falling victim to marketing which portrays exotic ingredients as more natural or healthier than typical ingredients. There is no truth to this marketing – and there is no evidence that these ingredients are any more natural or healthier than more typical ingredients. This is just good marketing that preys on our desire to do the best for our pets.

There is no proof that grain-free is better!

Many pet owners have, unfortunately, also bought into the grain-free myth. The fact is that food allergies are very uncommon, so there's no benefit of feeding pet foods containing exotic ingredients. And while grains have been accused on the internet of causing nearly every disease known to dogs, grains do not contribute to any health problems and are used in pet food as a nutritious source of protein, vitamins, and minerals.

Exotic ingredients are more difficult to use

Not only are the more exotic ingredients unnecessary, they also require the manufacturer to have much more nutritional expertise to be nutritious and healthy. Exotic ingredients have different nutritional profiles and different digestibility than typical ingredients, and also have the potential to affect the metabolism of other nutrients. For example, the bioavailability and metabolism of taurine is different in a lamb-based diet compared to a chicken-based diet or can be affected by the amount and types of fiber in the diet.

Small pet food manufacturers might be better at marketing than at nutrition and quality control

Making high quality, nutritious pet food is not easy! It's more than using a bunch of tasty-sounding ingredients. The right nutrients in the right proportions have to be in the diet, the effects of processing (or not processing) the food need to be considered, and the effects of all the other ingredients in the food need to be addressed, in addition to ensuring rigorous quality control and extensive testing. Not every manufacturer can do this.

How could diet be increasing the risk for DCM?

What is the consistent factor between the diets being implicated in diet-related DCM? It may be related to companies' inadequate nutritional expertise or rigorous quality control. We published a study several years ago in which we measured a single nutrient in 90 canned cat foods that all claimed to be nutritionally complete and balanced. We found that 15% of the diets were deficient in that nutrient (all of those diets were made by small companies). If companies don't have the quality control to ensure all nutrients are at the minimum levels, deficiencies could occur and could contribute to DCM. However, these problems could also be related to problems with bioavailability or interaction with other ingredients in the diet (especially the more exotic ingredients, which are not as well studied or understood). And DCM could even be the result of an ingredient in the diet that is toxic to the heart. The FDA is investigating this potential association between diet and DCM but, in the meantime, there are some things you can do.

What should you do?

- Reconsider your dog's diet. If you're feeding a boutique, grain-free, or exotic ingredient diets, I would reassess whether you could change to a diet with more typical ingredients made by a company with a long track record of producing good quality diets. And do yourself a favor – stop reading the ingredient list! Although this is the most common way owners select their pets' food, it is the least reliable way to do so. And be careful about currently available pet food rating websites that rank pet foods either on opinion or on based on myths and subjective information. It's important to use more objective criteria (e.g., research, nutritional expertise, quality control in judging a pet food). The best way to select what is really the best food for your pet is to ensure the manufacturer has excellent nutritional expertise and rigorous quality control standards (see our "Questions you should be asking about your pet's food" post).
- If you're feeding your dog a boutique, grain-free, or exotic ingredient diet, watch for early

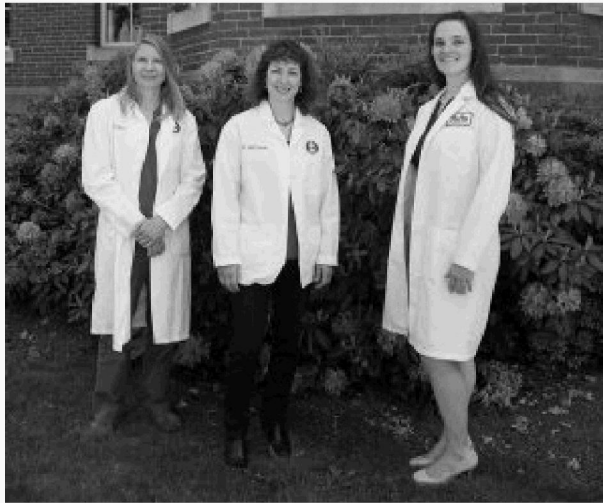
signs of heart disease – weakness, slowing down, less able to exercise, short of breath, coughing, or fainting. Your veterinarian will listen for a heart murmur or abnormal heart rhythm and may do additional tests (or send you to see a veterinary cardiologist), such as x-rays, blood tests, electrocardiogram, or ultrasound of the heart (echocardiogram).

- If your dog is diagnosed with DCM and eating one of these diets, I'd recommend the following steps:
 - Ask your veterinarian to test whole blood and plasma taurine levels (I recommend the University of California Davis [Amino Acid Laboratory](#))
 - [Report it to the FDA](#). This can be done either online or by telephone. The FDA may be able to help with testing costs for your dog. Reporting it will also help us to identify and solve this current problem.
 - Change your dog's diet to one made by a well-known reputable company and containing standard ingredients (e.g., chicken, beef, rice, corn, wheat). Changing to a raw or homecooked diet will not protect your dog from this issue (and may increase the risk for other nutritional deficiencies). If your dog requires a homecooked diet or has other medical conditions that require special considerations, be sure to talk to a veterinarian or a veterinary nutritionist ([acvn.org](#)) before making a dietary change. You can contact the Cummings Nutrition Service to schedule an appointment (vetnutrition@tufts.edu)
 - Start taurine supplementation. Your veterinarian or veterinary cardiologist can recommend an appropriate dose for your dog. Be sure to use a brand of taurine with [good quality control](#).
 - Any improvements in your dog's DCM can take 3-6 months. Your dog will need regular monitoring and may require heart medications during this time. There's no guarantee she'll improve but is certainly worth a try.
 - Make sure your dog is getting the best combination of medications to treat his heart disease, as this can make a difference in his outcome. You can find a board-certified veterinary cardiologist near you on this website: <http://find.vetspecialists.com/>

Sometimes, the changes we make in pet nutrition advance our knowledge and the health of our pets. In other cases, we can take a step in the wrong direction when the marketing outpaces the science. Hopefully, identifying this current issue will allow us to set a new, more science-based approach to the optimal nutrition of our pets.

For more information about heart disease in dogs, please see our [HeartSmart](#) website.

Why Trust Us?



As you're on this website right now, we can assume that you love pets and likely have a special dog or cat (or many) in your life. We love them, too! And not only do we love the pets, we also love their people, and you are our reason for making this site.

[Learn more about the Clinical Nutrition Team at Tufts](#)

The Clinical Nutrition Service at Foster Hospital for Small Animals offers in-person and telephone appointments to pet owners and case consultations to veterinarians within the Foster Hospital and throughout the country.

[MAKE AN APPOINTMENT](#)

The Tufts Obesity Clinic for Animals specializes in customized weight management plans that allow for safe weight loss with expert guidance from a board-certified veterinary nutritionist within the Clinical Nutrition Service.

[MAKE AN APPOINTMENT](#)

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Norris, Anne; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Hartogensis, Martine; DeLancey, Siobhan
Sent: 6/11/2018 4:00:58 PM
Subject: RE: Call with FDA to discuss recent findings
Attachments: 800.267-DCM-Grainfree analysis-UPDATED-PFI-redacted.pptx

Here is a version we could share. I can cut/add info as necessary.

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



From: Norris, Anne
Sent: Monday, June 11, 2018 10:34 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Call with FDA to discuss recent findings

If you use Chrome or Mozilla, you should be able to log in. Internet Explorer gave me trouble.

-----Original Appointment-----

From: Tabor, Peter [<mailto:peter@petfoodinstitute.org>]
Sent: Tuesday, June 05, 2018 7:17 PM
To: Tabor, Peter; Jones, Jennifer L; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Norris, Anne; Dana Brooks; Mary Emma Young; Tovey, Pat; Hartogensis, Martine
Subject: FW: Call with FDA to discuss recent findings
When: Monday, June 11, 2018 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: GoToMeeting - details below

Hope this works for everyone!

-----Original Appointment-----

From: Tabor, Peter [<mailto:peter@petfoodinstitute.org>]
Sent: Tuesday, June 05, 2018 5:47 PM
To: Tabor, Peter; Dana Brooks; Mary Emma Young; Tovey, Pat; Hartogensis, Martine
Subject: Call with FDA to discuss recent findings
When: Monday, June 11, 2018 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: GoToMeeting - details below

Many thanks for the call today, Martine. Per our conversation, I have set up a GoToMeeting for us. I hope the proposed time (an hour later) than discussed) works for you and your colleagues – we have a conflict at 9:30am I was unaware of when we spoke. Please forward the invite to all you think should attend.

Peter

Call with FDA to discuss recent findings

Mon, Jun 11, 2018 10:30 PM - 11:30 PM EDT

Please join my meeting from your computer, tablet or smartphone.

<https://global.gotomeeting.com/join>

B6

You can also dial in using your phone.

United States: +1

Access Code:

Joining from a video-conferencing room or system?

Dial: 67.217.95

Cisco devices

First GoToMeeting? Let's do a quick system check: <https://link.gotomeeting.com/system-check>

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica
CC: Norris, Anne; DeLancey, Siobhan
Sent: 4/13/2018 1:06:07 PM
Subject: FYI-FW: Call to discuss DCM cases

I'll keep everyone posted about a time for the meeting.

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



From: Jones, Jennifer L
Sent: Friday, April 13, 2018 9:05 AM
To: 'Darcy Adin' <dbadin@ncsu.edu>
Subject: Call to discuss DCM cases

Good morning Darcy,
I hope you're well. Are you able to chat more about the DCM cases from dogs eating grain free food that the cardiology community is seeing? I'd like to schedule a call with you and some of your colleagues who are also following the issue. I'd like to gather more information about the clinical findings and your ideas on what could be the cause. Do you have any contacts with Dr. Joshua Stern or other clinical research cardiologists that could provide additional information following this issue? I can include them on the call.

Thank you in advance for your time, and have a great weekend.
Jen

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



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 4/23/2018 7:22:37 PM
Subject: RE: hold-call with Dr. Adin re: DCM cases

Thank you, Lisa.

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



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Monday, April 23, 2018 8:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: hold-call with Dr. Adin re: DCM cases

Dear Jennifer

B5

Please let me know if you need additional info
Thanks for your work on this issue.
Lisa

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

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

B6

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

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

B5

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



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

[REDACTED] **B6**

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

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, [REDACTED] **B5**

B5

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

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

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



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Thursday, April 19, 2018 11:00 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6** [REDACTED] **B6**

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

[REDACTED] **B6**

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

B6

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

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

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

Sincerely,
Darcy Adin

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

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

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

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

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

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

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Meeting password **B6**

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B6

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

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University

NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Freeman, Lisa; Joshua A Stern <[REDACTED]> Rotstein, David
Sent: 8/16/2018 12:49:22 PM
Subject: Re: a few NCSU cases

Thanks Jennifer!

On Thu, Aug 16, 2018 at 8:13 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning everyone,

Here's our Vet-LIRN rapid necropsy document.

Take care,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Wednesday, August 15, 2018 2:49 PM
To: 'Freeman, Lisa' <Lisa.Freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>

Cc: Joshua A Stern <jstern@ucdavis.edu> <[REDACTED]> **B6**
Subject: RE: a few NCSU cases

Thank you, Darcy! We'll be on the lookout for the cases.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



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

Sent: Wednesday, August 15, 2018 8:50 AM

To: Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Joshua A Stern <jstern@ucdavis.edu>

B6

Subject: RE: a few NCSU cases

That's really interesting, Darcy!

I wonder

B5

Thanks for sharing

Lisa

From: Darcy Adin <dbadin@ncsu.edu>

Sent: Tuesday, August 14, 2018 8:00 PM

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

Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>

B6

B6

Subject: a few NCSU cases

Hi Jennifer,

I wanted to follow up on the case where NCSU sent you necropsy samples (B6 3 yr Fs Great Dane). I've attached her whole blood and plasma taurine concentrations for your records, which were normal.

One of my residents saw a littermate pair of Dobermans back for their 3 month recheck after being diagnosed with DCM while eating Acana. Taurines were normal on these dogs back in April and I honestly didn't have a ton of hope for these dogs (B6) because they were dobermans and their genetic tests were abnormal (the female is homozygous positive for one mutation and negative for a 2nd, the male was heterozygous positive for one mutation and negative for a 2nd). But, 3 months after a diet change to Purina grain-based (and no taurine supplementation), they both have shown significant improvement (the less severely affected female has near normalized and the severely affected male (who was in heart failure) has also significantly improved.

I have asked our resident to report these dogs to the FDA using the portal (B6) so hopefully you will see these soon. She will also be submitting a taurine deficient Golden eating Acana (B6 maybe the lowest I've ever seen).

Thank you!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L; Darcy Adin
CC: Joshua A Stern; [REDACTED B6] Rotstein, David
Sent: 8/16/2018 6:17:49 PM
Subject: RE: a few NCSU cases

Hi Jen

[REDACTED B5] Just want to be sure we get what you're looking for.

We appreciate your putting this together. This will be helpful
Thanks
Lisa

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, August 16, 2018 8:13 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>
Cc: Joshua A Stern <jstern@ucdavis.edu>; [REDACTED B6] Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: a few NCSU cases

Good morning everyone,
Here's our Vet-LIRN rapid necropsy document.
Take care,
Jen

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



From: Jones, Jennifer L
Sent: Wednesday, August 15, 2018 2:49 PM
To: 'Freeman, Lisa' <Lisa.Freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>
Cc: Joshua A Stern <jstern@ucdavis.edu>; [REDACTED B6]
Subject: RE: a few NCSU cases

Thank you, Darcy! We'll be on the lookout for the cases.

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



From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Wednesday, August 15, 2018 8:50 AM
To: Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Joshua A Stern <jstern@ucdavis.edu>; [REDACTED B6]
Subject: RE: a few NCSU cases

That's really interesting, Darcy!

I wonder [REDACTED B5]

Thanks for sharing
Lisa

From: Darcy Adin <dbadin@ncsu.edu>

Sent: Tuesday, August 14, 2018 8:00 PM

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

Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <istern@ucdavis.edu>; [REDACTED] B6

[REDACTED] B6

Subject: a few NCSU cases

Hi Jennifer,

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I have asked our resident to report these dogs to the FDA using the portal [REDACTED] B6 hopefully you will see these soon. She will also be submitting a taurine deficient Golden eating Acana [REDACTED] B6 maybe the lowest I've ever seen).

Thank you!
Darcy

--

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

Owner: **B6**

Accession Number: **B6**

Reference Number:

Case Coordinator: **B6**

Received: **B6**

Finalized: **B6**

Sampled:

To: **B6**

Phone #: **B6**

Addended Report

ANATOMIC PATHOLOGY RESULTS

SMALLANIMAL NECROPSY

ANIMAL ID **B6**

REF CASE NO 212267

SPECIES Canine

BREED Schnauzer

SEX Mc

AGE 3y

SPECIMEN DESC Body

GROSS An 8.2 kg, 2.5-year-old, castrated male miniature schnauzer dog is presented for postmortem examination. The animal was euthanized and the body is in fair postmortem condition with a euthanasia?to?necropsy interval of approximately 16 hours. **B6**

B6

B6

B6 The heart is subjectively enlarged. **B6**

B6

Addended Report

Accession Number: **B6**

ANATOMIC PATHOLOGY RESULTS

B6

GROSS DIAGNOSIS

B6

2. Heart: mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation

B6

REPORT STATUS
COMMENTS

PRELIMINARY REPORT-HISTOLOGY PENDING

Except for gross evidence of moderate to marked pulmonary edema and mild cardiac changes, gross examination is otherwise mostly unremarkable. The heart is mildly enlarged with mild mitral valve endocardiosis and associated mild left atrial dilation and left ventricular hypertrophy. This mild degree of cardiac changes does not fit well with the moderate to severe degree of pulmonary edema present. In addition to the mild structural changes, a functional cardiac abnormality may have been contributing to clinical disease in this patient. Samples of lung and heart were rushed and examined histologically. In addition to the pulmonary edema, there is also histologic evidence of diffuse, acute alveolar injury. These pulmonary changes can explain this patient's signs of respiratory distress. However, the heart is histologically unremarkable and the skeletal muscle was grossly unremarkable; as such, a cause for the markedly elevated CK is not yet identified. Histology of skeletal muscle is pending.

PATH RESIDENT
SENIOR PATH
DATE

B6

Final Necropsy Report
MICROSCOPIC

B6

Addended Report

Accession Number: **B6**

ANATOMIC PATHOLOGY RESULTS

B6

Heart (slide 1), Skeletal muscle (slide 3), Kidneys (slide 3), Spleen (slide 3), Stomach (slide 4), Small intestine (slide 4), Colon (slide 4), Pancreas (slide 4), Adrenal gland (slide 4); **B6**

B6

FINAL DIAGNOSIS

B6

2. Heart: mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation

B6

COMMENTS

Histology reveals:

B6

B6

PATH RESIDENT
SENIOR PATH
FINALIZED DATE

B6

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 8/23/2018 3:56:57 PM
Subject: RE: updates

Hi Lisa,
Do we have permission to contact [B6] about the 2 dobermans?
Thank you,
Jen

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



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

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

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

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

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 8/24/2018 11:29:51 AM
Subject: RE: updates

Thank you, Lisa. I'll contact them.

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



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Thursday, August 23, 2018 12:26 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: updates

Hi Jen. They gave permission to report so i think it would be fine til contact but I can specifically check if you'd prefer
Lisa

Sent from my iPhone

On Aug 23, 2018, at 11:57 A Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Lisa,
Do we have permission to contact [B6] about the 2 dobermans?
Thank you,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<image001.png> <image002.png>

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

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

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

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cummings School of Veterinary Medicine

Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/24/2019 10:08:57 PM
Subject: Acana: Lisa Freeman - EON-380708
Attachments: 2063115-report.pdf; 2063115-attachments.zip

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

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

Below is the summary of the report:

EON Key: EON-380708

ICSR #: 2063115

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

AE Date	02/16/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Terrier - Bull - American Pit		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063115

Product Group: Pet Food

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

Description: DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

B6

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 2/24/2019 11:05:45 PM
Subject: ps - **B6**

Hi Jen

I forgot to mention that I have diet samples for the Natural Balance and Acana for

B6

Lisa

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

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/10/2019 9:32:54 PM
Subject: Acana: Lisa Freeman - EON-390104
Attachments: 2068046-report.pdf; 2068046-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390104] has been created in the EON System.

A "PDF" report by name "2068046-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 "2068046-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390104

ICSR #: 2068046

EON Title: Related PFR Event created for Acana Natural Balance Petcurean (see diet history for additional details); 2068046

AE Date	02/16/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Terrier - Bull - American Pit		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068046

Product Group: Pet Food

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

Description: DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

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

This report is linked to:

Initial EON Event Key: EON-380708

Initial ICSR: 2063115

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

B6

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

B6

B6

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Client: **B6**
Patient:

Chem 21 - 5/13/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6	Sex: SF	Provider: B6
Patient ID: 439571	Age: 5	Order Location: V320559: Investigation into
Phone number:	Species: Canine	Sample ID: 1905130113
Collection Date: 5/13/2019 1:50 PM	Breed: Pit Bull	
Approval date: 5/13/2019 2:51 PM		

Research Chemistry Profile - Small Animal (Cobas)

		Ref. Range/Females
SMACHUNSKI		
Glucose		67-135 mg/dL
Urea		8-30 mg/dL
Creatinine		0.6-2.0 mg/dL
Phosphorus		2.6-7.2 mg/dL
Calcium 2		9.4-11.3 mg/dL
Magnesium 2+		1.8-3.0 mEq/L
Total Protein		5.5-7.8 g/dL
Albumin		2.8-4.0 g/dL
Globulins		2.3-4.2 g/dL
A/G Ratio	H	0.7-1.6
Sodium	H	140-150 mEq/L
Chloride		106-116 mEq/L
Potassium	B6	3.7-5.4 mEq/L
tCO2(Bicarb)		14-28 mEq/L
AGAP		8.0-19.0
NA/K		29-40
Total Bilirubin		0.10-0.30 mg/dL
Alkaline Phosphatase		12-127 U/L
GGT		0-10 U/L
ALT		14-86 U/L
AST		9-54 U/L
Creatine Kinase		22-422 U/L
Cholesterol		82-355 mg/dL
Triglycerides		30-338 mg/dl
Amylase		409-1250 U/L
Osmolality (calculated)		291-315 mmol/L

Sample ID: 1905130113/1
END OF REPORT (Final)

Reviewed by: _____

Client:
Patient:

B6

B6

-proBNP 5/13/2019

B6



B6

PET OWNER: **B6**
SPECIES: Canine
BREED: Pit Bull, American
GENDER: Female
AGE:
PATIENT ID:

Tufts University Attn: Lisa Freeman
200 Westboro Rd.
North Grafton, MA 01536
508-839-5395
ACCOUNT #: 88933
ATTENDING VET: **B6**

LAB ID: 2301800020
ORDER ID: 1A
COLLECTION DATE: 5/12/19
DATE OF RECEIPT: 5/13/19
DATE OF RESULT: 5/14/19

IDEXX Services: **Cardiopet® proBNP-Canine***

Chemistry



5/13/19 (Order Received)
5/14/19 11:57 AM (Last Updated)

2/16/19

TEST

RESULT

REFERENCE VALUE

Cardiopet
proBNP
(Canine)

B6

0 - 900 pmol/L

B6

B6

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

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

Troponin 5/31/2019



Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474



Website User ID: lisa.freeman@tufts.edu OR **B6**@tufts.edu

GI Lab Assigned Clinic ID: 23523

B6
Tufts Cummings School of Vet Med - Cardiology/Nutrition
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4696
Fax:
Animal Name: **B6**
Owner Name:
Species: Canine
Date Received: May 30, 2019

Tufts Cummings School of Vet Med -
Cardiology/Nutrition Tracking Number:
439571

GI Lab Accession: **B6**

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	05/31/19

B6

Comments:

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: **B6**

Provider: **B6**

Patient ID: 439571

Sex: SF

Order Location: V320559: Investigation into

Phone number:

Age: 5

Sample ID: 1905130113

Collection Date: 5/13/2019 1:50 PM

Species: Canine

Approval date: 5/13/2019 2:51 PM

Breed: Pit Bull

Research Chemistry Profile - Small Animal (Cobas)

		Ref. Range/Females
SMACHUNSKI		
Glucose		67-135 mg/dL
Urea		8-30 mg/dL
Creatinine		0.6-2.0 mg/dL
Phosphorus		2.6-7.2 mg/dL
Calcium 2		9.4-11.3 mg/dL
Magnesium 2+		1.8-3.0 mEq/L
Total Protein		5.5-7.8 g/dL
Albumin		2.8-4.0 g/dL
Globulins		2.3-4.2 g/dL
A/G Ratio		0.7-1.6
Sodium		140-150 mEq/L
Chloride		106-116 mEq/L
Potassium		3.7-5.4 mEq/L
tCO2(Bicarb)		14-28 mEq/L
AGAP		8.0-19.0
NA/K		29-40
Total Bilirubin		0.10-0.30 mg/dL
Alkaline Phosphatase		12-127 U/L
GGT		0-10 U/L
ALT		14-86 U/L
AST		9-54 U/L
Creatine Kinase		22-422 U/L
Cholesterol		82-355 mg/dL
Triglycerides		30-338 mg/dl
Amylase		409-1250 U/L
Osmolality (calculated)		291-315 mmol/L

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 11/10/2018 6:44:26 PM
Subject: Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food [B6] EON-370755
Attachments: 2058695-report.pdf; 2058695-attachments.zip

A PFR Report has been received and PFR Event [EON-370755] has been created in the EON System.

A "PDF" report by name "2058695-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 "2058695-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370755

ICSR #: 2058695

EON Title: PFR Event created for Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food; 2058695

AE Date	08/06/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Retriever - Golden		
Age	[B6] years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2058695

Product Group: Pet Food

Product Name: Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food

Description: Low taurine level, eating Wellness Simple grain free for 3 months prior to testing and Wellness Core Low fat Grain Free food for 3 years before that. Taurine level was [B6] Echo showed NO DCM

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food		

Sender information

B6

USA

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

B6

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

B6

B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED] B6
Sent: 11/10/2018 6:44:26 PM
Subject: Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food [REDACTED] B6 EON-370755
Attachments: 2058695-report.pdf; 2058695-attachments.zip

A PFR Report has been received and PFR Event [EON-370755] has been created in the EON System.

A "PDF" report by name "2058695-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 "2058695-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370755

ICSR #: 2058695

EON Title: PFR Event created for Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food; 2058695

AE Date	08/06/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Retriever - Golden		
Age	[REDACTED] B6 years		
District Involved	PFR [REDACTED] B6 DO		

Product information

Individual Case Safety Report Number: 2058695

Product Group: Pet Food

Product Name: Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food

Description: Low taurine level, eating Wellness Simple grain free for 3 months prior to testing and Wellness Core Low fat Grain Free food for 3 years before that. Taurine level was [REDACTED] B6 Echo showed NO DCM

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food		

Sender information

B6

USA

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UC VETERINARY MEDICAL CENTER-SAN DIEGO
PHONE: (858) 875-7505

10435 SORRENTO VALLEY RD, STE 101
SAN DIEGO, CA 92121

CARDIOLOGY
FAX: (858) 875-7583

August 23, 2018

Cardiology Report

Dr. **B6**

B6 is a 6-year-old FS golden retriever belonging to **B6** who presented to the UC Veterinary Medical Center - San Diego for a cardiac evaluation.

Cardiac Diagnosis: Normal echocardiogram.

Chief Concerns/Major History: **B6** presented for an initial cardiac examination. He is part of a Golden Retriever lifetime study. Recent bloodwork showed a low normal taurine level of under 250. **B6** so it was suggested that he receive an echocardiogram. **B6** is doing well at home and not showing any clinical signs of heart disease. He is eating a low fat grain free diet. **B6** is currently receiving eye medication for corneal dystrophy.

Cardiology Exam:

B6

CV: I/VI left apical systolic heart murmur. Regular rhythm. Strong and synchronous pulses.

B6

Echocardiogram Subjective Findings:

B6

B6

Echocardiogram Objective Findings:

B6

B6

Assessment/Recommendations: There is no evidence of significant cardiomyopathy seen on this exam. There are trace insufficiencies of the mitral and tricuspid valves, which are hemodynamically insignificant at this time. No cardiac medications are warranted at this time. **B6**

B6

Medications: No cardiac medications warranted at this time.

Follow-up: No recheck necessary unless signs of a heart murmur is ausculted or an arrhythmia is seen or ausculted.

Thank you very much for allowing me to be of service to you and your clients. Please feel free to contact me with any questions or concerns.

B6 DVM, DACVIM (Cardiology)

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/25/2019 1:05:02 PM
Subject: Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-380743
Attachments: 2063134-report.pdf; 2063134-attachments.zip

A PFR Report has been received and PFR Event [EON-380743] has been created in the EON System.

A "PDF" report by name "2063134-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 "2063134-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380743

ICSR #: 2063134

EON Title: PFR Event created for Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey chicken liver and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063134

AE Date	02/01/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Stable
Breed	Bulldog		
Age	8 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063134

Product Group: Pet Food

Product Name: Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: Housemate (half sister; B6) - (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with

ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated)

Submission Type: Initial

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

B6

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

B6

=====
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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/25/2019 12:52:56 PM
Subject: Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-380742
Attachments: 2063133-report.pdf; 2063133-attachments.zip

A PFR Report has been received and PFR Event [EON-380742] has been created in the EON System.

A "PDF" report by name "2063133-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 "2063133-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380742

ICSR #: 2063133

EON Title: PFR Event created for Wellness Core grain-free ocean fish dry Wellness core grain free turkey chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063133

AE Date	01/15/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Stable
Breed	Bulldog		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063133

Product Group: Pet Food

Product Name: Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food

Submission Type: Initial

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

B6

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through your local district FDA office.

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

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 2/25/2019 1:20:54 PM
Subject: Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-380745
Attachments: 2063135-report.pdf; 2063135-attachments.zip

A PFR Report has been received and PFR Event [EON-380745] has been created in the EON System.

A "PDF" report by name "2063135-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 "2063135-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380745

ICSR #: 2063135

EON Title: PFR Event created for Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey chicken liver and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063135

AE Date	02/20/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Stable
Breed	Bulldog		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063135

Product Group: Pet Food

Product Name: Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: Eating BEG diet - 2 other dogs in household diagnosed with DCM [B6] (already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts

2/20/19 Probable **B5** diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Taurine and troponin pending

Submission Type: Initial

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

B6

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

B6

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 6/11/2019 7:17:00 PM
Subject: Earthborn grain free weight management dry: Lisa Freeman - EON-390207
Attachments: 2068098-report.pdf; 2068098-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390207] has been created in the EON System.

A "PDF" report by name "2068098-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 "2068098-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390207

ICSR #: 2068098

EON Title: Related PFR Event created for Earthborn grain free weight management dry; 2068098

AE Date	11/05/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Doberman Pinscher		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068098

Product Group: Pet Food

Product Name: Earthborn grain free weight management dry

Description: Diagnosed with DCM, CHF, and atrial fibrillation 11/5/18. Currently hospitalized. Taurine submitted to UC Davis. Unclear if related to diet, given breed but eating boutique, grain-free diet. Only prior history is traumatic injury in 2015. Genetic testing - negative for DCM1 & DCM2 Normal taurine levels - plasma [B6] whole blood [B6] Patient was humanely euthanized [B6] due to worsening CHF. Specimens were not collected for evaluation per owner.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

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

This report is linked to:

Initial EON Event Key: EON-370708

Initial ICSR: 2058678

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 6/10/2019 2:56:47 PM
Subject: PureVita Venison & Red Lentils Grain-Free Dry Dog Food [B6]
EON-390031
Attachments: 2067992-report.pdf; 2067992-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390031] has been created in the EON System.

A "PDF" report by name "2067992-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 "2067992-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390031

ICSR #: 2067992

EON Title: Related PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula; 2067992

AE Date	03/01/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	American Pit Bull Terrier		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2067992

Product Group: Pet Food

Product Name: PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula

Description: Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related.

Patient was placed on **B6** and taurine. Taurine levels prior to supplementation was WNL.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NutriSource Adult Chicken and Rice formula		
PureVita Venison & Red Lentils Grain-Free Dry Dog Food		

This report is linked to:

Initial EON Event Key: EON-386301

Initial ICSR: 2066404

Sender information

B6

200 Westboro Road
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

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Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

Name/DOB: **B6**

Patient ID: **B6**

Phone number:

Collection Date: 5/3/2019 11:51 AM

Approval date: 5/3/2019 12:55 PM

Sex: CM

Age: 2

Species: Canine

Breed: Pit Bull

Provider: **B6**

Order Location: Foster Hospital for Small Animals

Sample ID: **B6**

Research Chemistry Profile - Small Animal (Cobas)

		Ref. Range/Males
DNOYES		
Glucose		67-135 mg/dL
Urea		8-30 mg/dL
Creatinine		0.6-2.0 mg/dL
Phosphorus		2.6-7.2 mg/dL
Calcium 2		9.4-11.3 mg/dL
Magnesium 2+		1.8-3.0 mEq/L
Total Protein		5.5-7.8 g/dL
Albumin		2.8-4.0 g/dL
Globulins	B6	2.3-4.2 g/dL
A/G Ratio		0.7-1.6
Sodium		140-150 mEq/L
Chloride		106-116 mEq/L
Potassium		3.7-5.4 mEq/L
tCO2(Bicarb)		14-28 mEq/L
AGAP		8.0-19.0
NA/K		29-40
Total Bilirubin		0.10-0.30 mg/dL
Alkaline Phosphatase	Hemolysis may affect result(s)	12-127 U/L
GGT	B6	0-10 U/L
ALT		14-86 U/L
AST		9-54 U/L
Creatine Kinase	Hemolysis may affect result(s)	22-422 U/L
Cholesterol		82-355 mg/dL
Triglycerides	B6	30-338 mg/dl
Amylase		409-1250 U/L
Osmolality (calculated)		291-315 mmol/L
Comments (Chemistry)	B6 hemolysis	

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

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

A "PDF" report by name "2058683-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2058683-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-370715

ICSR #: 2058683

EON Title: PFR Event created for Zignature trout & salmon dry; 2058683

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

Product information

Individual Case Safety Report Number: 2058683

Product Group: Pet Food

Product Name: Zignature trout & salmon dry

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 2

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

B6 USA

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

B6

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

B6

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 3/28/2019 9:01:34 PM
Subject: Rachel Ray peak open range recipe (beef: Lisa Freeman - EON-383627
Attachments: 2064872-report.pdf; 2064872-attachments.zip

A PFR Report has been received and Related PFR Event [EON-383627] has been created in the EON System.

A "PDF" report by name "2064872-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 "2064872-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383627

ICSR #: 2064872

EON Title: Related PFR Event created for Rachel Ray peak open range recipe (beef venison lamb); 2064872

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

Product information

Individual Case Safety Report Number: 2064872

Product Group: Pet Food

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

Description: DCM and arrhythmias diagnosed at time of **B6** surgery so unclear if sepsis/post-op or true DCM. Had recheck echo 10/31/18 and still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Rachel Ray peak open range recipe (beef, venison, lamb)		

This report is linked to:

Initial EON Event Key: EON-370720

Initial ICSR: 2058685

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/25/2019 12:52:56 PM
Subject: Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-380742
Attachments: 2063133-report.pdf; 2063133-attachments.zip

A PFR Report has been received and PFR Event [EON-380742] has been created in the EON System.

A "PDF" report by name "2063133-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 "2063133-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380742

ICSR #: 2063133

EON Title: PFR Event created for Wellness Core grain-free ocean fish dry Wellness core grain free turkey chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063133

AE Date	01/15/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Stable
Breed	Bulldog		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063133

Product Group: Pet Food

Product Name: Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food

Submission Type: Initial

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

B6

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

B6

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

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

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

Below is the summary of the report:

EON Key: EON-367849

ICSR #: 2055795

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

AE Date	02/02/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055795

Product Group: Pet Food

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

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

B6

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

B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 1/22/2018 11:28:12 PM
Subject: California Natural Grain-Free Kangaroo and Red Lentils Recipe; [B6]
- EON-345833
Attachments: 2040529-report.pdf; 2040529-attachments.zip

A PFR Report has been received and PFR Event [EON-345833] has been created in the EON System.

A "PDF" report by name "2040529-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 "2040529-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-345833

ICSR #: 2040529

EON Title: PFR Event created for California Natural Grain-Free Kangaroo and Red Lentils Recipe; 2040529

AE Date	08/18/2017	Number Fed/Exposed	4
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Retriever - Labrador		
Age	5 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2040529

Product Group: Pet Food

Product Name: California Natural Grain-Free Kangaroo and Red Lentils Recipe

Description: [B6] had been diagnosed with a new heart murmur a couple of months earlier, then developed difficulty breathing and cough and was diagnosed with congestive heart failure. Echocardiogram showed evidence of dilated cardiomyopathy and chronic degenerative valve disease. [B6] is the biologic niece of

[B4] - FDA ICSR ID 2040528

Submission Type: Initial

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

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

Number of Animals Treated With Product: 4

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
California Natural Grain-Free Kangaroo and Red Lentils Recipe		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

B6

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REPORT INFORMATION

Report Profile

Report Version FPSR.FDA.PETF.V.V1
Report Category Pet Food Safety Report
Submitted 2018-09-16 11:38:42 EST
FDA ICSR ID 2054966
Submitted by lisa.freeman@tufts.edu

Report Identifying Information

Enter a title to help you identify this report

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting? Adverse Event (a symptom, reaction or disease associated with the product)

Contact Information - Reporter Sender

May the FDA contact you to follow-up, if necessary? Yes

Preferred method of contact: Email

Confirm Email lisa.freeman@tufts.edu

First Name Lisa

Last Name Freeman

Primary Phone 5088874523

Other Phone <blank>

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

Street Address Line 2 <blank>

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

Contact Information - Healthcare Professional

Veterinary Practice Name Tufts Cummings School of Veterinary Medicine

First Name Lisa

Last Name Freeman

Primary Phone (508) 887-4523

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

Contact Information - Animal Owner

First Name

B6

Last Name

Primary Phone
Other Phone
Email
Country
Street Address Line 1
Street Address Line 2
City/Town
State
ZIP/Postal Code

B6

Can you provide contact information for the animal owner? Yes

Contact Information - Receiver

Indicate any other parties that you notified about this issue <blank>

Relevant Details

Animal Name/Identifier **B6**

Number of animals given the product 2

Number of animals reacted 1

Species Dog

Breed Great Dane

Age **B6**

Select Unit of Measure Years

Weight 69.5

Select Unit of Measure Kilogram

Gender Male

Reproductive status Neutered

Was the animal pregnant at time of event? <blank>

Was the animal lactating at time of event? <blank>

Prior to the event, what was the animal's overall state of health? Excellent

Problem Details

Did the animal have any health problems and/or was taking medication prior to the event? Yes

Please describe: **B6**

Product Information

Full name of product as it appears on the package label Taste of the Wild Prey Beef dry (will provide full diet history)

Product Type Pet Food

UPC from label <blank>

Package Type BAG

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

Product Lots

Product Use Details

Describe how the product was used or administered 9 cups/day

Date the product was first given to the animal 06/01/2018

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

Contact Information

Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Product Information

Full name of product as it appears on the package label 4Health beef stew canned

Product Type Pet Food

UPC from label <blank>

Package Type CAN

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

Product Lots

Product Use Details

Describe how the product was used or administered 2 tablespoons 3x/day since Jan, 2017

Date the product was first given to the animal <blank>

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

Contact Information

Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Description and Details

Date problem started 09/12/2018

Date of recovery <blank>

Describe what happened

DCM and CHF - had been having respiratory signs for ~1 month prior to diagnosis at Tufts Littermate is **B6** (already reported by owner after being diagnosed with DCM and CHF in July 2018) Owner has another Great Dane at home (~1 year of age) eating the same diet that will be screened soon Owner approved submission of this report and talking to FDA Will send rest of medical records by email (sorry - too many to upload)

Was a veterinarian consulted? <blank>

Outcome to date Stable

Attached Files

FILENAME taurine.pdf

Description of Attachment Taurine results

Attachment Type Laboratory Report

Client: **B6**
 Veterinarian: **B6**
 Patient ID: **B6**
 Visit ID: **B6**

Patient: **B6**
 Species: Canine
 Breed: Great Dane
 Sex: Male (Neutered)
 Age: **B6** Years Old

Lab Results Report

Chemistry 21 (Cobas)		9/14/2018 12:28:20 PM	Accession ID: B6
Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)	291 - 315	mmol/L	



REPORT INFORMATION

Report Profile

Report Version FPSR.FDA.PETF.V.V1
 Report Category Pet Food Safety Report
 Submitted 2018-09-16_11:38:42 EST
 FDA ICSR ID 2054966
 Submitted by lisa.freeman@tufts.edu

Report Identifying Information

Enter a title to help you identify this report

Regulatory Status Voluntary

Type of Submission Initial

What type of report are you submitting? Adverse Event (a symptom, reaction or disease associated with the product)

Contact Information - Reporter Sender

May the FDA contact you to follow-up, if necessary? Yes

Preferred method of contact: Email

Confirm Email lisa.freeman@tufts.edu

First Name Lisa

Last Name Freeman

Primary Phone 5088874523

Other Phone <blank>

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

Street Address Line 2 <blank>

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

Contact Information - Healthcare Professional

Veterinary Practice Name Tufts Cummings School of Veterinary Medicine

First Name Lisa

Last Name Freeman

Primary Phone (508) 887-4523

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

Contact Information - Animal Owner

First Name

B6

Last Name

Primary Phone B6

Other Phone <blank>

Email B6

Country United States

Street Address Line 1 B6

Street Address Line 2 <blank>

City/Town

State B6

ZIP/Postal Code

Can you provide contact information for the animal owner? Yes

Contact Information - Receiver

Indicate any other parties that you notified about this issue <blank>

Relevant Details

Animal Name/Identifier B6

Number of animals given the product 2

Number of animals reacted 1

Species Dog

Breed Great Dane

Age B6

Select Unit of Measure Years

Weight 69.5

Select Unit of Measure Kilogram

Gender Male

Reproductive status Neutered

Was the animal pregnant at time of event? <blank>

Was the animal lactating at time of event? <blank>

Prior to the event, what was the animal's overall state of health? Excellent

Problem Details

Did the animal have any health problems and/or was taking medication prior to the event? Yes

Please describe: **B6**

Product Information

Full name of product as it appears on the package label Taste of the Wild Prey Beef dry (will provide full diet history)

Product Type Pet Food

UPC from label <blank>

Package Type BAG

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

Product Lots

Product Use Details

Describe how the product was used or administered 9 cups/day

Date the product was first given to the animal 06/01/2018

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

Contact Information

Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Product Information

Full name of product as it appears on the package label 4Health beef stew canned

Product Type Pet Food

UPC from label <blank>

Package Type CAN

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

Product Lots

Product Use Details

Describe how the product was used or administered 2 tablespoons 3x/day since Jan, 2017

Date the product was first given to the animal <blank>

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

Contact Information

Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

Description and Details

Date problem started 09/12/2018

Date of recovery <blank>

Describe what happened

DCM and CHF - had been having respiratory signs for ~1 month prior to diagnosis at Tufts Littermate is **B6** (already reported by owner after being diagnosed with DCM and CHF in July 2018) Owner has another Great Dane at home (~1 year of age) eating the same diet that will be screened soon Owner approved submission of this report and talking to FDA Will send rest of medical records by email (sorry - too many to upload)

Was a veterinarian consulted? <blank>

Outcome to date Stable

Attached Files

FILENAME taurine.pdf

Description of Attachment Taurine results

Attachment Type Laboratory Report

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 9/7/2018 8:54:26 PM
Subject: Another Tufts! FW: Zignature Kangaroo limited ingredient grain free dry: Lisa Freeman - EON-364572
Attachments: 2054747-report.pdf; 2054747-attachments.zip

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



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From: PFR Event <pfreventcreation@fda.hhs.gov>
Sent: Friday, September 07, 2018 4:44 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6
Subject: Zignature Kangaroo limited ingredient grain free dry: Lisa Freeman - EON-364572

A PFR Report has been received and PFR Event [EON-364572] has been created in the EON System.

A "PDF" report by name "2054747-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2054747-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-364572
ICSR #: 2054747
EON Title: PFR Event created for Zignature Kangaroo limited ingredient grain free dry; 2054747

AE Date	07/23/2016	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Recovered Completely

Breed	Mixed (Dog)		
Age	5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2054747

Product Group: Pet Food

Product Name: Zignature Kangaroo limited ingredient grain free dry

Description: Developed DCM and CHF on Zignature Kangaroo limited ingredient grain free dry. Changed to Hill's ideal balance chicken and rice dry at time of diagnosis and has improved significantly on last echo (6/13/18) - fractional shortening and heart size now normal and starting to wean off meds

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Recovered Completely

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature Kangaroo limited ingredient grain free dry		

Sender information

Lisa Freeman
 200 Westboro Rd
 North Grafton, MA 01536
 USA

Owner information

B6
 USA

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

B6

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

B6

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

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From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Rotstein, David; Jones, Jennifer L
Sent: 4/30/2018 8:15:16 PM
Subject: RE: DCM cases - proposed diet history

Thanks – on my list for tomorrow morning to have a read – the day has flown by. The good news – they reinstalled SAS and JMP today, so baby steps...

From: Rotstein, David
Sent: Friday, April 27, 2018 9:00 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Fwd: DCM cases - proposed diet history

Lee Anne,

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

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

[REDACTED] B6

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

Hi everyone

I'm attaching a proposed diet history form. I met with our cardiology group yesterday [REDACTED] B5

[REDACTED] B5

[REDACTED] B5

Please let me know if you have any comments – [REDACTED] B5

[REDACTED] B5

[REDACTED] B5

Our group also discussed a [REDACTED] B5

[REDACTED] B5

[REDACTED] B5

Thanks
Lisa

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

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

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

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

B6

B6

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

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

Importance: High

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

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



From: Jones, Jennifer L

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

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

B6

B6

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

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

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

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

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

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



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

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

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

<rfries@illinois.edu>

B6

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

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

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

Dear Dr. Jones,

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

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

Just a brief introduction for the FDA group:

B6

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

B6

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

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

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

Sincerely,
Darcy Adin

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

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

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

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

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

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

From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Rotstein, David; Burkholder, William; Palmer, Lee Anne; Jones, Jennifer L; DeLancey, Siobhan
CC: Carey, Lauren; Norris, Anne; Lovell, Randall A; Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah; Conway, Charlotte; Edwards, David; Atkinson, Krisztina Z; Hodges, April
Sent: 5/21/2018 11:50:08 AM
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent, thank you!

Martine

From: Rotstein, David
Sent: Monday, May 21, 2018 7:49 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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



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From: Hartogenesis, Martine
Sent: Monday, May 21, 2018 7:47 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

At this point I think:

B5

B5

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

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



From: Hartogenesis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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



From: Hartogenesis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work! One question though...do we see any issues

B5

B5

Thanks in advance!

Martine

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

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

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

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to **B6** talk about nutrition and cardiomyopathies. See attached slide.

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

Date: May 17, 2018 at 2:06:04 PM EDT

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

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

Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi there – is the slide set for tomorrow’s meeting? Great work!

B5

B5

B5

B5

From: Hartogenesis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

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

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

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

Just a few questions. On slide 6 (or the spreadsheet)
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 <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

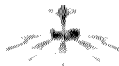
We

B5

B5

Please see the PPT for the rationale/summary

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



From: Rotstein, David

Sent: Monday, May 14, 2018 10:22 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

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

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

From what I've read, it can be a

B5

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic.

B5

B5

B5

B5

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

Date: May 11, 2018 at 4:06:05 PM EDT

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

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there -

B5

B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

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

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

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

Date: May 9, 2018 at 4:09:18 PM EDT

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

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5 I want to confirm it, then will send it along – could be Friday before I get this in shape to send... not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

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

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with **B6** Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison

B6 (BB)



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From: Hartogenesis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

B6

B6

Keep us posted!

Thanks again!

Martine

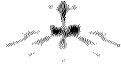
Hi Martine,

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

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

B6

(BB)



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

From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: [REDACTED] B6
Sent: 7/18/2019 11:11:54 AM
Subject: RE: [REDACTED] B6 FDA-CVCA Study for Dilated Cardiomyopathy
Importance: High

Good morning Mr. [REDACTED] B6

Are you interested in speaking with me about [REDACTED] B6 case? Please see my previous email below.

If so, please send me your availability for a 30-minute phone call on the following days:

- Tuesday July 23: 10 am to 12 noon eastern, or 1 to 3 pm
- Wednesday July 24: 6:30 am to 11 am eastern
- Thursday July 25: 6:30 am to 3 pm eastern
- Friday July 26: 6:30 am to 11:30 am eastern.

If you are unwilling to perform the interview, please let me know. I can then remove you from the interview list.

Thank you,

Dr. Jones

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



From: Jones, Jennifer L
Sent: Friday, July 05, 2019 12:52 PM
To: [REDACTED] B6
Subject: [REDACTED] B6 FDA-CVCA Study for Dilated Cardiomyopathy
Importance: High

Good afternoon [REDACTED] B6

We have been working with CVCA to better understand Dilated Cardiomyopathy in dogs that ate pet foods labelled "grain free" and contain higher amounts of legumes and/or potato products. As part of that investigation, we would like to ask you some questions about [REDACTED] B6's past and current diet and environmental exposures.

The phone interview lasts approximately 30 minutes. Please send me 3 times when you would be available to speak between 6:30 am and 3 pm eastern time the following days:

- 7/11
- 7/12
- 7/15
- 7/16
- 7/17
- 7/18

I attached a copy of our network procedures. They describe how owners help with our case investigations.

Thank you kindly,

Dr. Jones

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

new tel: 240-402-5421

fax: 301-210-4685

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

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



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Andrea Fascetti'
Sent: 3/25/2019 6:57:47 PM
Subject: reference ranges for plasma amino acids

Hi Andrea,

Do you have specific reference

B5

B5

Thank you in advance,
Jen

Jennifer L. A. Jones, DVM

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



From: [REDACTED] B6
To: Jones, Jennifer L; Andrea Fascetti
CC: Guag, Jake
Sent: 4/1/2019 11:34:02 PM
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi Dr. Jones,

I will correct the mislabels and get back to you tomorrow.

Thanks,

[REDACTED] B6

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Monday, April 1, 2019 4:30 AM
To: Andrea Fascetti; [REDACTED] B6
Cc: Guag, Jake
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Good morning Andrea and [REDACTED] B6

I was reviewing the results and needed some clarification of the results for 2 cases. The results you sent show plasma amino acid values for cv-09 but not cv-14. However, I did not send any plasma for cv-09. I did send plasma for cv-14 (attached inventory sheet). Can you please clarify which set of plasma values belong to cv-14?

Thank you in advance and have a wonderful week,

Jen

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



From: Andrea Fascetti <ajfascetti@ucdavis.edu>
Sent: Saturday, March 23, 2019 1:30 PM
To: [REDACTED] B6
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hello Jen and Jake- Please see attached file with your results. Thanks for the heads-up on the species. We have to know in case someone in the lab comes in contact with the blood (especially through a cut). Our occupational health and safety folks then have us file a report and follow up on those cases to ensure vaccination status etc.

We will bill according to your comments below.

Have a nice weekend.

Andrea

On Mar 21, 2019, at 10:51 AM, [REDACTED] B6 wrote:

Hi Jake,

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>

Sent: Tuesday, March 12, 2019 8:53 AM

To: B6

Cc: Jones, Jennifer L

Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi Joshua,

Hope you are well. We shipped 800.267 samples on dry ice to you.

Box#1 has urine samples its tracking number is 1ZA4420T0194520315 with UPS.

Box#2 has whole blood and serum samples and its tracking number is 1ZA4420T0192121929 with UPS. Both boxes are expected to arrive your location tomorrow (Mar. 13th, 2019)

Please charge the urine sample analysis under AA contract.

Please provide invoice for the blood and serum analysis.

Thank you

Jake

Jake Guag, MPH, CPH

Biologist (FDA/CVM/OR/Vet-LIRN)

8401 Muirkirk Road

Laurel, Maryland 20708

Email: jake.guag@fda.hhs.gov

Tel: 240-402-0917

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6 Andrea Fascetti
CC: Guag, Jake
Sent: 4/2/2019 11:19:19 AM
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Received. Thank you, [REDACTED] B6

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



From: [REDACTED] B6
Sent: Monday, April 01, 2019 8:06 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Andrea Fascetti <ajfascetti@ucdavis.edu>
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi Dr. Jones,

Attached please find the corrected data file.

Kind Regards,

[REDACTED] B6

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Monday, April 1, 2019 4:30 AM
To: Andrea Fascetti; [REDACTED] B6
Cc: Guag, Jake
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Good morning Andrea and [REDACTED] B6

I was reviewing the results and needed some clarification of the results for 2 cases. The results you sent show plasma amino acid values for cv-09 but not cv-14. However, I did not send any plasma for cv-09. I did send plasma for cv-14 (attached inventory sheet). Can you please clarify which set of plasma values belong to cv-14? Thank you in advance and have a wonderful week,
Jen

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



From: Andrea Fascetti <ajfascetti@ucdavis.edu>
Sent: Saturday, March 23, 2019 1:30 PM
To: [REDACTED] B6
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hello Jen and Jake- Please see attached file with your results. Thanks for the heads-up on the species. We have to know in case someone in the lab comes in contact with the blood (especially through a cut). Our occupational health and safety folks then have us file a report and follow up on those cases to ensure vaccination status etc.

We will bill according to your comments below.

Have a nice weekend.

Andrea

On Mar 21, 2019, at 10:51 AM, [REDACTED] B6 [REDACTED]@ucdavis.edu> wrote:

Hi Jake,

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks,

[REDACTED] B6 [REDACTED]

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, March 12, 2019 8:53 AM
To: [REDACTED] B6 [REDACTED]
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi [REDACTED] B6 [REDACTED]

Hope you are well. We shipped 800.267 samples on dry ice to you.

Box#1 has urine samples its tracking number is 1ZA4420T0194520315 with UPS.

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Please charge the urine sample analysis under AA contract.

Please provide invoice for the blood and serum analysis.

Thank you

Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: B6
CC: 'Guag, Jake * (Jake.Guag@fda.hhs.gov)'
Sent: 3/22/2019 10:35:43 AM
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi B6
They are all dogs.
Thank you,
Jen

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



From: Guag, Jake
Sent: Thursday, March 21, 2019 2:09 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Jen, could you please provide me info or where I can find the info?

Thanks
Jake

From: B6
Sent: Thursday, March 21, 2019 1:52 PM
To: Andrea Fascetti <ajfascetti@ucdavis.edu>
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Fw: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi Jake,

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, March 12, 2019 8:53 AM
To: B6
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

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Please charge the urine sample analysis under AA contract.

Please provide invoice for the blood and serum analysis.

Thank you
Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: [REDACTED] B6
CC: Andrea Fascetti
Sent: 8/20/2019 11:44:03 AM
Subject: Question about results

Good morning [REDACTED] B6 and Andrea,
I had two quick general questions about the plasma and urine amino acid results.

[REDACTED] B5

Thank you in advance,
Jen

Jennifer L. A. Jones, DVM

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



From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: [REDACTED] B6
Sent: 6/27/2019 4:48:27 PM
Subject: RE: Fw: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi [REDACTED] B6

Thanks. You are correct. I forgot to update the CV-10 samples.

[REDACTED] B6

Could you please provide me when we can expect to get results?

Thanks

From: [REDACTED] B6 <[REDACTED]@ucdavis.edu>
Sent: Thursday, June 27, 2019 12:41 PM
To: [REDACTED] B6 <Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Re: Fw: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hello Jake-

Attached please find the completed inventory form. The only thing of note is there were 2 vials of cv-10 plasma, otherwise everything was in order.

Kind regards-

[REDACTED] B6

On Thu, Jun 27, 2019 at 9:26 AM [REDACTED] B6 <[REDACTED]@ucdavis.edu> wrote:

Hi [REDACTED] B6

Could you fill their sample inventory forms and email a PDF to Jake?

Thanks,

[REDACTED] B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Thursday, June 27, 2019 9:21 AM
To: [REDACTED] B6
Subject: RE: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi [REDACTED] B6

Could you please provide me filled out sample inventory forms?

Thanks
Jake

From: [REDACTED] <[REDACTED]@ucdavis.edu>
Sent: Tuesday, June 25, 2019 1:16 PM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: Andrea Fascetti <ajfascetti@ucdavis.edu>; [REDACTED] <[REDACTED]@ucdavis.edu>
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi Jake,

Thanks for the notice. I will Let Dr. Fascetti know your plan. I am not in charge of the billing issues.

Kind Regards,

[REDACTED]

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, June 25, 2019 9:17 AM
To: [REDACTED]
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN (FDA) shipped 800.267-CV-R3 samples

Hi [REDACTED]

I shipped 800.267 R3 samples on dry ice to your place this morning. R3 Urine samples are in Box#1, and R3 whole blood and plasma samples are in Box #2.

Both boxes will be arrive tomorrow (Jun 26, 2019), and their tracking numbers are [REDACTED] (Box#1) and [REDACTED] (Box#2) with UPS.

Inside you will find sample an inventory sheet in each box. Please fill out and provide to me (Scan or Fax).

[REDACTED]

Thanks
Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 9/22/2018 10:40:31 PM
Subject: Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor-Before that: Lisa Freeman - EON-366516
Attachments: 2055229-report.pdf; 2055229-attachments.zip

A PFR Report has been received and PFR Event [EON-366516] has been created in the EON System.

A "PDF" report by name "2055229-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 "2055229-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-366516

ICSR #: 2055229

EON Title: PFR Event created for Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that fed 3-4 bags of Pine Forest Before that had been feeding Pacific Stream for several years; 2055229

AE Date	09/08/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055229

Product Group: Pet Food

Product Name: Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years

Description: DCM and CHF Probably primary DCM in predisposed breed but given diet history, some possibility of diet-associated DCM Taurine WNL.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

B6

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

B6

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

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Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: S200403

B6

Canine

Years Old Male (Neutered) Doberman

Pinscher

Black/Tan

Cardiology Appointment Report

Date: 9/20/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

CVT, VTS (Cardiology)

Student:

B6

V19

Presenting Complaint:

Recheck of DCM with active CHF

General Medical History:

Has been his normal self, went on one 20 min walk since he was last here and had no trouble at all.

PU/PD (due to lasix)

Diet and Supplements:

Fromm Mature: 4 cups a day

Cardiovascular History:

Prior CHF diagnosis? Yes

Prior heart murmur? Yes, grade III/VI

Prior ATE?, N

Prior arrhythmia? Y, VPCs

Monitoring respiratory rate and effort at home? N, but havent noticed any labored breathing

Cough? N

Shortness of breath or difficulty breathing? N

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? N

Current Medications Pertinent to CV System:

Medication: B6

B6

Medication: B6

B6

Medication: B6

B6

Medication: B6

Can we call their pharmacy with a script for this?

Cardiac Physical Examination:

General PE:

MM Color and CRT:

BCS (1-9):

BW (kg): 34.2 Kg

Heart rate:

Respiratory rate:

Temp (if possible):

Muscle condition:

- Normal
- Mild muscle loss

- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

Murmur location/description:

Jugular vein:

- Bottom 1/3 of the neck
- Middle 1/3 of the neck
- 1/2 way up the neck
- Top 2/3 of the neck

Arterial pulses:

- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other:

Arrhythmia:

- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia

Gallop:

- Yes
- No
- Intermittent

- Pronounced
- Other:

Pulmonary assessments:

- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

Problems:

Differential Diagnoses:

Diagnostic plan:

- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure

- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests:

Assessment and recommendations:

Final Diagnosis:

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II

- IIIa
- IIIb

ACVIM Classification:

- A
- B1
- B2

- C
- D

Discharge Instructions

Patient

Name: B6
Species: Canine
Black/Tan Male (Neutered) Doberman
Pinscher
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: S200403

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

TS (Cardiology)

Student: B6 V19

Admit Date: B6 1:05:31 PM

Discharge Date: B6

Diagnoses:

1. Dilated cardiomyopathy (DCM)— stable
2. Congestive heart failure— resolved

Case summary:

Thank you for bringing in B6 for his recheck appointment with us today. He is such a sweet boy! We are so happy to hear he has been doing so well on his medications and has not had any coughing, difficulty breathing, or exercise intolerance. We are so glad B6 is responding so well to his medications and is feeling so comfortable.

Today we performed a recheck quick ultrasound of his heart, an ECG to recheck his ventricular arrhythmias, and took some blood to recheck his kidney values since being on the B6 for 10 days. His heart seems to be contracting a little stronger than it was previously. His left ventricle was still dilated, but his left atrium was smaller today since his last visit, which means he is improving on his current medications. He did not have any arrhythmias when we performed his ECG today. The blood work results are normal and we would like to continue him on his current medication doses (see list below), and also continue exercise restricting him to only leash walks.

Monitoring at Home:

- o We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- o In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is

fairly minimal if heart failure is controlled.

- An increase in breathing rate or effort will usually mean that you should give an extra dose of **B6** if difficulty breathing is not improved by within 60-90 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

Diet suggestions:

We suggest **B6** to be in one of the diets we recommended (see list). Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (<http://vet.tufts.edu/heartsmart/diet/>)

Exercise Recommendations:

Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that **B6** is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck echocardiogram for **B6** is recommended in 3-4 months.
B6 as an appointment with us on October 2nd at 4 pm.)

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

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case **B6**

Owner **B6**

Discharge Instructions

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 4/1/2019 9:48:46 PM
Subject: ACANA - Heritage Red Meat Formula Dog Food (Grain-free): Kelsey Weeks - EON-383914
Attachments: 2065085-report.pdf; 2065085-attachments.zip

A PFR Report has been received and PFR Event [EON-383914] has been created in the EON System.

A "PDF" report by name "2065085-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 "2065085-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383914

ICSR #: 2065085

EON Title: PFR Event created for ACANA - Heritage Red Meat Formula Dog Food (Grain-free); 2065085

AE Date	03/15/2019	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Shepherd Dog - German		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2065085

Product Group: Pet Food

Product Name: ACANA - Heritage Red Meat Formula Dog Food (Grain-free)

Description: 3/15/2019 - Acute onset of difficulty breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
ACANA - Heritage Red Meat Formula Dog Food (Grain-free)		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

B6

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 4/22/2019 5:16:54 PM
Subject: Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food; [B6] EON-385697
Attachments: 2066104-report.pdf; 2066104-attachments.zip

A PFR Report has been received and PFR Event [EON-385697] has been created in the EON System.

A "PDF" report by name "2066104-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 "2066104-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-385697

ICSR #: 2066104

EON Title: PFR Event created for Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food Natural Chicken & Brown Rice; 2066104

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	12 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2066104

Product Group: Pet Food

Product Name: Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice

Description: Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd [B6] and referred to Tufts

for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice		
Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification; [REDACTED]
Sent: 6/11/2019 6:20:55 PM
Subject: Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food; [REDACTED] - EON-390198
Attachments: 2068091-report.pdf; 2068091-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390198] has been created in the EON System.

A "PDF" report by name "2068091-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068091-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390198

ICSR #: 2068091

EON Title: Related PFR Event created for Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food Natural Chicken & Brown Rice; 2068091

AE Date	03/17/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	12 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068091

Product Group: Pet Food

Product Name: Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice

Description: Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O

suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd **B6** and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF Normal plasma and whole blood taurine levels

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice		
Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food		

This report is linked to:

Initial EON Event Key: EON-385697

Initial ICSR: 2066104

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

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Client: **B6**
Patient:

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Wednesday, May 8, 2019 at 9:07:06 PM
Heart Rate: **B6** bpm Duration: 29 s



Meins, Elmer, RCH, ... Scale: 25mm/s, J.Crosby

B6

Client:
Patient: **B6**

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Thursday, May 9, 2019 at 9:03:43 PM
Heart Rate: **86** bpm Duration: 39 s



Meiss filter: 80Hz Scale: 25mm/s 10mm/mV

B6

Client: **B6**
Patient:

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Thursday, May 9, 2019 at 9:03:43 PM
Heart Rate: **B6**bpm Duration: 39 s



Main filter: 80Hz Scale: 25mm/s, 10mm/mV

B6

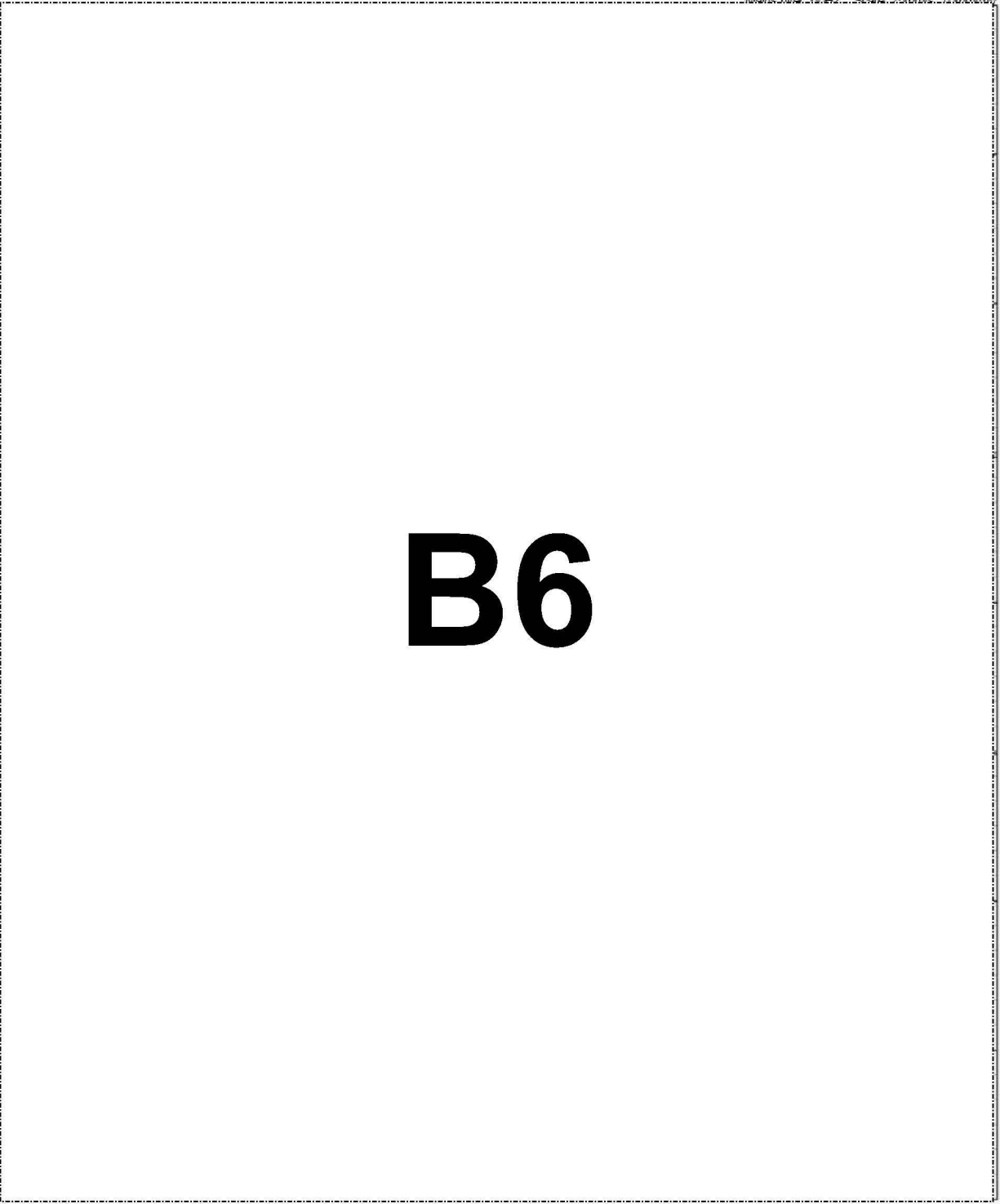
Client:
Patient: **B6**

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Friday, May 10, 2019 at 10:00:45 PM
Heart Rate: **B6**bpm Duration: 28 s



...Main Filter: 60Hz...Scale: 25mm/s...1.0mV/cm...



B6

Client:
Patient: **B6**

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Sunday, May 12, 2019 at 8:06:48 PM
Heart Rate: **86** bpm Duration: 40 s



B6

Client:
Patient: **B6**

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Sunday, May 12, 2019 at 8:06:48 PM
Heart Rate: **B6** bpm Duration: 40 s



Main Filter: 60Hz Scale: 25mm/s 10mm/mV

B6

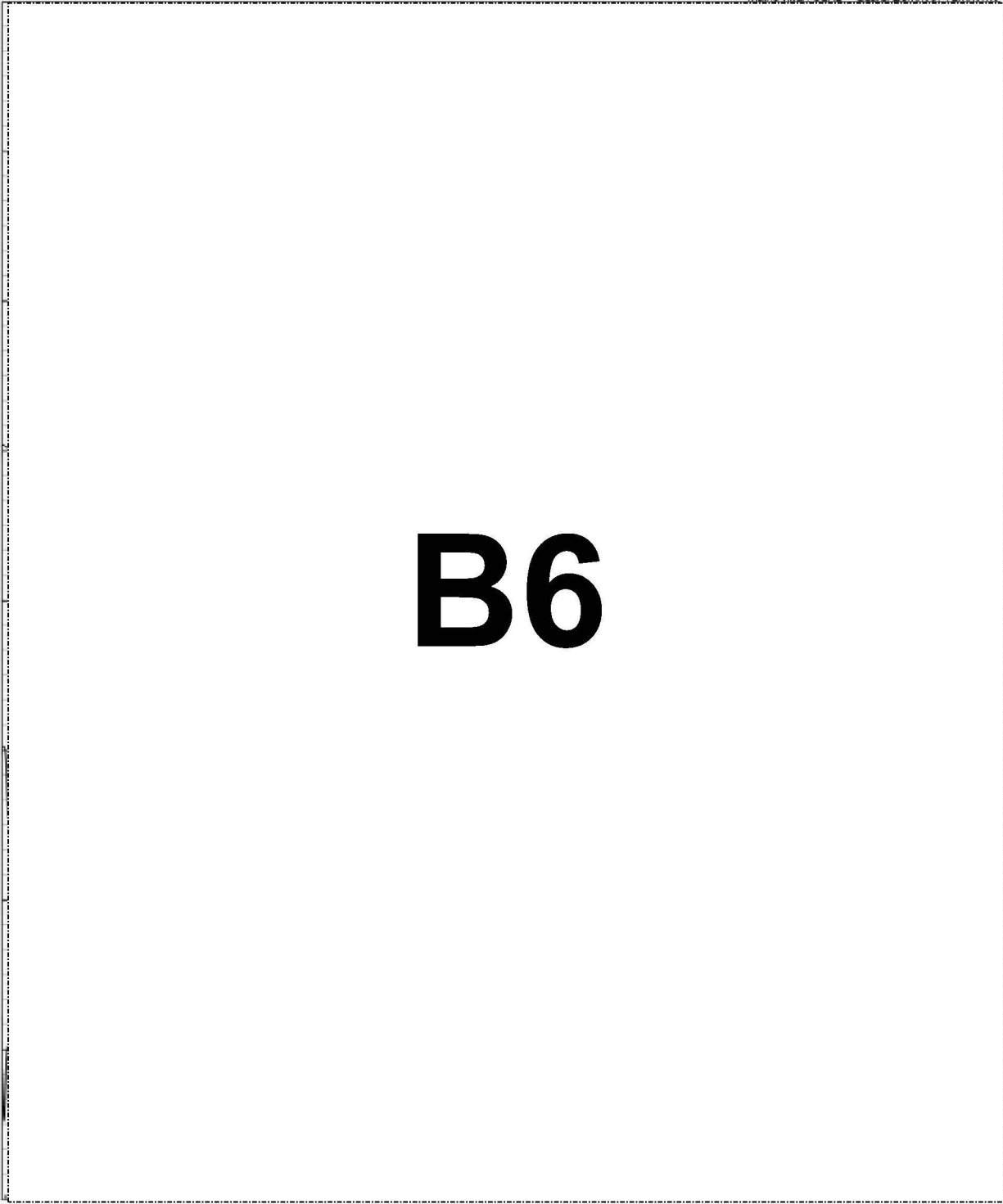
Client:
Patient: **B6**

Alivecor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Monday, May 13, 2019 at 8:43:21 PM
Heart Rate: **B6** bpm Duration: 43 s



Main filter: 60Hz Scale: 25mm/s, 10mm/mV

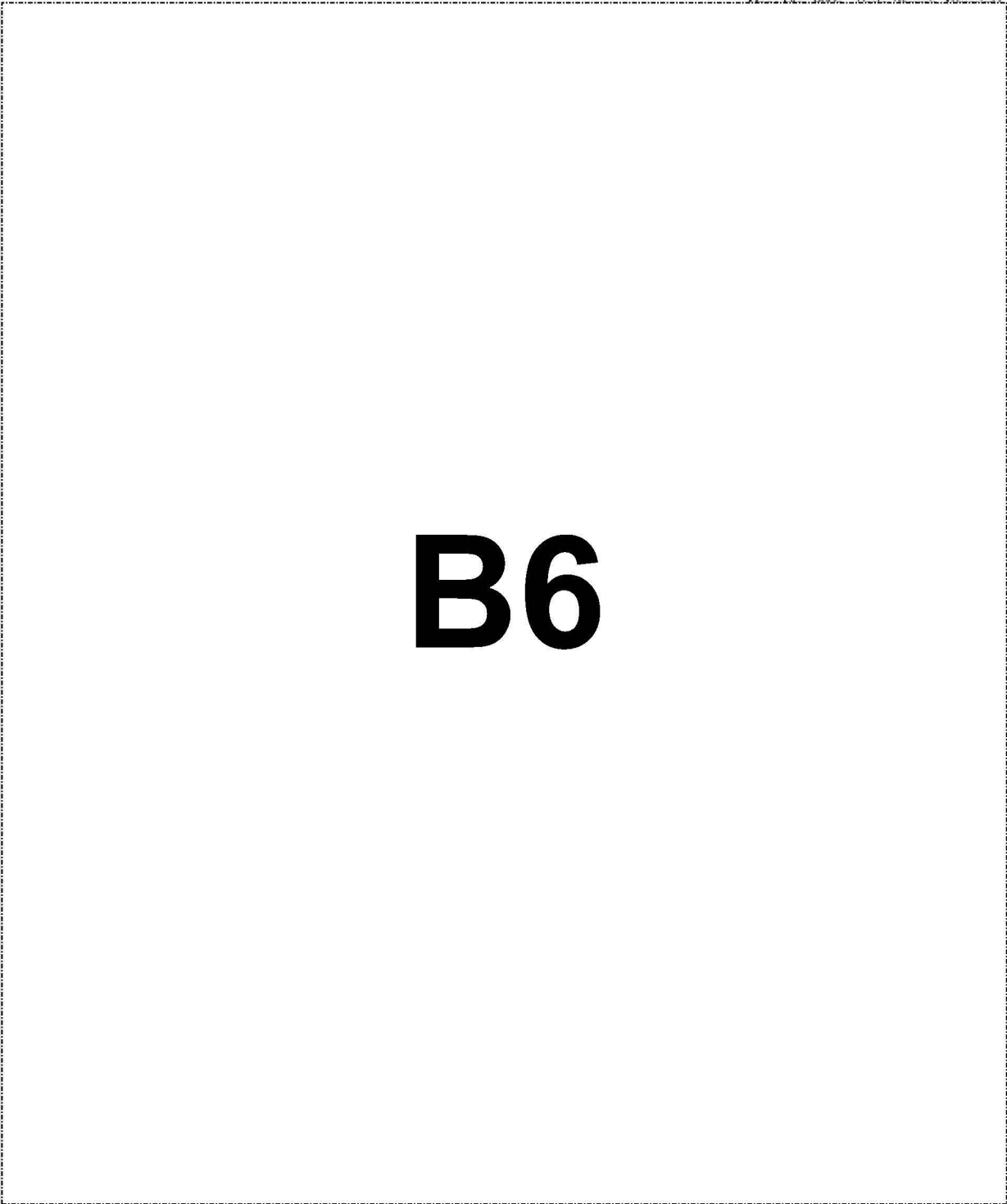


B6

Client:
Patient: **B6**

Alivecor ECG

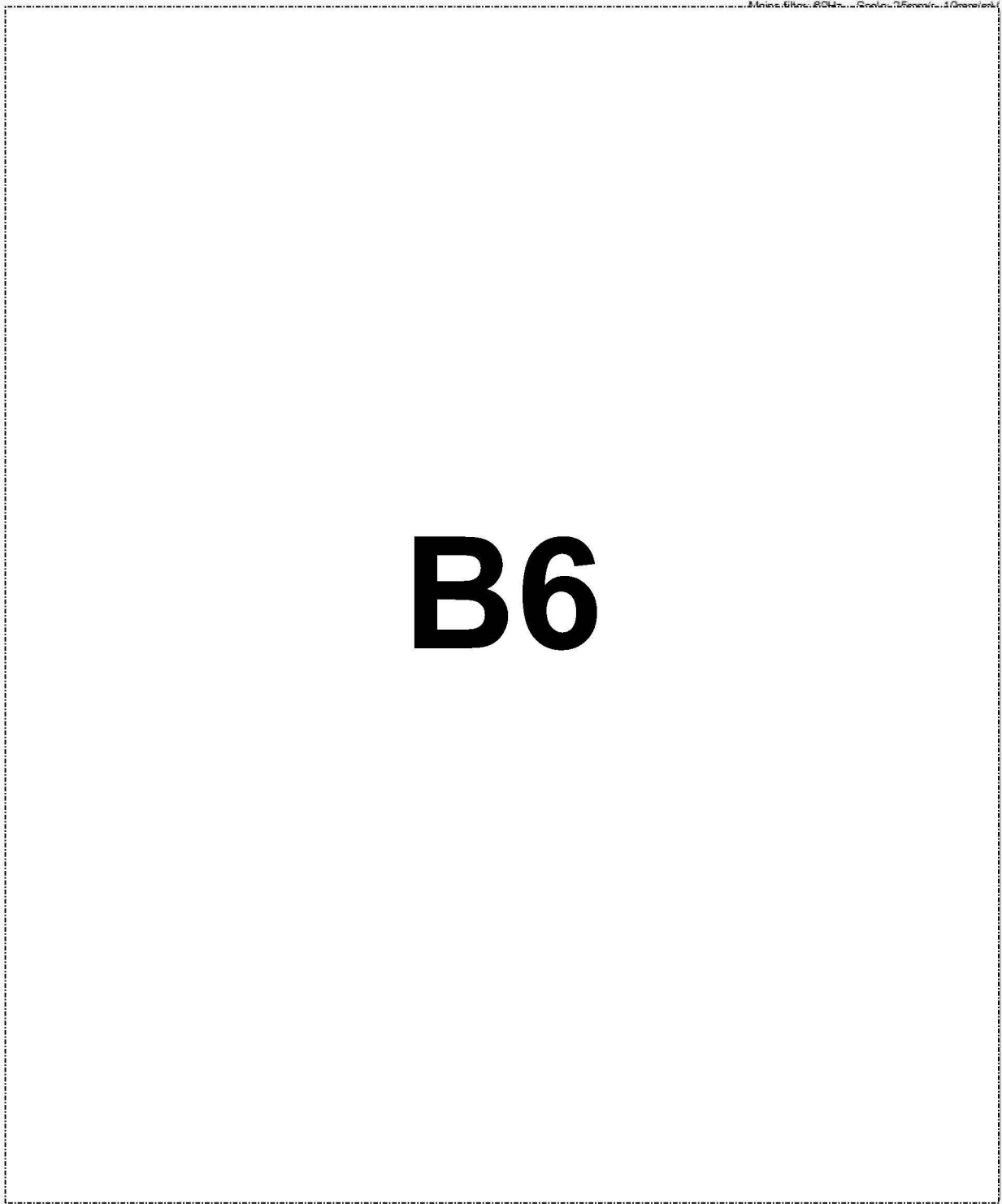
Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Monday, May 13, 2019 at 8:43:21 PM
Heart Rate: **B6**bpm Duration: 43 s



Client: **B6**
Patient:

Alivecor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Wednesday, May 15, 2019 at 9:34:29 PM
Heart Rate: **B6**bpm Duration: 39 s



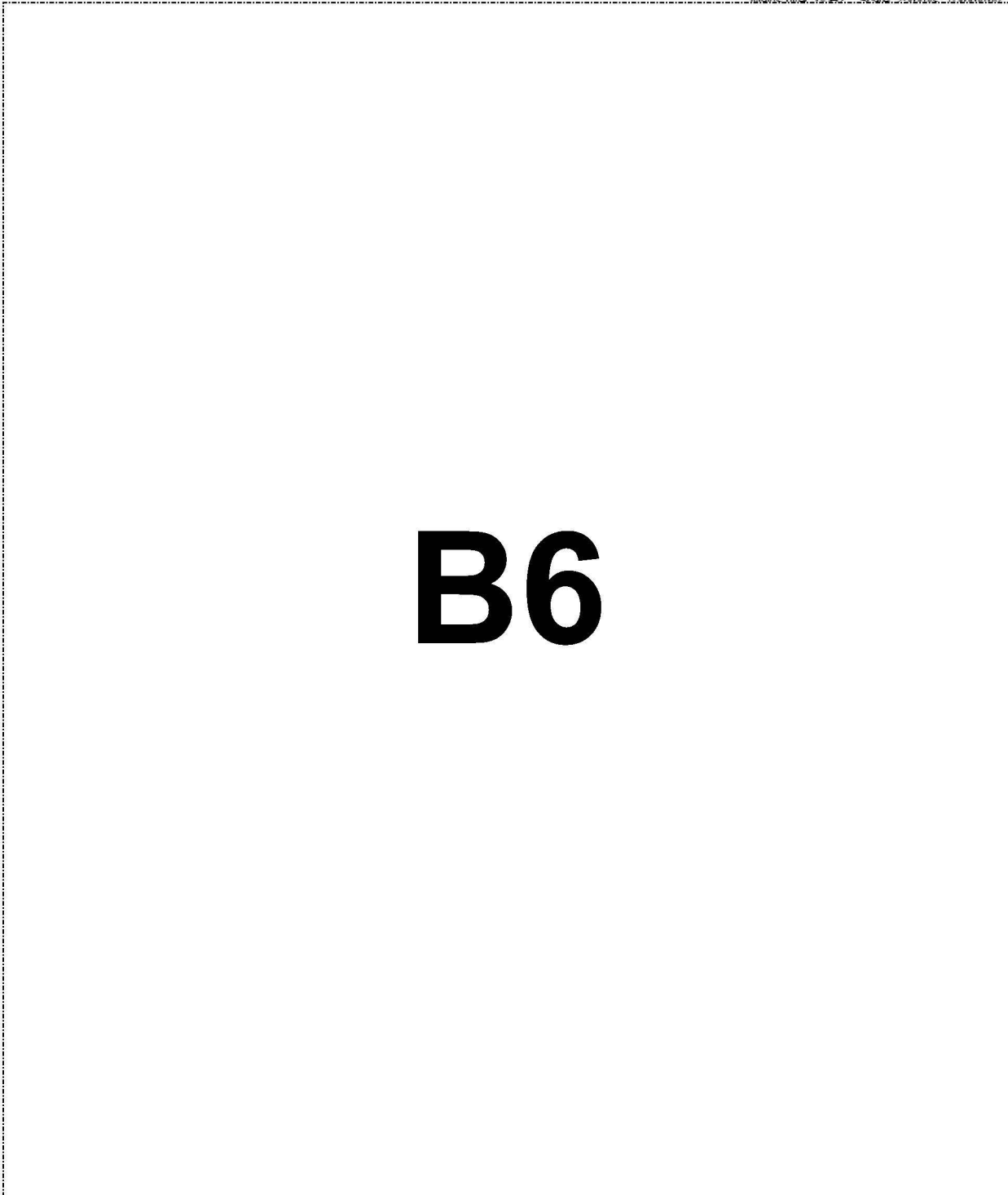
Client: **B6**
Patient:

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Wednesday, May 15, 2019 at 9:34:29 PM
Heart Rate: **B6** bpm Duration: 39 s



Max Filter: 60Hz Scale: 25mm/mV 100mm/s



Client: **B6**
Patient:

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Sunday, May 19, 2019 at 8:35:18 PM
Heart Rate: **B6** bpm Duration: 32 s



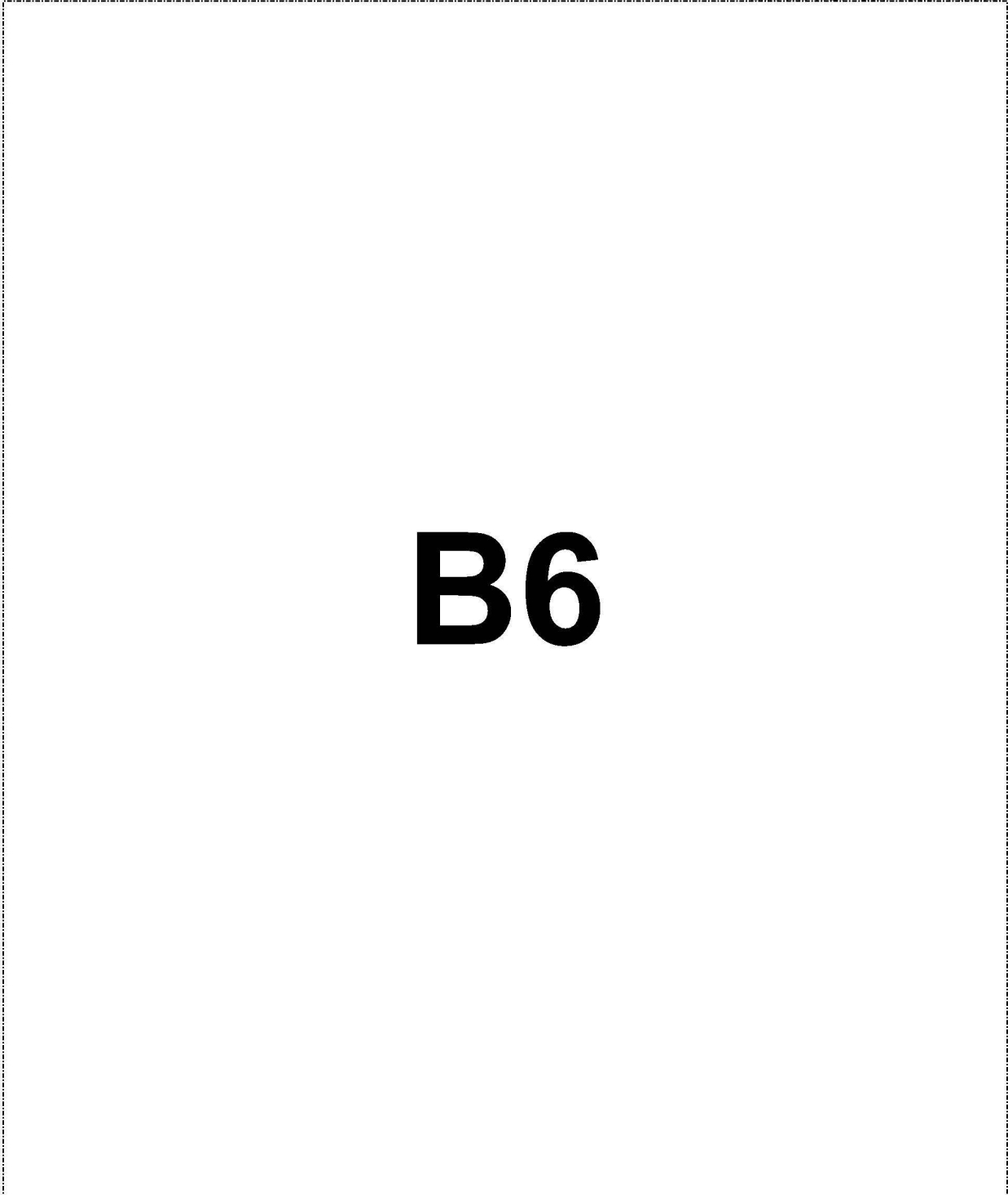
Meas. Filter: 60Hz Scale: 2.5mm/s 10mm/mV

B6

Client:
Patient: **B6**

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Monday, May 27, 2019 at 9:41:45 PM
Heart Rate: **B6** bpm Duration: 36 s



Client: **B6**
Patient:

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Monday, May 27, 2019 at 9:41:45 PM
Heart Rate: **B6** bpm Duration: 36 s



Mains filter: 60Hz Scale: 25mm/s 1.0mV/cm

B6

Client: **B6**
Patient:

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Sunday, June 9, 2019 at 9:45:27 PM
Heart Rate: **B6**bpm Duration: 32 s



Meas. Filter: 60Hz Scale: 2.5mm/10mm/s

B6

Client:
Patient: **B6**

AliveCor ECG

Patient: **B6**
Breed/Species: Golden / Canine
Recorded: Sunday, June 9, 2019 at 9:45:27 PM
Heart Rate: **B6**bpm Duration: 32 s



Meiss filter: 80Hz Scale: 25mm/s 10mm/mV

B6

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 4/29/2019 8:12:57 PM
Subject: PureVita Venison & Red Lentils Grain-Free Dry Dog Food; [B6] - EON-386301
Attachments: 2066404-report.pdf; 2066404-attachments.zip

A PFR Report has been received and PFR Event [EON-386301] has been created in the EON System.

A "PDF" report by name "2066404-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 "2066404-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-386301

ICSR #: 2066404

EON Title: PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula; 2066404

AE Date	03/01/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	American Pit Bull Terrier		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2066404

Product Group: Pet Food

Product Name: PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula

Description: Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on [B6] Taurine levels prior to supplementation was WNL.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NutriSource Adult Chicken and Rice formula		
PureVita Venison & Red Lentils Grain-Free Dry Dog Food		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/10/2019 2:56:47 PM
Subject: PureVita Venison & Red Lentils Grain-Free Dry Dog Food: B6 -
EON-390031
Attachments: 2067992-report.pdf; 2067992-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390031] has been created in the EON System.

A "PDF" report by name "2067992-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 "2067992-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390031

ICSR #: 2067992

EON Title: Related PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula; 2067992

AE Date	03/01/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	American Pit Bull Terrier		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2067992

Product Group: Pet Food

Product Name: PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula

Description: Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related.

Patient was placed on **B6** Taurine levels prior to supplementation was WNL.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NutriSource Adult Chicken and Rice formula		
PureVita Venison & Red Lentils Grain-Free Dry Dog Food		

This report is linked to:

Initial EON Event Key: EON-386301

Initial ICSR: 2066404

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

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Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

Name/DOB: **B6**

Patient ID:

Sex: CM

Provider: **B6**

Order Location: Foster Hospital for Small Animals

Phone number:

Age: 2

Sample ID: 1905030068

Collection Date: 5/3/2019 11:51 AM

Species: Canine

Approval date: 5/3/2019 12:55 PM

Breed: Pit Bull

Research Chemistry Profile - Small Animal (Cobas)

DNOYES

Glucose

Urea

Creatinine

Phosphorus

Calcium 2

Magnesium 2+

Total Protein

Albumin

Globulins

A/G Ratio

Sodium

Chloride

Potassium

tCO2(Bicarb)

AGAP

NA/K

Total Bilirubin

Alkaline Phosphatase

GGT

ALT

AST

Creatine Kinase

Cholesterol

Triglycerides

Amylase

Osmolality (calculated)

Comments (Chemistry)

B6

Ref. Range/Males

67-135 mg/dL

8-30 mg/dL

0.6-2.0 mg/dL

2.6-7.2 mg/dL

9.4-11.3 mg/dL

1.8-3.0 mEq/L

5.5-7.8 g/dL

2.8-4.0 g/dL

2.3-4.2 g/dL

0.7-1.6

140-150 mEq/L

106-116 mEq/L

3.7-5.4 mEq/L

14-28 mEq/L

8.0-19.0

29-40

0.10-0.30 mg/dL

12-127 U/L

0-10 U/L

14-86 U/L

9-54 U/L

22-422 U/L

82-355 mg/dL

30-338 mg/dl

409-1250 U/L

291-315 mmol/L

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 5/28/2019 7:41:41 PM
Subject: Bil Jac Picky No More--Small Breed-Persnickety Recipe w/ chicken liver:
B6 - EON-388960
Attachments: 2067506-report.pdf; 2067506-attachments.zip

A PFR Report has been received and PFR Event [EON-388960] has been created in the EON System.

A "PDF" report by name "2067506-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 "2067506-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-388960

ICSR #: 2067506

EON Title: PFR Event created for Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver; 2067506

AE Date	05/17/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Spaniel - Cocker American		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2067506

Product Group: Pet Food

Product Name: Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver

Description: Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermittent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided

heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver		

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

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Client: **B6**
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 12:45	B6	1.000	B6	B6	0.0000	0.0000

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 12:45	B6 - FHSA	1.000	B6	0.0000	0.0000	

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 12:55	B6	1.000	B6	0.0000	0.0000	

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 12:55	B6	1.000	B6	0.0000	0.0000	

Client: **B6**
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 13:07	B6	1.000	B6	0.0000	0.0000	

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 14:49	B6 tablets - FHSA	B6	B6	0.0000	0.0000	

Client: **B6**
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 14:50	B6 tablets VETMEDIN	90.000	B6	0.0000	0.0000	

Client: **B6**
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 14:50	B6 Tablets - FHSA	100.000	B6	0.0000	0.0000	

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 14:54	Pharmacy Finished	1.000	0.000	0.0000	0.0000	0.0000

Client: **B6**
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 16:11	B6 (ECC STOCK) B6	0.600	B6	0.0000	0.0000	

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18 May 2019 18:12	B6 (ECC STOCK) B6	0.600	B6	0.0000	0.0000	

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Friday, 24 May 2019 13:53	Appointment: Cardiology Study	1.000	0.000	0.0000	0.0000	0.0000

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Friday, 24 May 2019 14:01	B6 Tablets - FHSA	30.000	B6	0.0000	0.0000	

B6

B6

Female (Spayed)

Canine Cocker Spaniel Black

Patient ID: **B6**

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tufts University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 16% applied to the average daily balance outstanding, with a minimum fee of \$50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above-agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name: Date:

Owner's address:

B6

B6

**If the individual admitting the animal is someone other than the legal owner,
please complete the portion below:**

The owner of the animal, , has granted me authority to obtain medical treatment and to bind this owner to pay the veterinary medical services provided at Cummings School pursuant to the terms and conditions described above.

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Discharge Instructions

Patient

Name: B6
Signalment: B6 Years Old Black Female (Spayed) Cocker Spaniel

Owner

Name:
Address: B6

Patient ID: B6
Emergency Clinician: B6 DVM

ER Supervisor:

B6

Admit Date: 5/18/2019 11:15:21 AM
Check Out Date: 5/18/2019

Diagnoses:

- Chronic valvular disease with mitral regurgitation, congestive heart failure with pulmonary edema
- Arrhythmia
- B6

Clinical findings:

B6 has leaky heart valves, the mitral valve and tricuspid valve. This leak has resulted in a loud heart murmur and enlargement of her heart. The problem with her mitral valve is a common one in dogs, due to aging changes to the valve that result in thickening and a subsequent leak of the valve. The heart enlargement has now progressed to the point where fluid is backing up into the lungs causing pulmonary edema, a condition called congestive heart failure. We cannot do anything to change the thickening or leak at the valve, but we can use cardiac medications and some changes to the diet to make B6 comfortable and have him/her breathing easier. Unfortunately, this is a progressive disease and the treatment options cannot reverse the damage to the valve.

Diagnostic test results:

B6

Monitoring at home:

We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted

by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing rate or effort will usually mean that you should give an extra dose of [B6] difficulty breathing is not improved within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that [B6] be evaluated by an emergency clinic.

There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>). We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.

Recommended Medications:

B6

Diet suggestions:

Continue feeding [B6] current diet until her recheck appointment.

Exercise Recommendations:

For the first 7 to 10 days after starting medications for heart failure, we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that [B6] is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high-energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck/Follow-up:

A recheck has been scheduled for [B6] on Friday, May 24th at 12:00pm with [B6]

Thank you for entrusting us with [B6] care.

Prescription Refill Disclaimer:

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

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us,

please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

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

Day Respiratory B6 Dose
Rate/Minute AM PM

Appetite

Sample	32	1 tab (12.5mg)	1/2 tab (6.25mg)	<input checked="" type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes: Breathing better
1:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
2:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
3:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
4:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
5:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
6:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
7:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
8:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
9:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
10:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
11:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
12:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
13:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
14:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
15:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
16:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
17:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
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21:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
22:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
23:				<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:

24:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
25:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
26:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
27:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
28:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
29:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
30:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:
31:	<input type="checkbox"/> Excellent	<input type="checkbox"/> Good	<input type="checkbox"/> Fair	<input type="checkbox"/> Poor	Notes:

Respiration Rate: Count the number of breaths for 30 seconds and multiply times 2 to get the respiratory rate per minute. In dogs, obtain the respiratory rate when they are at rest and not panting. In cats, get the respiratory rate at rest when they are not purring. In animals with well controlled heart failure, the breathing rate is often less than 35-40 breaths per minute. When the breathing rate is climbing, or when there is more effort to the chest wall or belly muscles during breathing, then fluid is likely accumulating in the lungs and more furosemide may be indicated. Please bring this sheet with you to your next veterinary exam.

Please visit our HeartSmart Website for further information
<http://vet.tufts.edu/heartsmart/at-home-monitoring/>

Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:

1. Most other dog treats are high in sodium.
2. If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

Product	Calories per treat
Dogs	
Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat	8
Hill's Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat	34
Hill's Science Diet Soft Savories Peanut Butter & Banana, Beef & Cheddar, or Chicken & Yogurt Dog Treat	25-27, depending on flavor
Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots, Duck & Pumpkin, or Beef & Sweet Potato Dog Treat	12-13, depending on flavor
Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken & Barley	27-29, depending on flavor
Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb or beef, bacon, cheese, peanut butter)	16
Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)	58
Royal Canin Original Canine treat	5
Cats	
Royal Canin Original Feline treat	2
Fancy Feast Duos Natural Rotisserie Chicken Cat treat	2
Fancy Feast Duos Tuna with Accents of Parsley Cat treat	2

Taste enhancers to can make your pet's food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes:

1. All foods in this list should be prepared without salt
2. These taste enhancers should be added in small amounts. If your pet eats too much of them, they will unbalance the diet and increase your pet's risk for nutritional deficiencies

Dogs

- ♥ Honey or maple syrup
- ♥ Homemade chicken, beef, or fish broth (made without salt; avoid all deli meats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- ♥ Sugar (brown or white) – Domino pourable light brown sugar is a good option
- ♥ Vanilla or fruit yogurt – One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
- ♥ Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- ♥ Applesauce (be sure they have less than 50 mg sodium per serving)
- ♥ Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- ♥ Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico's no salt added)
- ♥ Frosted Mini Wheats Original – these can be crumbled on his food
- ♥ Lean meats, cooked (chicken, turkey, beef, or fish) – not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- ♥ Eggs, cooked

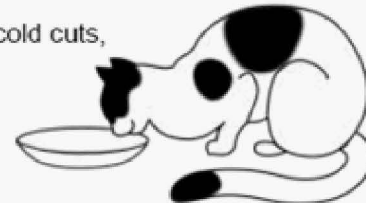


Dogs (continued)

- ♥ Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium). Avoid all canned soups unless labeled as no salt added
- ♥ Low-salt breakfast cereal - the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- ♥ Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- ♥ Low sodium canned dog foods

Cats

- ♥ Lean meats, cooked (chicken, turkey, beef, or fish) – not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- ♥ Eggs, cooked
- ♥ Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- ♥ Low sodium canned cat foods



Foods to avoid

- ♥ Fatty foods (meat trimmings, cream, ice cream)
- ♥ Baby food
- ♥ Pickled foods
- ♥ Bread
- ♥ Pizza
- ♥ Condiments (ketchup, soy sauce, barbecue sauce, etc – unless they are unsalted or no salt added)
- ♥ Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- ♥ Rotisserie chicken
- ♥ Most cheeses, including "squirtable" cheeses
- ♥ Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- ♥ Canned vegetables (unless "no salt added")
- ♥ Potato chips, packaged popcorn, crackers, and other snack foods
- ♥ Soups (unless homemade without salt)
- ♥ Most commercial pet treats

Tips for administering medications

Foods commonly used to administer your pet's pills can provide a large amount of additional salt to your pet's diet. Preferable ways to give medications include:

- ♥ Have one of our staff show you how to give medications without using food
- ♥ Insert medications into one of the following foods:

Dogs or cats

- Low-sodium canned pet food
- Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
- Whipped cream (Reddi Wip)
- Marshmallows
- Greenies Pill Pockets
 - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
 - Avoid grain-free duck and pea which is high in sodium
 - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
 - Caution: Not all similar products from other companies are low in sodium .

Dogs

- Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
- Peanut butter (only if labeled as "no salt added") – examples include Smucker's Natural Creamy Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
- Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol). Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting)

You may find our Petfoodology post called, "Pill-popping pets" helpful for additional ideas:

http://vetnutrition.tufts.edu/2018/09/foods_for_giving_pills/

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: **B6**

B6

Canine

Years Old Female (Spayed) Cocker
Spaniel

Black BW: Weight (kg) 14.40

Cardiology Consultation

Date: 5/18/2019

Weight: Weight (kg) 14.40

Requesting Clinician: **B6**

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?

- Yes - in SS
 Yes - in PACS
 No

Yes in ECC email

Patient location: ER

Presenting complaint and important concurrent diseases:

Enlarged heart on rDVM radiographs, cough

Current medications and doses:

B6

At-home diet (name, form, amount, frequency)

Bill Jack Persnickety - BID

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.)

Murmur and enlarged heart on radiographs, cough

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)

- Yes (explain): 0 waiting
 No

STOP - remainder of form to be filled out by Cardiology

Physical Examination

B6

Muscle condition:

- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam

Murmur Grade:

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

Murmur location/description: left apical, systolic

Jugular vein:

- Bottom 1/3 of the neck
- Middle 1/3 of the neck
- Top 2/3 of the neck
- 1/2 way up the neck

Arterial pulses:

- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

Arrhythmia:

- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary Crackles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram Findings:

B6

Mitral inflow:

- Summated
- Normal
- Delayed relaxation

- Pseudonormal
- Restrictive

ECG findings:

B6

Assessment and recommendations:

Findings consistent with advanced DMVD with active left-sided CHF. Despite patient having received 3 oral doses of **B6** over the last 18h (less than 2mg/kg each dose), there is still significant CHF. Since hospitalization is not possible, recommend **B6** **B6** every 4 hours. There is moderate PHTN, but LCHF should be addressed first. Reduced contractile function is not routinely seen in DMVD, but there very frequent arrhythmias and BEG diet may contribute. **B6** **B6** ID for 1 week (and then decrease to every 24h) and switching to a grain-based low sodium diet are recommended. Recommend recheck bloodwork and EKG in 1 week and echocardiogram in 3 months.

Treatment plan:

B6

B6

Final Diagnosis:

Advanced DMVD with active L-CHF;
Moderate PHTN;
Frequent ventricular and supraventricular arrhythmias.

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM CHF Classification:

- A
- B1
- B2
- C
- D

M-Mode

IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
Time		ms
HR		BPM
CO(Teich)		l/min
CI(Teich)		l/min/m
IVSd		cm
TAPSE		cm
EPSS		cm

B6

M-Mode Normalized

IVSdN		{0.290 - 0.520}
LVIDdN		{1.350 - 1.730} !

B6

LVPWdN	B6	{0.330 - 0.530}
IVSsN		{0.430 - 0.710}
LVIDsN		{0.790 - 1.140} !
LVPWsN		{0.530 - 0.780}
Ao Diam N		{0.680 - 0.890}
LA Diam N		{0.640 - 0.900} !

2D

SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Major		cm
LV Minor		cm
Sphericity Index		
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml

Doppler

MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

Discharge Instructions

Patient

Name: B6

Species: Canine

Breed: Black Female (Spayed) Cocker Spaniel

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

Admit Date: 5/24/2019 11:54:53 AM

Discharge Date: 5/24/2019

Diagnoses: Chronic valvular disease with mitral regurgitation, congestive heart failure with pulmonary edema.

Clinical findings: Thank you for bringing B6 in for a recheck of her recent diagnosis of chronic valvular disease with mitral regurgitation and congestive heart failure with pulmonary edema. Since her last appointment, you report that she has been coughing, has had a decreased appetite, and you've had some difficulties giving her medication. Her respiratory (breathing) rate at rest, however, has been comfortable with no effort.

On physical examination, B6 is bright, alert, and responsive. B6 has a slower heart rate today and has little to no arrhythmias which is excellent news! While it is difficult to assess her breathing rate here due to her stress and anxiety, you indicate that she does start to pant much more frequently when out on a walk. Her tongue is a little blue today, which indicates she is still having issues fully oxygenating, and she coughed occasionally during the exam.

Her arrhythmias have dramatically decreased and seems to be pretty well controlled from her anti-arrhythmias. Other findings were consistent with her previous echocardiogram. While she has not fully recovered, B6 seems to be doing much better comparatively to her initial presentation this past Saturday.

Monitoring at home:

We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing

rate or effort will usually mean that you should give an extra dose of **B6**. If difficulty breathing is not improved within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that **B6** be evaluated by an emergency clinic. There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>). We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.

Recommended Medications:

B6

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many treats, most people foods, and the supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site. In addition, your dog's usual diet may have more sodium than recommended - we want your dog to eat their usual diet for the first 7 to 14 days so we can make sure they are tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). Hopefully you can find a diet on the list that **B6** likes to eat. Alternatively, you can research the amount of sodium in your dog's current diet to ensure that the sodium content is similar to those on the list. The HeartSmart web site also has some information on supplements such as fish oil, taurine, and other supplements that you might have questions about (<http://vet.tufts.edu/heartsmart/diet/>).

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching **B6** to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Option:

Royal Canin Early Cardiac (veterinary diet)

Canned Food Options:

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise Recommendations:

Please continue limiting B6 activity and avoiding any strenuous exercise when possible.

Recheck Visits: We want to recheck her in 10-14 days (06/07/19). At this visit we will want to check B6 breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram and/or chest radiographs (x-rays) are recommended in 3 months.

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

Please visit our HeartSmart website for more information
<http://vet.tufts.edu/heartsmart/>

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6
Canine
Years Old Female (Spayed) Cocker Spaniel
Black

Cardiology Appointment Report

Date: 5/24/2019

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V20

Presenting Complaint: Recheck for hx of advanced DMVD with active left sided CHF on B6

Concurrent Diseases: None

General Medical History: Still coughing and doing a lot of panting. When sleeping, has to splay on the ground on a cold surface. When walking any tiny bit, she will start panting. She hasn't been really eating. Having a hard time giving her medication and tries to grind it into her food but P is not really eating much of her food.

Diet and Supplements:

Bill Jack Persnickety - BID

Cardiovascular History:

Prior CHF diagnosis? Y

Prior heart murmur? Y

Prior ATE? N

Prior arrhythmia? Y

Monitoring respiratory rate and effort at home? N

Cough? Y

Shortness of breath or difficulty breathing? Y

Syncope or collapse? Has not collapsed since last Saturday during her last incident.

Sudden onset lameness? N

Exercise intolerance? Y

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

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

Cardiovascular Physical Exam:

Murmur Grade:

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

Murmur location/description: left apical systole

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

- None
- Sinus arrhythmia
- Premature beats

- Bradycardia
- Tachycardia

Gallop:

- Yes
- No
- Intermittent

- Pronounced
- Other:

Pulmonary assessments:

- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

Problems:

CHF with advanced DMVD
Pulmonary hypertension

Diagnostic plan:

- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure

- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests

Echocardiogram Findings:

B6

Assessment and recommendations:

Findings consistent with advanced DMVD with active left-sided CHF. Heart rhythm is better control and rare ventricular arrhythmias were seen today. Patient still has some respiratory effort, but seems brighter and alert. Reduced contractile function is not routinely seen in DMVD, but since there were very frequent arrhythmias and patient has been on a BEG diet, these factors should also be considered. Recommend give B6 Recheck in 7 days.

Final Diagnosis:

Advanced DMVD with active CHF.

Reduced contractile function.

Heart Failure Classification Score:

ISACHC Classification:

Ia

Ib

II

IIIa

IIIb

ACVIM Classification:

A

B1

B2

C

D

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/10/2019 8:20:57 PM
Subject: Fromm Game Bird Recipe Dog - Four-Star - Dry -Grain-Free formula B6
B6 EON-390092
Attachments: 2068038-report.pdf; 2068038-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390092] has been created in the EON System.

A "PDF" report by name "2068038-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068038-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390092

ICSR #: 2068038

EON Title: Related PFR Event created for Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula; 2068038

AE Date	04/16/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Hound (unspecified)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068038

Product Group: Pet Food

Product Name: Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula

Description: Patient presented to rDVM for evaluation of abdominal distension x 5 weeks and increase in respiratory rate and effort. FAST scan revealed moderate ascites. Patient was referred to Tufts for further evaluation. Findings consistent with advanced DMVD with suspect L-CHF and poor contractile function.

Considering LA enlargement and severity of MR and AI, we would expect a better systolic function.

B6

10mg BID is recommended. Mild respiratory effort and occasional b-lines vote in favor to L-CHF.

There is enough cardiac changes to justify L and R CHF. Since patient is on a BEG diet, it is unclear whether diet is playing a role on decreased contractile function. Recommend transition to a grain-based, low sodium diet and consider Taurine supplementation. Abdominocentesis was performed (5 liters of serous sanguineous fluid) and analysis is recommended. Recommend hospitalization, patient on telemetry monitoring and respiratory watch. Fluid check in the morning and kidney values daily while in the hospital. Since patient is on a BEG diet, recommend transition to a grain-based, low sodium diet.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula		

This report is linked to:

Initial EON Event Key: EON-388971

Initial ICSR: 2067510

Sender information

B6

Owner information

B6

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

<https://eon.fda.gov/eon/browse/EON-390092>

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

<https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issuelid=407364&parentIssueTypeId=12>

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Palmer, Lee Anne; Rotstein, David; Palmer, Lee Anne; Queen, Jackie L
CC: Ceric, Olgica; Nemser, Sarah; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'
Sent: 5/9/2018 10:53:13 AM
Subject: RE: Zignature Kangaroo Formula: 800.261- EON-351031- [B6] vet
Attachments: EON-351031- [B6] MRx.pdf

This was the product with low Taurine we recently tested (per feline AAFCO minimum Tau).

Golden Retriever with low blood taurine and a persistent history of arytoid dysfunction, possible [B6] responsive infectious [B6] Since 9 months old

MRx summary:

Presenting complaint 2/23/2018: CHF possible, consult; tachycardia, last 3 days dyspneic, no cough, poor appetite for 2 days, usually ravenous, decreased energy level, on [B6] over a year, tried [B6] but discontinued because it wasn't helping; long history of a panting and swallowing disorder à diagnosed w/ DCM & L-CHF, tentative pulmonary edema à start [B6] à 2/27 breathing better, eating ok, increased [B6] for gagging à 3/1 Tau low, dog still on Zignature Kangaroo diet à vet said legumes in the diet likely prevent Met & Cys absorption à switched to Royal Canin Kangaroo & Oat; the dog was on Zignature Kangaroo last 2-3 years, eats milkbones and baked dog treats from a bakery; before the Zignature, he ate Acana Ranch Lamb, Natural Balance Bison & SP, Natural Balance Fish & SP, Zignature Trout & Salmon à no supplements were taken before the DCM diagnosis à by 3/13 dog was eating Royal Canin Kangaroo à 3/22 restless at night but [B6] try: [B6]

PE 2/23: [B6] gallop, panting; at rest/lying down still tachypneic

Labs: 2/23 **Whole Blood Tau:** [B6]

2/23 Echocardiogram: dilated LV w/ poor systolic function, LA enlarged, mod MR & TR, dec aortic and pulmonic flow

Prior MHx: [B6]

B6

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



From: Jones, Jennifer L
Sent: Friday, April 13, 2018 6:39 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Zignature Kangaroo Formula: [B6] - EON-351031

Thanks, Lee Anne. No, I wasn't expecting it, but I can start with MRx!

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



From: Palmer, Lee Anne
Sent: Thursday, April 12, 2018 1:39 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: FW: Zignature Kangaroo Formula: [REDACTED] - EON-351031

Hi Jen – were you expecting this one? Thx - LA

From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Thursday, April 12, 2018 1:36 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [REDACTED]
Subject: Zignature Kangaroo Formula: [REDACTED] - EON-351031

A PFR Report has been received and PFR Event [EON-351031] has been created in the EON System.

A "PDF" report by name "2045676-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-351031

ICSR #: 2045676

EON Title: PFR Event created for Zignature Kangaroo Formula; 2045676

AE Date	02/22/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	6 Years		
District Involved	PFR [REDACTED] DO		

Product information

Individual Case Safety Report Number: 2045676

Product Group: Pet Food

Product Name: Zignature Kangaroo Formula

Description: Feb 23, 2018 Patient presented to the cardiology service at [REDACTED]

Falls for tachypnea. He was diagnosed with dilated cardiomyopathy and left side congestive heart failure. Whole blood taurine level was [REDACTED] At the time, patient consuming Zignature Kangaroo Formula and was advised to change.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

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

Sender information

B6

USA

Owner information

B6

USA

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

B6

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

B6

B6

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 6/10/2019 4:39:12 PM
Subject: couple more related DCM- PFRs-FW: Zignature trout & salmon dry: Lisa Freeman - EON-390034 + Pure VitaVenison and Red Lentisl
Attachments: 2067994-report.pdf; PureVita Venison & Red Lentils Grain-Free Dry Dog Food: **B6**
EON-386301; PureVita Venison & Red Lentils Grain-Free Dry Dog Food: **B6**
EON-390031; Zignature trout & salmon dry: Lisa Freeman - EON-370715; 2067994-attachments.zip

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

B6



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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Monday, June 10, 2019 11:13 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> **B6**
Subject: Zignature trout & salmon dry: Lisa Freeman - EON-390034

A PFR Report has been received and Related PFR Event [EON-390034] has been created in the EON System.

A "PDF" report by name "2067994-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2067994-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390034
ICSR #: 2067994
EON Title: Related PFR Event created for Zignature trout & salmon dry; 2067994

AE Date	11/07/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2

Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	3 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2067994

Product Group: Pet Food

Product Name: Zignature trout & salmon dry

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

Submission Type: Followup

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

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

Number of Animals Treated With Product: 3

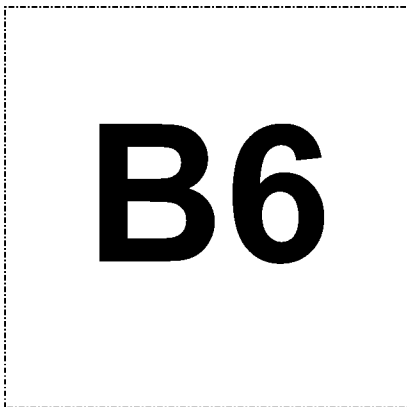
Number of Animals Reacted With Product: 2

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

This report is linked to:

Initial EON Event Key: EON-370715

Initial ICSR: 2058683



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

<https://eon.fda.gov/eon//browse/EON-390034>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issuelid=407306&parentIssueTypeId=12>

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From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Reimschuessel, Renate; Queen, Jackie L; Palmer, Lee Anne; Jones, Jennifer L; Ceric, Olgica; Carey, Lauren
Sent: 7/11/2017 9:45:50 PM
Subject: Fwd: Alternated feedings between:-California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and Lentils: Darcy Adin - EON-323519
Attachments: 2023230-report.pdf

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

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From: PFR Event <pfreventcreation@fda.hhs.gov>
Date: July 11, 2017 at 5:36:16 PM EDT
To: HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>, **B6** Cleary, Michael *
<Michael.Cleary@fda.hhs.gov>
Subject: Alternated feedings between:-California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and Lentils: Darcy Adin - EON-323519

A PFR Report has been received and PFR Event [EON-323519] has been created in the EON System.

A "PDF" report by name "2023230-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-323519

ICSR #: 2023230

EON Title: PFR Event created for Alternated feedings between: California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and Lentils; 2023230

AE Date	06/22/2017	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Schnauzer - Miniature		
Age	7 Years		
District Involved	PFR-New York DO		

Product information

Individual Case Safety Report Number: 2023230

Product Group: Pet Food

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

Description: Please note: Dr. Jennifer Jones was consulted prior to submission of this report. She would like to be involved in the case review. [B6] housemate [B6] (separate report submitted) was diagnosed with DCM and CHF 2/17 and was euthanized after aggressive treatment of CHF. At that time [B6] had 2 syncopal events closely related to each other. His appetite for dog food declined but he would eat it if tempted with treats mixed in. He was presented 6/22/17 for more syncopal events and was similarly diagnosed with severe DCM and CHF. He was able to be successfully treated however and is clinically doing well on CHF medications as of 7/10/17. A re-review of the myocardial histopathology for [B6] housemate [B6] was requested at this time because of the unusual diagnosis of DCM in a small breed dog living in the same house as another dog similarly diagnosed a few months ago. This re-review by one of our pathologists showed myofiber vacuoles reminiscent of the changes seen in doxorubicin toxicity. Since the dog had not received [B6]

B6

(unrelated, younger miniature schnauzer), [B6] had been fed California Naturals Adult - both kangaroo with lentils and venison with lentils along with Milo's kitchen treats. We have samples of these foods from 6/17 but not the original bags from when he was presented 2/17. These samples were provided at the time [B6] also presented with severe DCM and CHF. Like [B6] had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation, we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure. We have plasma, serum, urine and myocardial tissue samples (latter only for [B6] stored at -80 Celsius in addition to food and treat samples.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Alternated feedings between: California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and Lentils		

Sender information

Darcy Adin
1060 William Moore Dr
Raleigh, NY 27607
USA

Owner information

B6

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

<https://eon.fda.gov/eon//browse/EON-323519>

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=338851>

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NC State University
Veterinary Hospital
1052 William Moore Drive
Raleigh, NC 27607
Discharge Comments

Fax: Admin
Fax: Referral

Small Animal (919) 513-6500
Large Animal (919) 513-6630

Client B6	Patient B6 SCHNAUZER MC BLACK CANINE	Case # 212267 8.2 kg	Attending DVM Student Discharging DVM Referring DVM	B6 B6 B6
---------------------	--	-----------------------------	--	----------------

Admission Date/Time: B6 Discharge Date/Time: B6 Discharge Status:

*****NOTICE OF EUTHANSIA*****

Case Summary

Diagnosis:

- 1) Biventricular congestive heart failure (left significantly worse than right)
- 2) Cardiomyopathy (suspect secondary) vs. myocarditis vs. tachycardia-induced cardiomyopathy vs. other

History:

B6 is a 2 and 1/2 year old male castrated Miniature Schnauzer who presented the NCSU ER on B6 for labored breathing and was subsequently transferred to NCSU Cardiology. B6 initially developed a cough three weeks ago; B6 describes the cough as a wheezing-type cough that occurred more frequently at night. When B6 showed no signs of improvement, B6 presented to his primary veterinarian on Thursday (1/26). Kennel cough was suspected as the underlying cause. On Monday, B6 B6 became uninterested in his food and began vomiting. The following day B6 continued vomiting and developed labored breathing and subsequently re-presented to the rDVM for evaluation. Bloodwork and thoracic radiographs were performed. Bloodwork was reportedly unremarkable at this time and there B6

B6 While in-hospital, B6 regurgitated. On Wednesday, B6 had improvement in respiratory effort but he still was not eating; B6

B6 The day of presentation, B6 syringe fed B6 but as she attempted he B6 developed marked labored breathing following this and was presented to an emergency hospital. Thoracic radiographs were performed (uploaded in eFilm) and revealed cardiomegaly; a diffuse, severe mixed interstitial to alveolar pattern that is most severe caudodorsally; hepatomegaly; and decreased abdominal serosal contrast. B6 was referred to NCSU for further care and ventilation if indicated.

B6

B6 lives with one other dog (not a relative) who is healthy and is currently up to date on his vaccinations. B6 is not current on any flea/tick prevention but receives heartworm prevention. B6 is fed California Natural dog food.

Physical Exam Findings (on presentation):

B6

B6

B6

Brief Daily Summary:

B6 presented late in the evening on **B6** to the ER and after a TFAST was performed showing severe cardiomegaly with hypocontractility of the ventricles in addition to reviewing the rDVM radiographs, **B6** and **B6** were given. An

echocardiogram was then performed (performed sternally cage-side given patient status) and a diagnosis of severe cardiomyopathy (primary vs. secondary DCM vs. myocarditis, vs. pacing-induced cardiomyopathy vs. other) and he was quickly given another dose of

B6

B6 After the second B6 was given he was immediately placed on a B6 and B6 at

B6

B6 Immediately after B6 (approximately 1:30AM) which showed a marked improvement in terms of B6 significantly improved. He was maintained on B6

B6 He handled this quite well and while B6 as the B6 he clinically was markedly improved from presentation. His B6

B6

B6

I am sorry for the loss of your patient. Both B6 were absolutely wonderful to work with. If you have any questions at all, please do not hesitate to call us at B6

B6

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Peloquin, Sarah; Nemser, Sarah; Carey, Lauren; Ceric, Olgica; Glover, Mark; Palmer, Lee Anne
Sent: 8/13/2018 4:52:20 PM
Subject: follow-up tau EON-360238-FW: Taste of the Wild Pine Forrest: [REDACTED] B6 - EON-362010
Attachments: 2053631-report.pdf; Taste of the Wild Pine Forrest: [REDACTED] B6 - EON-360238; 2053631-attachments.zip

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



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From: Related PFR Event [mailto:pfrsignificantactivitycreation@fda.hhs.gov]
Sent: Monday, August 13, 2018 12:48 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [REDACTED] B6
Subject: Taste of the Wild Pine Forrest: [REDACTED] B6 - EON-362010

A PFR Report has been received and Related PFR Event [EON-362010] has been created in the EON System.

A "PDF" report by name "2053631-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 "2053631-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-362010

ICSR #: 2053631

EON Title: Related PFR Event created for Taste of the Wild Pine Forrest Venison and Legumes; 2053631

AE Date	05/08/2017	Number Fed/Exposed	
Best By Date		Number Reacted	1

Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-[B6] DO		

Product information

Individual Case Safety Report Number: 2053631

Product Group: Pet Food

Product Name: Taste of the Wild Pine Forrest, Venison and Legumes

Description: Just before [B6] second birthday, her energy level dropped and she developed a dry cough in the mornings. On the advice of a friend, I had her blood tested for taurine at the [B6] at UC Davis because she was on a grain-free food high in legumes. The result was [B6] ml by the plasma test (normal level is 60-120 ml). I then took her to board certified cardiologist Dr. Joshua Stern at UCD VMTH. Dr. Stern did an echocardiogram and also found the Mitral Valve Dysplasia, but did not see SAS. He found Mild to Moderate DCM. His report reads: "Moderately dilated left ventricular chamber and LV systolic dysfunction - ddx: taurine responsive DCM vs idiopathic DCM. Lv chamber has significantly increased in the recheck interim (LVIDD [B6] m today, [B6] previous July 2016)." He prescribed increasing the taurine and l-carnitine supplements and return for repeat echo in 3-4 months. She returned for additional echos in November 2017 and March 2018. Copies of all three visit reports and echos are attached. I'm going to try to attach a copy of her blood report of before and after supplementation.

Submission Type: Followup

Report Type: Both

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

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Pine Forrest, Venison and Legumes		

This report is linked to:

Initial EON Event Key: EON-360238

Initial ICSR: 2052688

Sender information

B6

USA

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

<https://eon.fda.gov/eon/browse/EON-362010>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=10100&issueId=378744&parentIssueTypeId=12>

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; **B6**
Sent: 8/21/2018 7:48:36 PM
Subject: Zignature Kangaroo Grain Free Formula; **B6** - EON-362973
Attachments: 2054024-report.pdf; 2054024-attachments.zip

A PFR Report has been received and PFR Event [EON-362973] has been created in the EON System.

A "PDF" report by name "2054024-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 "2054024-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-362973

ICSR #: 2054024

EON Title: PFR Event created for Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain Free; 2054024

AE Date	B6	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mastiff		
Age	6 Years		
District Involved	PFR-Atlanta DO		

Product information

Individual Case Safety Report Number: 2054024

Product Group: Pet Food

Product Name: Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain Free

Description: Presented to NCSU ER **B6** for lethargy, coughing and a terminal wretch for 4 days. He was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine = **B6** nmol/ml. Slowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown significant improvement. Still not sure at this point if the DCM is breed or diet related, or both. Owner has another Mastiff which also was on Zignature Kangaroo Grain Free.

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 Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Earthborne Naturals Lamb Grain Free		
Zignature Kangaroo Grain Free Formula		

Sender information

B6

USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-362973>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=379707>

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification [B6]
Sent: 8/21/2018 7:48:36 PM
Subject: Zignature Kangaroo Grain Free Formula [B6] EON-362973
Attachments: 2054024-report.pdf; 2054024-attachments.zip

A PFR Report has been received and PFR Event [EON-362973] has been created in the EON System.

A "PDF" report by name "2054024-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 "2054024-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-362973

ICSR #: 2054024

EON Title: PFR Event created for Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain Free; 2054024

AE Date	[B6]	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mastiff		
Age	6 Years		
District Involved	PFR-Atlanta DO		

Product information

Individual Case Safety Report Number: 2054024

Product Group: Pet Food

Product Name: Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain Free

Description: Presented to NCSU ER [B6] for lethargy, coughing and a terminal wretch for 4 days. He was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine = [B6] nmol/ml. Slowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown significant improvement. Still not sure at this point if the DCM is breed or diet related, or both. Owner has another Mastiff which also was on Zignature Kangaroo Grain Free.

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 Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Earthborne Naturals Lamb Grain Free		
Zignature Kangaroo Grain Free Formula		

Sender information

B6

USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-362973>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=379707>

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 9/25/2018 5:16:12 PM
Subject: Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food; EON-366756 [B6]
Attachments: 2055325-report.pdf

A PFR Report has been received and PFR Event [EON-366756] has been created in the EON System.

A "PDF" report by name "2055325-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-366756

ICSR #: 2055325

EON Title: PFR Event created for Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food, The Farmer's Dog Beef Recipe; 2055325

AE Date	09/24/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	8.5 Years		
District Involved			

Product information

Individual Case Safety Report Number: 2055325

Product Group: Pet Food

Product Name: Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food, The Farmer's Dog Beef Recipe

Description: [B6] has been fed grain free dog food since 2013. I acquired [B6] at 9 weeks of age from a reputable breeder. She was fed Purina ProPlan for Puppies from birth - early 2013. In early 2013, [B6] was diagnosed with an impacted anal gland that ruptured and the vet recommended she be fed grain-free dog food. At that time, I began feeding Fromm's Beef Firtitta Grain Free. In late 2016, [B6] began to experience steady diarrhea. After much vet intervention including a 2 night stay at vet hospital on IV, I changed [B6] from Fromm's to a short transition time on ground beef w/rice and then to a fresh dog food, The Farmer's Dog Beef with Lentils.

Her diarrhea completed cleared and she remained on The Farmer's Dog Beef with Lentils until I begin reading about the issue with Low Taurine in Golden Retrievers. Based on UC Davis and Dr Stern studies, I obtained a blood sample for testing. UC Davis completed the test and her taurine level is low at **B6** while the level for a Golden Retriever is 250+. I had an echocardiogram done yesterday, Sept 24, 2018. The canine cardiologist evaluation is as follows: "Mild/early dilated cardiomyopathy-suspect taurine responsive. Trace mitral valve regurgitation. Normal left atrial dimensions. High normal left ventricular dimensions with moderately decreased heart muscle function. Normal right heart size. History of eating a grain-free diet. Low taurine." "No medications are indicated at this time. Begin Taurine 1000 mg twice daily. In two weeks, begin L-carnitine 1850 mg three times daily. In four weeks, begin fish oil supplements (omega-3 fatty acids) at approximately EPA 1500 mg and DHA 925 mg total per day. Change diet from grain free, legume foods. Cardiologist recommends follow up in 6 months.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food		
The Farmer's Dog Beef Recipe		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-366756>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=383670>

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Queen, Jackie L; Palmer, Lee Anne; Carey, Lauren
CC: Peloquin, Sarah; Ceric, Olgica
Sent: 10/2/2018 6:36:27 PM
Subject: RE: 800.267-EON-362878-[B6]-Acana Free Run Poultry dry
Attachments: EON-362878-owner interview-10.2.2018.pdf

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



From: Jones, Jennifer L
Sent: Thursday, September 20, 2018 10:27 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-EON-362878-[B6]-Acana Free Run Poultry dry

Interview pending, Cough since early 2017! Norm Tau; Housemate [B6]-also Tau norm, maybe got echo (checking)

[B6] MC Doberman Pinscher

Hx: [B6] report of nonproductive hacking cough recently-O thought after sniffing dust, eating Valor Freeze dried food; 3/10/2017-PD, morning cough-o thinks allergies, MAP crytals are check had none-rare; 7/26/2017-possible anxiety in dark, seasonal allergies (spring/summer) worse, occ little cough but normal for him, on Grandma Lucy raw and Earthborne; 2/14/2018-Grandma Lucy and Acana poultry

B6

B6

B6 Housemate
8/20/2018 WB Tau: **B6**

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



From: PFR Event <pfpreventcreation@fda.hhs.gov>
Sent: Monday, August 20, 2018 4:44 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> **B6**
Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-362878

A PFR Report has been received and PFR Event [EON-362878] has been created in the EON System.

A "PDF" report by name "2053969-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 "2053969-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-362878
ICSR #: 2053969
EON Title: PFR Event created for Acana Free Run Poultry dry; 2053969

AE Date	08/06/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2053969

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

Description: Taken to RDVM for lameness. Dilated cardiomyopathy and CHF diagnosed 8/6/18 **B6**

B6 We saw at Tufts 8/16/18. Clinically improved but still has significant DCM and **B6** We added **B6** fish oil, and taurine. WB taurine

pending. Another dog in household (also a Doberman) was eating the same food but was echoed today and has no signs of DCM.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

<https://eon.fda.gov/eon//browse/EON-362878>

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

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

B6

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

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

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

Below is the summary of the report:

EON Key: EON-374786

ICSR #: 2060599

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

AE Date	08/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	10 Years		
District Involved	PFR [B6] DO		

Product information

Individual Case Safety Report Number: 2060599

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA



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

<https://eon.fda.gov/eon//browse/EON-374786>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=391795>

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 3/21/2019 9:41:00 PM
Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-383005
Attachments: 2064397-report.pdf; 2064397-attachments.zip

A PFR Report has been received and Related PFR Event [EON-383005] has been created in the EON System.

A "PDF" report by name "2064397-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 "2064397-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383005

ICSR #: 2064397

EON Title: Related PFR Event created for Acana Free Run Poultry dry; 2064397

AE Date	08/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Doberman Pinscher		
Age	[B6]		
District Involved	PFR-[B6]DO		

Product information

Individual Case Safety Report Number: 2064397

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

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

Submission Type: Followup

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

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

This report is linked to:

Initial EON Event Key: EON-374786

Initial ICSR: 2060599

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

<https://eon.fda.gov/eon//browse/EON-383005>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=10100&issueId=400103&parentIssueTypeId=12>

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Report Details - EON-390034

ICSR:	2067994
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-06-10 11:03:47 EDT
Initial Report Date:	11/09/2018
Parent ICSR:	2058683
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Older housemate diagnosed with DCM and CHF. Screening: B6 because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation
	Date Problem Started:	11/07/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Zignature trout & salmon dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: B6 is four and was born on B6. He ate Zignature trout & salmon from 09/30/15-10/01/18. 1.25 cups twice daily of Zignature. The primary cookies he ate was Earthborn Holistic Grain-Free, all varieties, and he might have had 3-4 cookies per day. The only other cookies he would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give medication, we always used the Greenies Pill Pockets.
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Labrador
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	25.9 Kilogram
	Age:	3 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	3
	Number of Animals Reacted:	2
Owner Information:	Owner Information provided:	Yes
	Contact: Name:	B6
	Phone:	B6

			Email: B6	
	Address:	B6		
		United States		
Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine		
	Contact:	Name:	Lisa Freeman	
		Phone:	(508) 887-4523	
		Email:	lisa.freeman@tufts.edu	
Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States			
Sender Information:	Name:	Lisa Freeman		
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	Contact:	Phone:	5088874523	
		Email:	lisa.freeman@tufts.edu	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
	Reported to Other Parties:	None		
Additional Documents:	Attachment:	Med Records pt 2.pdf		
	Description:	Medical Records		
	Type:	Medical Records		
	Attachment:	Med Records pt 1.pdf		
	Description:	Medical Records		
	Type:	Medical Records		

Report Details - EON-370715

ICSR: 2058683
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-09 17:46:50 EST

Reported Problem:
Problem Description: Older housemate diagnosed with DCM and CHF. Screening: B6 because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation
Date Problem Started: 11/07/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Zignature trout & salmon dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** B6 is four and was born on B6. He ate Zignature trout & salmon from 09/30/15-10/01/18. 1.25 cups twice daily of Zignature. The primary cookies he ate was Earthborn Holistic Grain-Free, all varieties, and he might have had 3-4 cookies per day. The only other cookies he would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give medication, we always used the Greenies Pill Pockets.
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Retriever - Labrador
Gender: Male
Reproductive Status: Neutered
Weight: 25.9 Kilogram
Age: 3 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 3
Number of Animals Reacted: 2
Owner Information: Owner Information provided: Yes
Contact: Name: B6
 Phone: B6
 Email: B6
Address: B6

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

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

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

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

Below is the summary of the report:

EON Key: EON-374786

ICSR #: 2060599

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

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

Product information

Individual Case Safety Report Number: 2060599

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

<https://eon.fda.gov/eon/browse/EON-374786>

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

<https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=391795>

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS /CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Queen, Jackie L; Palmer, Lee Anne; Carey, Lauren; Peloquin, Sarah
Sent: 9/24/2018 11:23:36 AM
Subject: Fwd: Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor-Before that: Lisa Freeman - EON-366516
Attachments: 2055229-report.pdf; 2055229-attachments.zip

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

Date: September 22, 2018 at 6:40:54 PM EDT

To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification

<HQPetFoodReportNotification@fda.hhs.gov>

B6

Subject: Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor-Before that: Lisa Freeman - EON-366516

A PFR Report has been received and PFR Event [EON-366516] has been created in the EON System.

A "PDF" report by name "2055229-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 "2055229-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-366516

ICSR #: 2055229

EON Title: PFR Event created for Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that fed 3-4 bags of Pine Forest Before that had been feeding Pacific Stream for several years; 2055229

AE Date	09/08/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		

Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055229

Product Group: Pet Food

Product Name: Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years

Description: DCM and CHF Probably primary DCM in predisposed breed but given diet history, some possibility of diet-associated DCM Taurine WNL

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years		

Sender information

Lisa Freeman
 200 Westboro Rd
 North Grafton, MA 01536
 USA

Owner information

B6 USA

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

<https://eon.fda.gov/eon//browse/EON-366516>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=383430>

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: [REDACTED] 6 Cleary, Michael *; HQ Pet Food Report Notification;
[REDACTED] B6
Sent: 3/26/2019 6:25:57 PM
Subject: 4Health whitefish and potato dry; Lisa Freeman - EON-383414
Attachments: 2064645-report.pdf; 2064645-attachments.zip

A PFR Report has been received and Related PFR Event [EON-383414] has been created in the EON System.

A "PDF" report by name "2064645-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2064645-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383414

ICSR #: 2064645

EON Title: Related PFR Event created for 4Health whitefish and potato dry, 4Health salmon and potato adult dog food; 2064645

AE Date	01/03/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Pit Bull		
Age	7.5 Years		
District Involved	PFR-New England DO		

Product Information

Individual Case Safety Report Number: 2064645

Product Group: Pet Food

Product Name: 4Health whitefish and potato dry, 4Health salmon and potato adult dog food

Description: Eating BEG diet Syncopal episodes - identified arrhythmia recently Owner changing diet and will recheck in 3 months Elevated BNP [REDACTED] B6; taurine and troponin pending 2 other dogs in household eating same diet - they have not been screened yet

Submission Type: Followup

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

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4Health salmon and potato adult dog food		
4Health whitefish and potato dry		

This report is linked to:

Initial EON Event Key: EON-376448

Initial ICSR: 2061217

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
B6 USA

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

<https://eon.fda.gov/eon//browse/EON-383414>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=400512&parentIssueTypeId=12>

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification [B6]
Sent: 1/31/2019 4:41:12 PM
Subject: Castor & Pollux Organix Grain Free [B6] - EON-378184
Attachments: 2062004-report.pdf; 2062004-attachments.zip

A PFR Report has been received and PFR Event [EON-378184] has been created in the EON System.

A "PDF" report by name "2062004-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 "2062004-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-378184

ICSR #: 2062004

EON Title: PFR Event created for Castor & Pollux Organix Grain Free, Primal Freeze Dried Nuggets for dogs; 2062004

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Terrier - Yorkshire		
Age	1 Years		
District Involved	PFR-Atlanta DO		

Product information

Individual Case Safety Report Number: 2062004

Product Group: Pet Food

Product Name: Castor & Pollux Organix Grain Free, Primal Freeze Dried Nuggets for dogs

Description: [B6] a 1-year-old intact male Yorkshire terrier mix, was presented to the NCSU ER in the early morning hours of [B6] and was subsequently transferred to the NCSU Cardiology Service for respiratory distress and suspected congestive heart failure. [B6] was observed to have labored breathing the morning of [B6] although his owner is unsure exactly when it started. He vomited clear frothy foam after coughing multiple times throughout the day and he had a decreased appetite. [B6] was taken to [B6]

B6 that evening for further evaluation. At **B6** a CBC showed a marked thrombocytopenia (automated, no smear performed) and thoracic radiographs showed an enlarged heart, a moderate diffuse unstructured interstitial pattern perihilar and caudodorsal lung lobes, and a mildly distended cranial lobar vein. Congestive heart failure was suspected and **B6**
B6 **B6** was subsequently referred to NCSU for further cardiac workup.
B6 other medical problems include recent vomiting and diarrhea. He vomits every once in a while, most recently a couple of weeks ago after eating houseplants. He also had a bad bout of diarrhea after eating the plants. He was taken to his primary veterinarian who prescribed medications and a probiotic. The vomiting resolved and his feces normalized until about 2 days ago when they became soft again.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Primal Freeze Dried Nuggets for dogs		
Castor & Pollux Organix Grain Free		

Sender information

B6

USA

Owner information

B6

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

<https://eon.fda.gov/eon//browse/EON-378184>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=395193>

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/11/2019 6:40:49 PM
Subject: Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-390201
Attachments: 2068094-report.pdf; 2068094-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390201] has been created in the EON System.

A "PDF" report by name "2068094-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 "2068094-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390201

ICSR #: 2068094

EON Title: Related PFR Event created for Wellness Core grain-free ocean fish dry Wellness core grain free turkey chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe; 2068094

AE Date	01/15/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Bulldog		
Age	8.5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068094

Product Group: Pet Food

Product Name: Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 4 have been

diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food **B6**- Owners elected humane euthanasia due to worsening heart failure. Samples of heart muscle were submitted to FDA from rDVM.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe		

This report is linked to:

Initial EON Event Key: EON-380742

Initial ICSR: 2063133

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-390201>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=10100&issueId=407473&parentIssueTypeId=12>

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Report Details - EON-390201

ICSR:	2068094
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	B6 14:32:32 EDT
Initial Report Date:	02/25/2019
Parent ICSR:	2063133
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 4 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food B6 B6 - Owners elected humane euthanasia due to worsening heart failure. Samples of heart muscle were submitted to FDA from rDVM.
	Date Problem Started:	01/15/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions	B6
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	Description:	Please see diet history
	Manufacturer /Distributor Information:		
	Purchase Location Information:		

Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	19.3 Kilogram	
	Age:	8.5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	6	
	Number of Animals Reacted:	4	
Owner Information:	Owner Information provided:	Yes	
	Contact:	Name:	B6
		Phone:	
	Email:		

	Address:	B6 United States
Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
	Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone: 5088874523 Email: lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Additional Documents:	Attachment:	Follow-up med records pt 2.pdf
	Description:	Med records
	Type:	Medical Records
	Attachment:	Follow-up med records pt 1.pdf
	Description:	Med records
	Type:	Medical Records

Report Details - EON-390205

ICSR:	2068096
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-06-11 14:55:22 EDT
Initial Report Date:	02/25/2019
Parent ICSR:	2063134
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Housemate (half sister; [B6]) - (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated) Patient DOA when owners arrived home on [B6] Suspected sudden death. Heart muscle samples were collected by rDVM and submitted to FDA for further evaluation.
	Date Problem Started:	02/01/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Died Other
	Date of Death:	[B6]

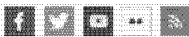
Product Information:	Product Name:	Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	Description: Please see diet history for more info (and refer to [B6] diet history for more complete info - all dogs eat same diets)
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	[B6]
	Type Of Species:	Dog
	Type Of Breed:	Bulldog
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	22.1 Kilogram
	Age:	8 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	6
	Number of Animals Reacted:	4
	Owner Information:	Owner Information provided: Yes
	Contact: Name: [B6]	

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

From: Rotstein, David
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L.; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L.; Rotstein, David
Subject: couple more related DCM- PFRs-FW: Zignature trout & salmon dry: Lisa Freeman - EON-390034 + Pure Vita Venison and Red Lentils
Date: Monday, June 10, 2019 12:39:19 PM
Attachments: 2067994-report.pdf
 2067994-attachments.zip
 PureVita Venison Red Lentils Grain-Free Dry Dog Food [REDACTED] EON-390031.msg
 PureVita Venison Red Lentils Grain-Free Dry Dog Food [REDACTED] EON-386301.msg
 Zignature trout salmon dry Lisa Freeman - EON-370715.msg
 image001.png

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



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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Monday, June 10, 2019 11:13 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [REDACTED]
Subject: Zignature trout & salmon dry: Lisa Freeman - EON-390034

A PFR Report has been received and Related PFR Event [EON-390034] has been created in the EON System.

A "PDF" report by name "2067994-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2067994-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390034
ICSR #: 2067994
EON Title: Related PFR Event created for Zignature trout & salmon dry; 2067994

AE Date	11/07/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	3 Years		
District Involved	PFR-New England DO		

Product Information

Individual Case Safety Report Number: 2067994
Product Group: Pet Food
Product Name: Zignature trout & salmon dry

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

Submission Type: Followup

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

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 2

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

This report is linked to:

Initial EON Event Key: EON-370715

Initial ICSR: 2058683

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

[B6]
[B6] USA

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

<https://eon.fda.gov/eon//browse/EON-390034>

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

<https://eon.fda.gov/eon//EventCustomDetailsActionViewReport.jsps?decorator=none&e=0&issueType=10100&issueId=407306&parentIssueTypeId=12>

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 4/29/2019 8:12:57 PM
Subject: PureVita Venison & Red Lentils Grain-Free Dry Dog Food; [B6]
EON-386301
Attachments: 2066404-report.pdf; 2066404-attachments.zip

A PFR Report has been received and PFR Event [EON-386301] has been created in the EON System.

A "PDF" report by name "2066404-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 "2066404-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-386301

ICSR #: 2066404

EON Title: PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula; 2066404

AE Date	03/01/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	American Pit Bull Terrier		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2066404

Product Group: Pet Food

Product Name: PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula

Description: Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on [B6] taurine. Taurine levels prior to supplementation was WNL.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NutriSource Adult Chicken and Rice formula		
PureVita Venison & Red Lentils Grain-Free Dry Dog Food		

Sender information

B6

USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-386301>

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=403429>

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: [B6] Cleary, Michael *; HQ Pet Food Report Notification;
[B6]
Sent: 3/21/2019 4:00:51 PM
Subject: Acana Lamb and Apple singles: Lisa Freeman - EON-382951
Attachments: 2064360-report.pdf; 2064360-attachments.zip

A PFR Report has been received and Related PFR Event [EON-382951] has been created in the EON System.

A "PDF" report by name "2064360-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 "2064360-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382951

ICSR #: 2064360

EON Title: Related PFR Event created for Acana Lamb and Apple singles; 2064360

AE Date	11/08/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Irish Wolfhound		
Age	3 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2064360

Product Group: Pet Food

Product Name: Acana Lamb and Apple singles

Description: Littermate diagnosed with DCM. Initial taurine level (plasma only) was [B6] WB taurine submitted at [B6] Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = [B6] troponin mildly elevated at [B6] (stat) and [B6] at Texas A&M Will recheck in 3-4 months Follow-up - NT-proBNP, troponin, echo and ECG

Submission Type: Followup

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Lamb and Apple singles		

This report is linked to:

Initial EON Event Key: EON-372606

Initial ICSR: 2059540

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-382951>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=10100&issueId=400049&parentIssueTypeId=12>

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 4/11/2019 9:22:54 PM
Subject: forwarding in case this was a case that was being follow-up-FW: Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-384837
Attachments: 2065714-report.pdf; Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-380707

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

B6



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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Thursday, April 11, 2019 5:21 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6
Subject: Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-384837

A PFR Report has been received and Related PFR Event [EON-384837] has been created in the EON System.

A "PDF" report by name "2065714-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-384837

ICSR #: 2065714

EON Title: Related PFR Event created for Purina One Smart Blend Lamb and Rice dry; 2065714

AE Date	08/01/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Other
Breed	Doberman Pinscher		

Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2065714

Product Group: Pet Food

Product Name: Purina One Smart Blend Lamb and Rice dry

Description: DCM and CHF diagnosed Aug 2018 We saw 1/11/19 - CHF still not well controlled Eating Purina Lamb and Rice - unlikely to be associated with DCM but reporting just in case Owner is now changing to different diet and will recheck in 3 months 2 other dogs eating same diet - we have not screened them yet. BNP = [B6] troponin [B6] but taurine normal ([B6] plasma [B6] whole blood)

Submission Type: Followup

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

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

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

This report is linked to:

Initial EON Event Key: EON-380707

Initial ICSR: 2063114

Sender information

[B6]

USA

Owner information

[B6]

[B6] USA

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

<https://eon.fda.gov/eon//browse/EON-384837>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=10100&issueId=401965&parentIssueTypeId=12>

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

All Medical Records

Patient: **B6**
Breed: Doberman
DOB: **B6**

Species: Canine
Sex: Male
(Neutered)

Home Phone: **B6**
Work Phone: **B6**
Cell Phone: **B6**

Referring Information

B6

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

Initial Complaint:

Scanned Record

Initial Complaint:

New - **B6** - CHF

SOAP Text Jan 11 2019 5:37PM - **B6**

Initial Complaint:

Chem 21 - **B6** - 5856

SOAP Text Jan 18 2019 3:04PM - **B6**

Disposition/Recommendations

Client:
Patient:

B6

Client: **B6**
Patient:

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client: **B6**
Veterinarian:
Patient ID: **B6**
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Doberman
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Accession ID:			
Test	Results	Reference Range	Units



3/3

B6

Printed Sunday, February 24, 2019

Vitals Results

1/11/2019 4:07:45 PM	Weight (kg)	B6
1/11/2019 4:43:10 PM	Nursing note	
1/18/2019 3:12:02 PM	Weight (kg)	

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification: **B6**
Sent: 2/26/2019 12:21:16 AM
Subject: Wellness Complete Health Fish and Sweet Potato dry: Lisa Freeman - EON-380848
Attachments: 2063189-report.pdf; 2063189-attachments.zip

A PFR Report has been received and PFR Event [EON-380848] has been created in the EON System.

A "PDF" report by name "2063189-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 "2063189-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380848

ICSR #: 2063189

EON Title: PFR Event created for Wellness Complete Health Fish and Sweet Potato dry; 2063189

AE Date	02/22/2019	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063189

Product Group: Pet Food

Product Name: Wellness Complete Health Fish and Sweet Potato dry

Description: Arrhythmia dx at RDVM July 2018 (had been "wheezing") Started wheezing again 1 week before admission. Diagnosed with DCM, CHF, and ventricular tachycardia 2/22/19 Was fed Wellness diet until 6/2018 then changed to Royal Canin Boxer (current diet). Taurine and troponin pending. Owner has another Boxer eating same diets - has not been screened Enrolled in DCM study. Changing to different diet (although Boxer diet is probably fine) and will recheck in 7 days and 3 months.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Wellness Complete Health Fish and Sweet Potato dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

<https://eon.fda.gov/eon//browse/EON-380848>

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=397857>

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From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: Ceric, Olgica; Nemser, Sarah
Sent: 1/4/2018 7:39:28 PM
Subject: Re: dog food concern

The myocardium is from [B6] Maybe we will wait to see what the blood levels show.

B5

Thanks!
Darcy

On Thu, Jan 4, 2018 at 2:14 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you for the update. I'll let you know the [B5] concentration from [B6] food after the results are back.

The frozen myocardium, is it from the [B6] case?

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, January 03, 2018 3:10 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Re: dog food concern

Hi Jennifer,

Thank you! We have not tested for [B5] in any of the dogs. We have stored blood samples from several dogs and have an inpatient right now that we can submit blood from [B4] (uns this). We will probably start with looking at blood samples from 2 dogs as a screening. We also have frozen myocardium from one dog - do you think this should also be evaluated?

Thank you!

Darcy

On Wed, Jan 3, 2018 at 2:30 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

Happy New Year! Thank you for the additional information. I discussed the information you provided below and from the previous case ([REDACTED] B6 Miniature Schnauzers-800.218) with my colleagues.

Based on our discussions, I will test some leftover food from the 800.218 case, for [REDACTED] B5 content. Have any of the dogs with DCM had blood or tissue [REDACTED] B5 levels tested?

Thank you kindly,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, January 03, 2018 11:31 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: dog food concern

Hi Dr. Jones,

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

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

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

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

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

Have you had any other reports of such an association? If you have any other thoughts or testing suggestions, I would be all ears!

Thank you!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

Report Details - EON-371239

ICSR:	2058943		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-11-16 10:04:13 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Our Golden Retriever, [B6], was diagnosed with diet-related Dilated Cardiomyopathy on 09/30/2018. Because [B6] and [B6] were fed the same food, Tufts in Grafton, MA chose to administer an echocardiogram on [B6] to see if he also has DCM. [B6] was diagnosed with DCM after his echocardiogram on 11/07/2018. His taurine levels were tested by University of California-Davis and results will be attached to this report.	
	Date Problem Started:	11/07/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	09/29/2015	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	After purchasing, the bag was opened and poured into an airtight plastic container.	
	Product Use Information:	Description:	[B6] ate 1 cup of this food twice per day.
		First Exposure Date:	09/30/2015
		Last Exposure Date:	10/01/2018
		Time Interval between Product Use and Adverse Event:	39 Months
Product Use Stopped After the Onset of the Adverse Event:		Yes	
Adverse Event Abate After Product Stop:		Yes	
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Definitely related	
Other Foods or Products Given to the Animal		Yes	

		During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	57 Pound	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	Cummings School of Veterinary Medicine at Tufts University
		Contact:	Name: B6 Phone: (508) 887-4696 Email: Liasons@tufts.edu
		Address:	200 Westboro Rd. N. Grafton Massachusetts 01536 United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	11/07/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	10/18/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	

	Address:	<div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 2em; font-weight: bold;">B6</div> United States	
	Contact:	Phone:	<div style="border: 1px dashed black; padding: 2px; display: inline-block;">B6</div>
		Email:	<div style="border: 1px dashed black; padding: 2px; display: inline-block;">B6</div>
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		
Additional Documents:	Attachment:	<div style="border: 1px dashed black; padding: 2px; display: inline-block;">B6</div> pdf	
	Description:	Tufts medical records and taurine test results	
	Type:	Medical Records	

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 1/15/2019 8:56:35 PM
Subject: Zignature - various flavors (venison: Lisa Freeman - EON-376446
Attachments: 2061214-report.pdf; 2061214-attachments.zip

A PFR Report has been received and PFR Event [EON-376446] has been created in the EON System.

A "PDF" report by name "2061214-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061214-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376446

ICSR #: 2061214

EON Title: PFR Event created for Zignature - various flavors (venison goat kangaroo lamb turkey pork); 2061214

AE Date	01/09/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061214

Product Group: Pet Food

Product Name: Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)

Description: 2 syncopal episodes in summer got echo in October 2018 and arrhythmia identified Feeding BEG diets all of her life (Zignature) DCM and VPCs identified 1/9/19 Owner changing to Purina EN Fiber and we will recheck in 3 months BNP elevated, troponin and taurine pending

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

<https://eon.fda.gov/eon//browse/EON-376446>

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=393455>

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Report Details - EON-376446		
ICSR:	2061214	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-15 15:49:52 EST	
Reported Problem:	Problem Description: 2 syncopal episodes in summer got echo in October 2018 and arrhythmia identified Feeding BEG diets all of her life (Zignature) DCM and VPCs identified 1/9/19 Owner changing to Purina EN Fiber and we will recheck in 3 months BNP elevated, troponin and taurine pending	
	Date Problem Started: 01/09/2019	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6 Successfully treated	
	Outcome to Date: Stable	
Product Information:	Product Name: Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)	
	Product Type: Pet Food	
	Lot Number:	
	Product Use Information: Description: Rotated proteins/flavors of Zignature for past 8-9 years	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Boxer (German Boxer)	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 21 Kilogram	
	Age: B6 Years	
	Assessment of Prior Health: Good	
	Number of Animals Given the Product: 1	
	Number of Animals Reacted: 1	
	Owner Information:	Owner Information provided: Yes
		Contact:
		Name: B6
		Phone: B6
		Email: B6
Address: B6 United States		
Healthcare Professional Information:	Practice Name: Tufts Cummings School of Veterinary Medicine	
	Contact:	
	Name: Lisa Freeman Phone: (508) 887-4523	

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

Report Details - EON-377321

ICSR:	2061666
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-01-23 18:29:48 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Began feeding Wellness CORE Ocean Dry Kibble Feb. 2015 as main source of nutrition, fed 1 cup 2x per day. Submitted Whole Blood sample to UC Davis Amino Acid Lab for Taurine Testing 6/26/2018. Lab Result: B6 Whole Blood Taurine Results which per Dr. Joshua Stern UC Davis DVM Cardiologist is BELOW the 250 minimum range for a Golden Retriever Dog. Per Dr. Stern's order continue feeding this food and supplement each daily meal with taurine rich foods for 3 months then ReTest. Supplemented kibble with 1/2cup pan fried Ground Sirloin, 1 Hardboiled Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole Blood Taurine Level October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24/2018 Lab Result Whole Blood Taurine Results: B6 . Improvement of B6 ; putting him within the "normal" range Dr. Stern has identified for Golden Retriever Dogs.
	Date Problem Started:	02/15/2015
	Date of Recovery:	10/24/2018
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Wellness Core Ocean Grain Free Protein-Rich Nutrition		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	1228J22	
		Expiration Date:	10/24/2019	
	UPC:	076344884132		
	Package Type:	BAG		
	Package Size:	12 Pound		
	Purchase Date:	01/04/2019		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	Bag has a ziplock freshness seal which was opened and resealed after each use.		
	Product Use Information:	Description:	Fed 1 cup kibble soaked in warm water 2x per day to	B6
		Last Exposure Date:	01/04/2019	
		Time Interval between Product Use and Adverse Event:	3 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		Yes		
Product Use Started Again:		No		
Perceived		Definitely related		

		Relatedness to Adverse Event:	
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Petco
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	73 Pound	
	Age:	7 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Email:	B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	06/26/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	B6 United States	
	Contact: Phone:	B6	
	Email:	B6	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact	Yes	

	Sender:	
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other Store/Place of Purchase

Additional Documents:	Attachment:	B6 Oct20182ndTaurineResults_23928.jpg.pdf
	Description:	Taurine Retest Lab Report after 3 months of adding Taurine Rich Foods to existing kibble which was causing the problem.
	Type:	Laboratory Report
	Attachment:	B6 June2620181stTaurineResultsT_19251.pdf
	Description:	First Taurine Results, Per Dr. Stern: "Those taurine levels are ok. I would prefer to see over 250. My recommendation would be either diet change and retest after 3 months or add in taurine rich ingredients and retest in 3 months. "
	Type:	Laboratory Report
	Attachment:	DrStern Lab Taurine RecommendationsAug2018.pdf
	Description:	Aug 2018 Letter from Dr. Joshua Stern DVM Cardiologist explaining the Taurine Deficeincy results specifically to Golden Retriever owners with the correct range that Golden Retriever dogs are to be in.
	Type:	Letter

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/11/2019 6:40:49 PM
Subject: Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-390201
Attachments: 2068094-report.pdf; 2068094-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390201] has been created in the EON System.

A "PDF" report by name "2068094-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 "2068094-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390201

ICSR #: 2068094

EON Title: Related PFR Event created for Wellness Core grain-free ocean fish dry Wellness core grain free turkey chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe; 2068094

AE Date	01/15/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Bulldog		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2068094

Product Group: Pet Food

Product Name: Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 4 have been

diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food

B6

Owners elected humane euthanasia due to worsening heart failure. Samples of heart muscle were submitted to FDA from rDVM.

Submission Type: Followup

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe		

This report is linked to:

Initial EON Event Key: EON-380742

Initial ICSR: 2063133

Sender information

Lisa Freeman

200 Westboro Rd

North Grafton, MA 01536

USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-390201>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=10100&issueId=407473&parentIssueTypeId=12>

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Report Details - EON-390201

ICSR:	2068094
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-06-11 14:32:32 EDT
Initial Report Date:	02/25/2019
Parent ICSR:	2063133
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 4 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food. B6 Owners elected humane euthanasia due to worsening heart failure. Samples of heart muscle were submitted to FDA from rDVM.	
	Date Problem Started:	01/15/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	

Product Information:	Product Name:	Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	Description:	Please see diet history
	Manufacturer /Distributor Information:		
	Purchase Location Information:		

Animal Information:	Name:	B6			
	Type Of Species:	Dog			
	Type Of Breed:	Bulldog			
	Gender:	Female			
	Reproductive Status:	Neutered			
	Weight:	19.8 Kilogram			
	Age:	B6 Years			
	Assessment of Prior Health:	Excellent			
	Number of Animals Given the Product:	6			
	Number of Animals Reacted:	4			
	Owner Information:	Owner Information provided:	Yes		
		Contact:	Name:	B6	
		Phone:	B6		
		Email:	B6		

		Address:	B6 United States	
Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine		
	Contact:	Name:	Lisa Freeman	
		Phone:	(508) 887-4523	
Email:		lisa.freeman@tufts.edu		
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States		
Sender Information:	Name:	Lisa Freeman		
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	Contact:	Phone:	5088874523	
		Email:	lisa.freeman@tufts.edu	
	Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email			
Additional Documents:	Attachment:	Follow-up med records pt 2.pdf		
	Description:	Med records		
	Type:	Medical Records		
	Attachment:	Follow-up med records pt 1.pdf		
	Description:	Med records		
	Type:	Medical Records		

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/27/2019 7:00:50 PM
Subject: CANIDAE- ALL LIFE STAGES-CHICKEN MEAL & RICE FORMULA--DRY
DOG FOOD: Lisa Freeman - EON-381040
Attachments: 2063286-report.pdf; 2063286-attachments.zip

A PFR Report has been received and PFR Event [EON-381040] has been created in the EON System.

A "PDF" report by name "2063286-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 "2063286-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-381040

ICSR #: 2063286

EON Title: PFR Event created for CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD; 2063286

AE Date	02/25/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063286

Product Group: Pet Food

Product Name: CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD

Description: DCM and CHF diagnosed 2/25/19. Eating BEG diet. 2 other dogs in household will be screened. Will change diet on B6 and reassess in 3 months. Just being discharged today. Taurine and troponin pending

Submission Type: Initial

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

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

<https://eon.fda.gov/eon//browse/EON-381040>

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=398049>

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From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: [B6] HQ Pet Food Report Notification; [B6]
Sent: 1/15/2019 9:05:17 PM
Subject: 4Health whitefish and potato dry: Lisa Freeman - EON-376448
Attachments: 2061217-report.pdf; 2061217-attachments.zip

A PFR Report has been received and PFR Event [EON-376448] has been created in the EON System.

A "PDF" report by name "2061217-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 "2061217-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376448

ICSR #: 2061217

EON Title: PFR Event created for 4Health whitefish and potato dry, 4Health salmon and potato adult dog food; 2061217

AE Date	01/03/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Pit Bull		
Age	7.5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2061217

Product Group: Pet Food

Product Name: 4Health whitefish and potato dry, 4Health salmon and potato adult dog food

Description: Eating BEG diet Syncopal episodes - identified arrhythmia recently Owner changing diet and will recheck in 3 months Elevated BNP [B6] taurine and troponin pending 2 other dogs in household eating same diet - they have not been screened yet

Submission Type: Initial

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

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

Number of Animals Treated With Product: 3

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4Health salmon and potato adult dog food		
4Health whitefish and potato dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

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

<https://eon.fda.gov/eon//browse/EON-376448>

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=393457>

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Foster Hospital for Small Animals

55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:
Address:

B6

All Medical Records

Patient: **B6**
Breed: Pit Bull
DOB: **B6**

Species: Canine
Sex: Male
(Neutered)

B6

Referring Information

B6

Client: **B6**
Patient:

Initial Complaint:
Scanned Record

Initial Complaint:
Cardiology New - will be here at 1:30 PM

SOAP Text Jan 3 2019 1:03PM

B6

Disposition/Recommendations

Client:
Patient:

B6

Client:
Patient:

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:
Veterinarian:
Patient ID:
Visit ID:

B6

Patient:

B6

Species:

Canine

Breed:

Pit Bull

Sex:

Male (Neutered)

Age:

B6 years Old

Lab Results Report

Accession ID:

Test

Results

Reference Range

Units



3/53

B6

Printed Tuesday, January 15, 2019

Client:
Patient:

B6

B6

History 9/2018-12/29/18

B6

INVOICE

For:

B6

Date	For	Qty	Description	Price	Discount	Net Price
------	-----	-----	-------------	-------	----------	-----------

40.00

B6

Client:
Patient:

B6

B6

History 9/2018-12/29/18

B6

B6

B6

History 9/2018-12/29/18

B6

Client:
Patient

B6

B6

History 9/2018-12/29/18

B6

INVOICE

B6

Client:
Patient:

B6

B6

History 9/2018-12/29/18

B6

Patient Chart

CLIENT INFORMATION

B6

Client: **B6**
Patient:

B6 History 9/2018-12/29/18

B6

Client:
Patient:

B6

B6

Med 3/17/18 3 year Rabies Cert

B6

Client: **B6**
Patient:

diet history 1/3/19

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Veterinarian: **B6**

B6

has been eating the health gran tree (alternating proteins)
for multiple years, just recently switched to
regular kibble (w/ grain)

has also been fed a very wide variety of canned
food, only used to give medications.
about 2 tablespoons twice daily

- pedigree
- pure balance
- 4 health

Client:
Patient:

B6

B6

ospital records

B6

Patent Chart

ELCIT RECORDS

B6

Client:
Patient:

B6

B6

ospital records

B6

Client:
Patient:

B6

B6

hospital records

B6

Client: **B6**
Patient:

B6

ospital records

B6

Client: **B6**

Patient: **B6**

B6

hospital records

B6

Client:
Patient:

B6

B6

hospital records

B6

Client:
Patient:

B6

B6

hospital records

B6

Client:
Patient:

B6

B6

hospital records

B6

Client:
Patient:

B6

B6

hospital records

B6

Client: **B6**
Patient:

B6 hospital records

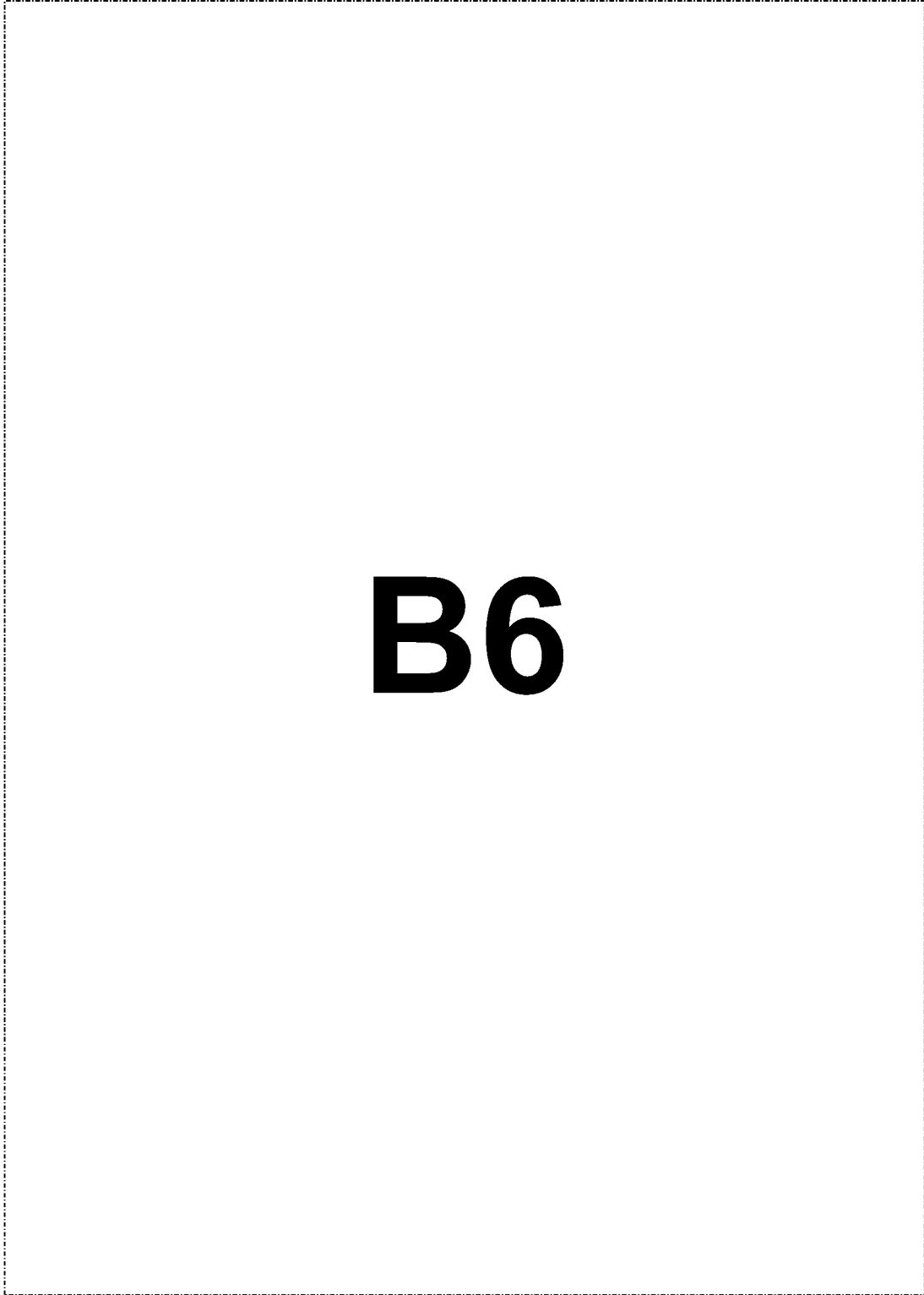
B6

Client:
Patient:

B6

B6

hospital records



Client:
Patient:

B6

B6

hospital records

B6

Client:

B6

Patient:

B6

hospital records

B6

Client:
Patient:

B6

B6

hospital records

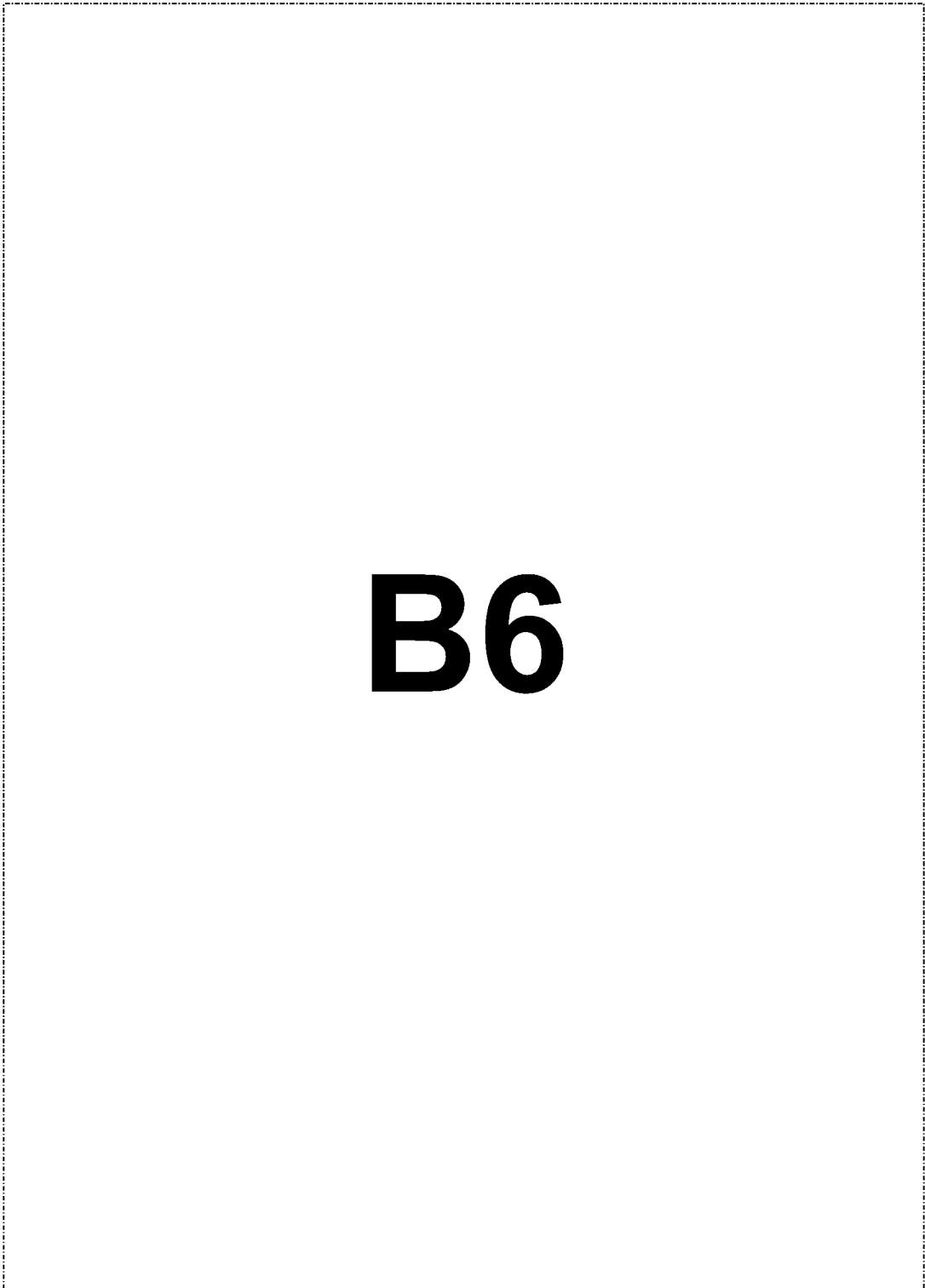
B6

Client:
Patient:

B6

B6

hospital records



Client:
Patient:

B6

B6

hospital records

B6

Client:
Patient:

B6

B6

hospital records

B6

Client:
Patient:

B6

IDEXX BNP - 1/3/2019

B6

Client:
Patient:

B6

CBC/CHEM - 1/3/2019



Tufts Cummings School Of Veterinary Medicine
300 Winthrop Road
North Grafton, MA 01134

DUPLICATE

B6

Client:
Patient:

B6

CBC/CHEM - 1/3/2019



Tufts Cummings School Of Veterinary Medicine
300 Winthrop Road
North Grafton, MA 01134

DUPLICATE

B6

Sample ID: D0110114
ACID-BASE REPORT (Cont)

Continuity _____
Page 1

Client:
Patient:

B6

Diet history 1/3/19

CARDIOLOGY DIET HISTORY FORM
Please answer the following questions about your pet

Pet's name

B6

Owner's name

B6

Today's date 1/5/19

B6

Client:
Patient:

B6

Diet history 1/3/19

Has been eating 4health grain free (alternating proteins)
for multiple years, just recently swapped to
regular kibble (Lufgran)

Has also been fed a very wide variety of canned
food, only used to give medications.
about 2 tablespoons twice daily

- pedigree
- pure balance
- 4 health

Client:
Patient:

B6

Lab Results IDEXX Leptospirosis Panel (MAT) 1/4/19

B6

Client:
Patient:

B6

B6

hospital UA results- 1/7/19

B6

Client:
Patient:

B6

B6

hospital UA results- 1/7/19

B6

Client:
Patient:

B6

IDEXX Chemistry 1/8/19

B6

B6

Client:
Patient:

B6

IDEXX Chemistry 1/8/19

B6

Client:
Patient:

B6

Taurine Panel send out 1/3/2019

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1388 Veterinary Medicine Drive, Davis, Ca 95616
Telephone: 925-752-4058, Fax: 925-752-4058
Email: aa@aminoacidlab.com
www.aminoacidlab.com/Products/AminoAcidLaboratory

B6

Veterinarian Contact: **B6**

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Andover, MA 01845

Email: Drpatt@Tufts.edu

Telephone: 802-882-4000

Fax: 802-882-7000

Billing Contact: **B6**

Email: **B6**

Billing Contact Phone: 802-882-4000

Tax ID: _____

Patient Name: **B6**

Species: CANINE

Breed: Labrador

Owner's Name: _____

Current Diet: _____

Sample type: Plasma Whole Blood Urine Food Other _____

Test: Taurine Complete Amino Acids Other _____

Taurine Results (lab use only)

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

	Plasma (nMol/ml)		Whole Blood (nMol/ml)	
	Normal Range	No known risk for deficiency	Normal Range	No known risk for deficiency
Plasma	40-70	1-10	450-600	1-200
Whole Blood	40-70	1-10	200-350	1-100

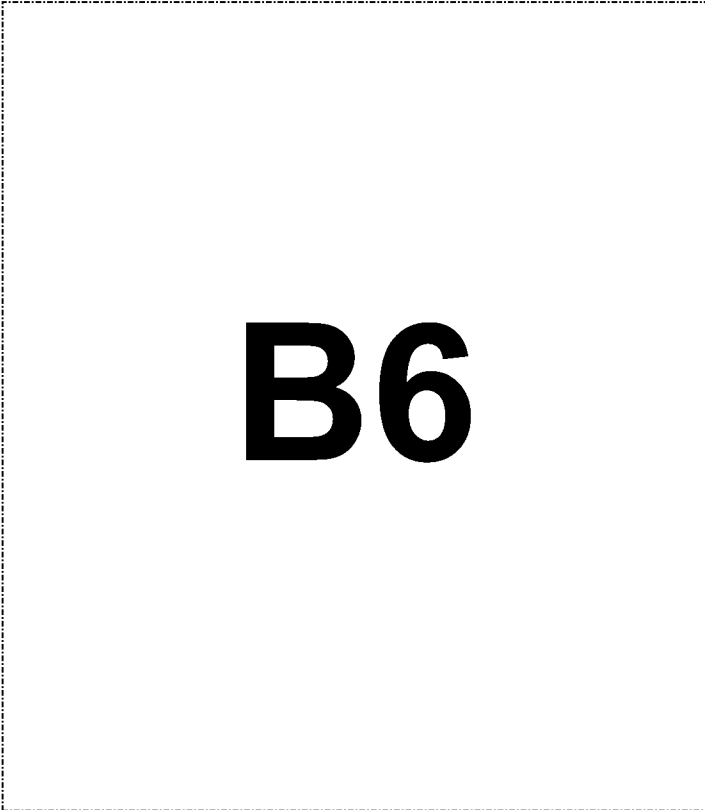
Client: **B6**
Patient:

Vitals Results

1/3/2019 1:44:42 PM	Weight (kg)	33.4000
1/3/2019 1:44:49 PM	Heart Rate (/min)	110.0000

Patient History

01/02/2019 12:50 PM	Appointment
01/03/2019 01:06 PM	UserForm
01/03/2019 01:16 PM	Treatment
01/03/2019 01:44 PM	Vitals
01/03/2019 01:44 PM	Vitals
01/03/2019 03:07 PM	Deleted Reason
01/03/2019 03:09 PM	Purchase
01/03/2019 03:10 PM	UserForm
01/03/2019 03:25 PM	Purchase
01/03/2019 03:25 PM	Purchase
01/03/2019 03:33 PM	Prescription
01/03/2019 03:33 PM	Prescription
01/03/2019 03:38 PM	Prescription
01/03/2019 03:47 PM	Purchase
01/03/2019 04:08 PM	Appointment
01/04/2019 06:18 PM	Purchase



Discharge Instructions

Patient:

Owner:

B6

Attending Cardiologist:

John F. Rush DVM, MS, DACVM (Cardiology), DACVCP

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student:

B6

Appointment Date: 1/3/2019

Diagnoses: Dilated cardiomyopathy (DCM)

Ventricular arrhythmias (ventricular tachycardia, ventricular bigeminy)

Case summary:

Thank you for bringing **B6** to Tufts Cardiology Service for evaluation of his collapsing episodes and arrhythmias that was noticed at your referring veterinarian. **B6** has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening, and also require medical management.

Fortunately, we caught this condition relatively early and **B6** does not appear to be in congestive heart failure yet.

However, if you notice that **B6** breathing rate is faster than normal at home we will want to have chest x-rays taken. **B6** also has some arrhythmias that are likely secondary to his heart disease. We will be starting him on some medications to mitigate the heart disease that he has and the arrhythmias that he is experiencing. We would like to adjust

B6 diet and we provided some dietary recommendations below.

B6

B6

B6

Dry Food Options:

Royal Canin Early Cardiac (ventriary diet)

Royal Canin Bloat

Purina Pro Plan Adult Weight Management (may be more cost-efficient)

Canned Food Options:

Hill's Science Diet Adult Beef and Barley Entrée

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew

Royal Canin Mature 8+

Recheck Visits:

Thank you for enrolling **B6** in our clinical study. We would like to see an Alvecor reading in around two weeks once he has had some time on the anti-arrhythmic medication, or send one earlier if you are having any concerns. It would also be great if you can obtain an Alvecor reading if Horton has another episode of collapse or abnormal behavior.

B6 is scheduled for an appointment on April 8th, 2019 at 4:00 PM. We will perform an echo, ECG and bloodwork at this time.

If you would like to have your other dogs who have been eating the same diet as **B6** screened as part of the study, please call or email to set up an appointment in the near future.

Thank you for enrolling us with **B6** and it was a pleasure to meet you all today and he was a very good boy. Please contact our Cardiology liaison at (508)-287-4676 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information:

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

Prescription Refill Disclaimer:

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

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-287-4676) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

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

Case

B6

Discharge Instructions

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
25 Wilbur Street
North Grafton, MA 01536
Telephone (508) 832-5295
Fax (508) 832-7251
<http://vetmed.tufts.edu/>

AliveCor/Kardia Handout

If you have an iPhone or Android, you may want to explore the option of purchasing an AliveCor/Kardia ECG monitor which will allow you to record and email your pet's heart rate and rhythm at home.

The device (Kardia) can be purchased at www.alivecor.com or www.amazon.com. The app for your phone is free.

If you have an iPhone:

- Search for "Veterinary AliveECG" app in the Apple Store
- You will need to sign-up for an account
- Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker port, say "OK/allow"

If you have an Android:

- Search for "Kardia" app in the Google Playstore
- You will need to sign-up for an account.
- Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker port, say "OK/allow"
- Once downloaded, it will require you to send a "test ECG" for activation of the app. Just place your fingers on the silver sensors and let it record
- If the test ECG is unable to record, try again, with less movement. If it still fails, then your phone is not compatible with the device

Recording an ECG:

- Apply rubbing alcohol (soaked cotton ball will work) to the chest region behind your pet's elbow (where you can feel the heart beat)
- Enough to wet the regions where both silver boxes will touch the animal
- If your pet is fluffy, you may have to clip a small patch of fur to allow for better contact
- Hold the device against your pet's chest with the silver areas being up and down (vertical) in contact with the animal
- With the app open, hold your phone near (within a few inches) the device.
- There is a signal bar in the upper left corner of the app to show whether it detects the device. If there are no bars then move your phone around/get closer to the device until they appear.
- Once you see a recording, hold everything in place for at least 30 seconds if possible.
- The human Kardia app will attempt to interpret the ECG; just ignore this as it is not always accurate.
- The heart rate that the apps report is also not always accurate.

Saving an ECG:

- The app will automatically save the ECG as long as the recording is long enough (>20seconds)
- You can click on the ID box with pencil icon) in the Veterinary AliveECG app to add your pet's name

Emailing an ECG:

- If you are in the recording screen on the Veterinary AliveECG app, click on "ECGs" to see the list of saved ECGs
- If you are in the home screen on the Kardia app, click "History".
- Select the ECG you wish to send. Go to "Share". Select "Email PDF". **SKIP** the Password protect feature and select the email app you wish to send it by (Gmail, outlook, yahoo, etc). **You must have a working email on your phone for this to work.**
- Select an ECG that you wish to send
- Click the mail icon (either a box with arrow or a letter symbol), and select "Email"
- Email to: cardlowet@tufts.edu (only monitored Monday-Friday 9AM-5PM)

B6

Cardiology Appointment Report
ENROLLED IN DCM STUDY

Date: 1/3/2019

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student:

B6

Presenting Complaint:

Episodes of collapse over past year

Concerning Diseases:

B6

General Medical History:

First episode occurred about a year ago - owner originally thought that she had given him too much trauma. He takes it in the winter because he is reactive to snow falling off the roof. Dog fight about to break out later that day and he collapsed.

Has had 5-6 episodes in the past year where he collapses - maintains consciousness, gum color is normal and he is alert. He is usually down for 30-60 seconds. Takes around a couple of hours after the event to go back to normal (lethargic).

All of these had been stimulated by a dog or a lot of arousal. Twice in past month.

Most recent episode was on Saturday - weasel in the yard and B6 got very worked up. Didn't fully collapse but laid down and wouldn't move. This more recent time he was spinning and acting nauseous (lip smacking). Took into the rDVM where they diagnosed an abnormal arrhythmia.

Chest radi from September, 4DX negative.

Diet has been reduced in the past week, will eat if the food is elevated.

Started urinating in the house about a year ago, believed to be behavioral.
Possibly PUPO in the past couple of months.

Diet and Supplements:

For Health grain free diet until 2 weeks ago For Health
Switched to non-grain free: For Health 1 cup and 1/4 BQ
Nupro powder

B6

B6

Problems:

Collapse
Arrhythmia

Differential Diagnosis:

DCM/CHF vs tachyarrhythmia vs bradyarrhythmia vs non-cardiac cause of collapse

Diagnostic plan:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Echocardiogram | <input type="checkbox"/> Dialysis profile |
| <input type="checkbox"/> Chemistry profile | <input checked="" type="checkbox"/> Thoracic radiographs +/- |
| <input checked="" type="checkbox"/> ECG | <input checked="" type="checkbox"/> NT-proBNP |
| <input type="checkbox"/> Renal profile | <input type="checkbox"/> Troponin I |
| <input type="checkbox"/> Blood pressure | <input type="checkbox"/> Other tests: |

B6

B6

Assessment and recommendations:

Echocardiogram and ECG reveal DCM and frequent ventricular arrhythmia. There is enough cardiac enlargement to be compatible with CHF and radiographs were discussed, but the owners perceive him to be breathing comfortably and will continue to monitor RR at home for now. If RR at home is 35 or higher then thoracic radiographs are recommended to assess for CHF. Holter monitor was discussed, but there was enough arrhythmia today to consider starting antiarrhythmic therapy and owners are planning to obtain a Kardia for at home ECG monitoring. The longstanding occurrence of collapse episodes (~1 year) is less consistent with these episodes being clearly related to his heart disease, but there is significant arrhythmia so it is possible the intermittent VT could be causing collapse. Recommend attempting to obtain a Kardia reading during an event if they continue, and if this is not successful then consider 24h Holter monitor. Recommend starting pimobendan, enalapril, and amiodarone. Recommend diet change to a main-stream brand suggestion from Dr Freeman. Patient was enrolled in DCM study so taurine levels, BNP, troponin, CBC/chemistry were submitted as part of the study. Recheck echo and blood work in 3 and 6 months as part of the study. Recheck sooner if clinical sign occur such as increased RR/RE, repeated collapse, cough, or exercise intolerance. The housemates of this dog who have been eating the same diet are eligible for screening as part of the DCM study.

Start:

B6

Final Diagnosis:

DCM

Ventricular arrhythmia (VPCs, couplets, triplets, non-sustained R on T VT)

Heart Failure Classification Score:

ISACH Classification:

- | | |
|--|-------------------------------|
| <input type="checkbox"/> Ia | <input type="checkbox"/> IIIa |
| <input checked="" type="checkbox"/> Ib | <input type="checkbox"/> IIIb |
| <input type="checkbox"/> II | |

ACVIM Classification:

- | | |
|--|----------------------------|
| <input type="checkbox"/> A | <input type="checkbox"/> C |
| <input type="checkbox"/> B1 | <input type="checkbox"/> D |
| <input checked="" type="checkbox"/> B2 | |

M-Mode

IVSd

LVIDd

LVPWd

IVSc

LVIDs

LVPWs

EDV(Teich)

ESV(Teich)

EF(Teich)

%S

SV(Teich)

Ao Diam

LA Diam

LA/Ao

Max LA

EPSS

M-Mode Normalized

IVSdN

LVIDdN

LVPWdN

IVScN

LVIDsN

LVPWsN

Ao Diam N

LA Diam N

ZD

SA LA

Ao Diam

SA LA / Ao Diam

IVSd

LVIDd

LVPWd

EDV(Teich)

IVSc

LVIDs

LVPWs

ESV(Teich)

EF(Teich)

%S

SV(Teich)

LV Major

LV Minor

Sphericity Index

LVID LAX

LVAd LAX

LVEDV A.L LAX

B6

cm

cm

cm

cm

cm

cm

ml

ml

%

%

ml

cm

cm

cm

cm

cm

(0.290 - 0.520)

(1.350 - 1.730) !

(0.330 - 0.530)

(0.430 - 0.710)

(0.790 - 1.140) !

(0.530 - 0.780) !

(0.680 - 0.890) !

(0.640 - 0.900) !

cm

cm

cm

cm

cm

cm

ml

cm

cm

cm

ml

ml

%

%

cm

cm

cm

cm

cm

ml

LVEDV MOD LAX
LVLs LAX
LVA_s LAX
LVESV A-L LAX
LVESV MOD LAX
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX

Doppler

MR Vmax
MR maxPG
MV E Vel
MV DecT
MV Dec Slope
MVA Vel
MV L/A Ratio
E'
E/E'
A'
AV Vmax
AV maxPG
PV Vmax
PV maxPG

B6

ml
cm
cm
ml
ml
BPM
%%ml
ml
l/min
l/min

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

m/s

m/s
m/s
mmHg
m/s
mmHg

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Forster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01526
Telephone (508) 829-5295
Fax (508) 829-7951
<http://vetmed.tufts.edu/>

B6

B6

1/4/2019

Dear Dr. **B6**

Thank you for referring **B6** with their pet **B6**

If you have any questions, or concerns, please contact us at 508-827-1901.

Thank you,

B6 (Cardiology)

Client:
Patient:

B6

Alivecor ECG

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Sunday, February 10, 2019 at 10:01:13 PM
Heart Rate: 158 bpm Duration: 16 s



B6

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

Bloodwork from **B6**

Client: (51432)
Patient Name: **B6**
Species: Canine
Breed:

Gender: **B6**
Weight:
Age: **B6**
Doctor: **B6** **B6**
HUMANE SOCIETY

Test	Results	Reference Interval	LOW	NORMAL	HIGH
Catalyst One (February 28, 2019 6:03 PM)					1/29/19 2:46 PM
GLU	B6	74 - 143			
CREA		0.5 - 1.8	HIGH		
BUN		7 - 27	HIGH		
BUN/CREA					
PHOS		2.5 - 6.8			
CA		7.9 - 12.0			
TP		5.2 - 8.2			
ALB		2.3 - 4.0			
GLOB		2.5 - 4.5			
ALB/GLOB					
ALT		10 - 125	HIGH		
ALKP		23 - 212			
GGT		0 - 11			
TBIL		0.0 - 0.9			
CHOL		110 - 320	HIGH		
AMYL		500 - 1500			
LIPA	200 - 1800				

Client:
Patient:

B6

Vitals Results

1/3/2019 1:44:42 PM	Weight (kg)	33.4000
1/3/2019 1:44:49 PM	Heart Rate (/min)	110.0000

Client:
Patient:

B6

ECG from cardio

B6

1/3/2019 3:28:10 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

B6

Client
Patient

B6

ECG from cardio

B6

1/3/2019 3:28:10 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

ECG from cardio

B6

1/3/2019 3:28:46 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

B6

Client:
Patient:

B6

ECG from cardio

B6

1/3/2019 3:29:45 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from cardio

B6

1/3/2019 3:30:38 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

B6

Client:
Patient:

B6

ECG from cardio

B6

1/3/2019 3:30:38 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client:
Patient:

B6

Radiograph

B6

9/20/18

B6

Client:
Patient:

B6

Urine strip

B6

Client:
Patient:

B6

Urine strip

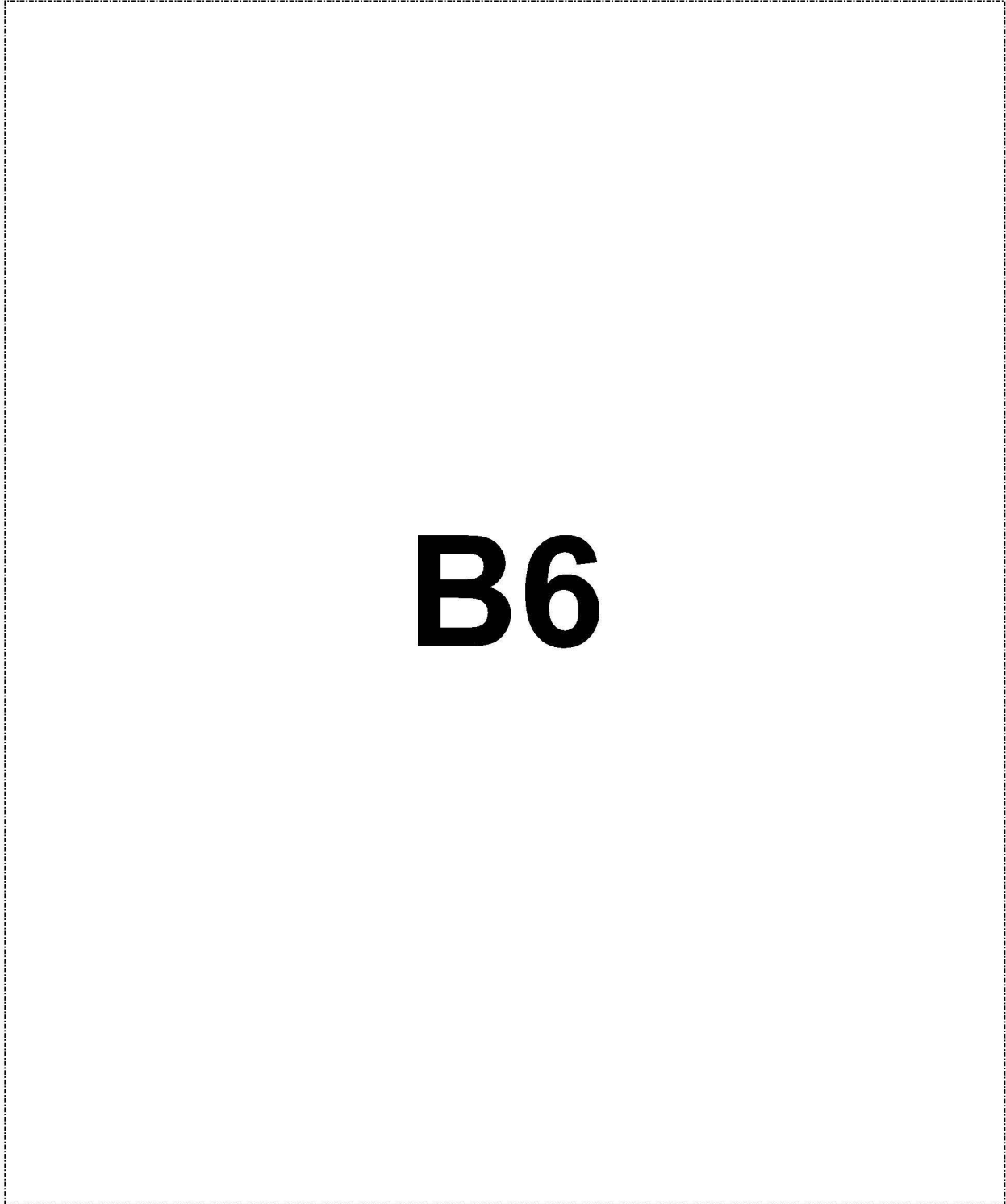
B6

Client:
Patient:

B6

Alivecor from cardio

Patient: **B6** (yrs)
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Monday, January 7, 2019 at 11:29:27 PM
Heart Rate: 140 bpm Duration: 34 s



B6

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

AliveCor from cardio

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Monday, January 7, 2019 at 11:29:27 PM
Heart Rate: 140 bpm Duration: 34 s



B6

Client:
Patient:

B6

Alivecor ECG

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Tuesday, January 29, 2019 at 9:23:52 PM
Heart Rate: 126 bpm Duration: 1 min 32 s

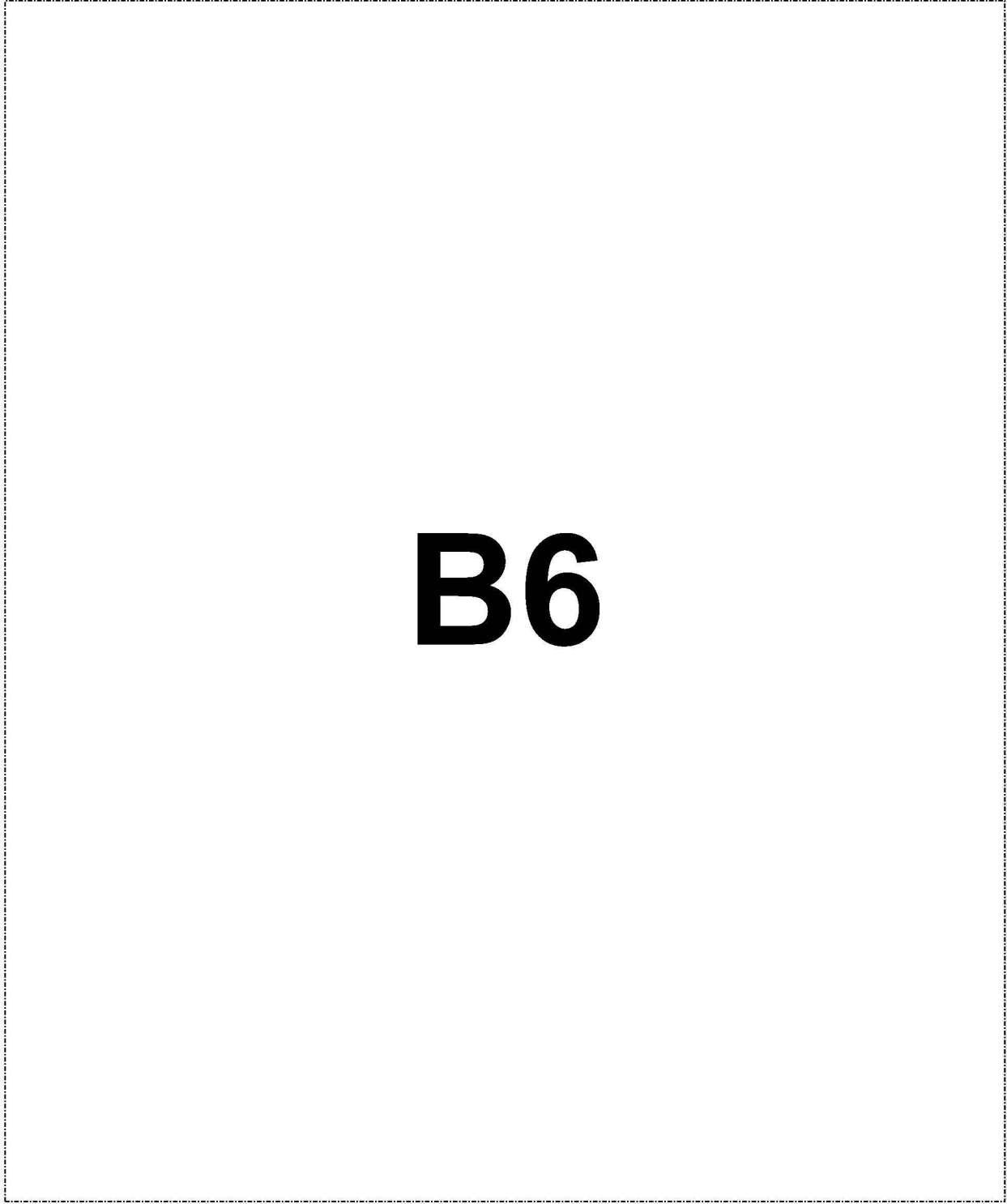


B6

Client: **B6**
Patient:

AliveCor ECG

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Tuesday, January 29, 2019 at 9:23:52 PM
Heart Rate: 126 bpm Duration: 1 min 32 s



Client:
Patient: **B6**

Alivecor ECG

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Tuesday, January 29, 2019 at 9:23:52 PM
Heart Rate: 126 bpm Duration: 1 min 32 s



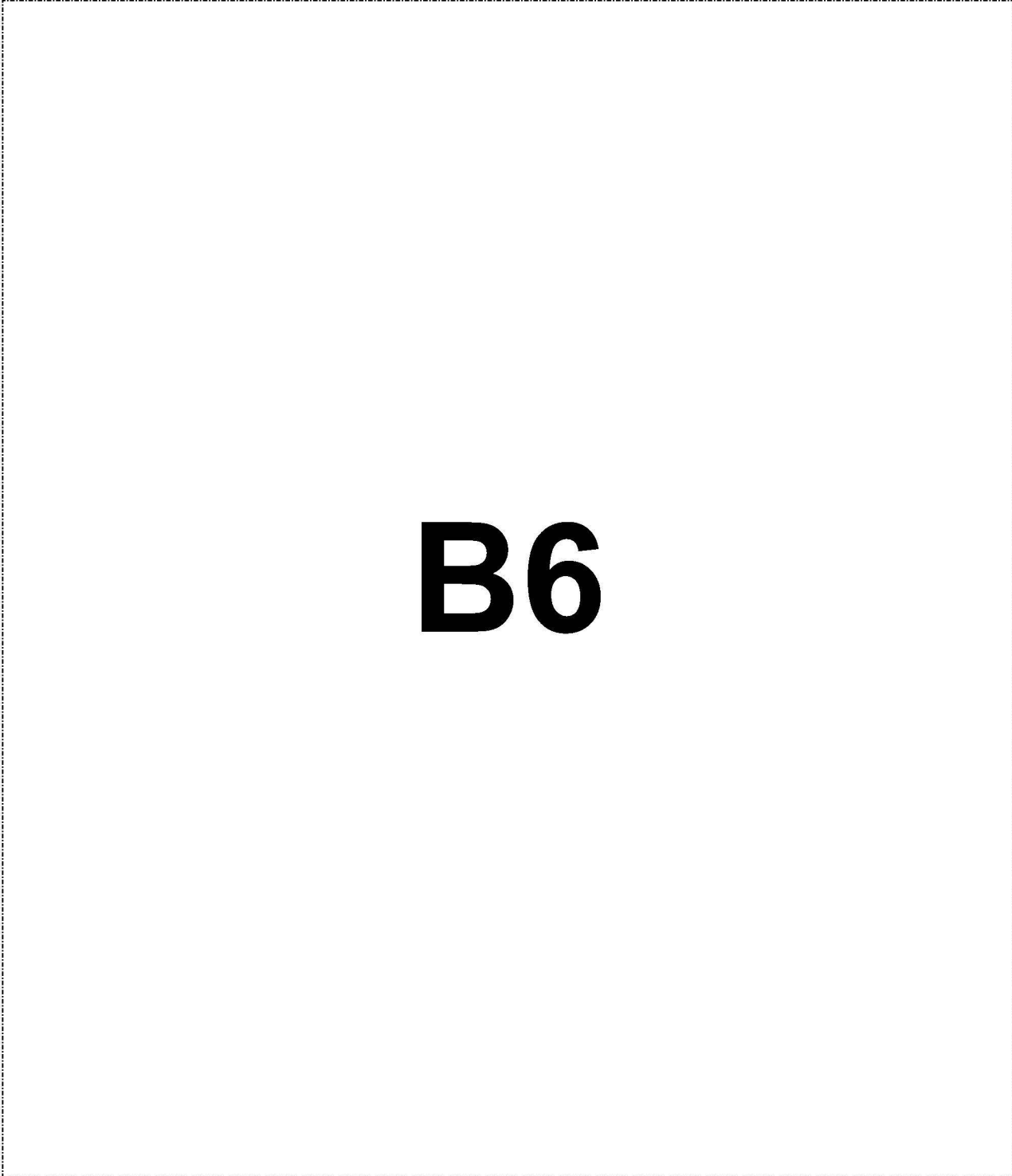
B6

Client:
Patient:

B6

Alivecor ECG

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Saturday, March 2, 2019 at 5:44:52 PM
Heart Rate: 93 bpm **Duration:** 1 min



B6

Client: **B6**
Patient:

Alivecor ECG

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Saturday, March 2, 2019 at 5:44:52 PM
Heart Rate: 93 bpm Duration: 1 min



B6

Client:
Patient:

B6

Alivecor ECG from cardio

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm Duration: 1 min 38 s



B6

Client:
Patient:

B6

Alivecor ECG from cardio

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm **Duration:** 1 min 38 s



B6

Client:
Patient:

B6

Alivecor ECG from cardio

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm Duration: 1 min 38 s



B6

Client:
Patient:

B6

Alivecor ECG from cardio

Patient: **B6**
Breed/Species: American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm **Duration:** 1 min 38 s



B6

Client:
Patient:

B6

Patient History

01/02/2019 12:50 PM	Appointment
01/03/2019 01:06 PM	UserForm
01/03/2019 01:16 PM	Treatment
01/03/2019 01:44 PM	Vitals
01/03/2019 01:44 PM	Vitals
01/03/2019 03:07 PM	Deleted Reason
01/03/2019 03:09 PM	Purchase
01/03/2019 03:10 PM	UserForm
01/03/2019 03:25 PM	Purchase
01/03/2019 03:25 PM	Purchase
01/03/2019 03:33 PM	Prescription
01/03/2019 03:33 PM	Prescription
01/03/2019 03:38 PM	Prescription
01/03/2019 03:47 PM	Purchase
01/03/2019 04:08 PM	Appointment
01/04/2019 06:18 PM	Purchase
01/17/2019 11:15 AM	Appointment

B6

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
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Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
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Thursday, 03 January 2019 15:09 Appointment: Cardiology Study

B6

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
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Thursday, 03 January
2019 15:33

B6

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
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Thursday, 03 January
2019 15:33

B6

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
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Thursday, 03 January
2019 15:38

B6

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Thursday, 03 January 2019 15:46	Pharmacy Finished	1.000	0.000	0.0000	0.0000	0.0000

Client:
Patient:

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
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Friday, 04 January
2019 18:18

B6

Foster Hospital for Small Animals

Phone: (508) 839-5395

FHSA@tufts.edu

<http://vetmed.tufts.edu/>

Patient Report Card For B6 1/2/2019

**Weight
(kg)**

Foster Hospital for Small Animals

Phone: (508) 839-5395

FHSA@tufts.edu

<http://vetmed.tufts.edu/>

B6

**Weight
(kg)**

Patient Report Card For **B6 3/2019**

Discharge Instructions

Patient

Name: B6
Species: Canine
Breed: Brindle/Blue Male (Neutered) Pit Bull
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: 436257

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

Appointment Date: 1/3/2019

Diagnoses: Dilated cardiomyopathy (DCM)

Ventricular arrhythmias (ventricular tachycardia, ventricular bigeminy)

Case summary:

Thank you for bringing B6 to Tufts Cardiology Service for evaluation of his collapsing episodes and arrhythmia that was noticed at your referring veterinarian. B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. Fortunately, we caught this condition relatively early and B6 does not appear to be in congestive heart failure yet. However, if you notice that B6 breathing rate is faster than normal at home we will want to have chest x-rays taken. B6 also have some arrhythmias that are likely secondary to his heart disease. We will be starting him on some medications to mitigate the heart disease that he has and the arrhythmias that he is experiencing. We would like to adjust B6 diet and we provided some dietary recommendations below.

Diagnostic test results and findings:

- **Echocardiogram findings:** The walls of the chambers of his heart are thinner than normal and he has reduced contractile function. The left ventricle and left atrium are dilated.
- **ECG findings:** The ECG showed arrhythmias that are ventricular in origin.
- **Labwork findings:** We will call you when we have the results of his bloodwork. Most of it should come back tomorrow, but some of it will take a week or so to return.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. If you notice that his respiratory rate is elevated, we recommend that you bring him to your referring veterinarian for chest x-rays so that we can see if his heart disease has progressed.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.

Recommended Medications:

B6

Exercise Recommendations:

B6

B6

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)

Royal Canin Boxer

Purina Pro Plan Adult Weight Management (may be more cost-efficient)

Canned Food Options:

Hill's Science Diet Adult Beef and Barley Entree

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew

Royal Canin Mature 8+

Recheck Visits:

Thank you for enrolling **B6** in our clinical study. We would like to see an Alivacor reading in around two weeks once he has had some time on the anti-arrhythmic medication, or send one earlier if you are having any concerns. It would also be great if you can obtain an Alivacor reading if **B6** has another episode of collapse or abnormal behavior.

B6 is scheduled for an appointment on April 4th, 2019 at 4:00 P.M. We will perform an echo, ECG and bloodwork at this time.

If you would like to have your other dogs who have been eating the same diet as **B6** screened as part of the study, please call or email to set up an appointment in the near future.

Thank you for entrusting us with **B6** care! It was a pleasure to meet you all today and he was a very good boy. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case:

B6

Owner:

B6

Discharge Instructions

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

AliveCor/Kardia Handout

If you have an iPhone or Android, you may want to explore the option of purchasing an AliveCor/Kardia ECG monitor which will allow you to record and email your pet's heart rate and rhythm at home.

The device (Kardia) can be purchased at www.alivecor.com or www.amazon.com. The app for your phone is free.

If you have an iPhone:

- Search for "Veterinary AliveECG" app in the Apple Store
- You will need to sign-up for an account
- Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker portal, say "OK/allow"

If you have an Android:

- Search for "Kardia" app in the Google Playstore
- You will need to sign-up for an account.
- Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker portal, say "OK/allow"
- Once downloaded, it will require you to send a "test ECG" for activation of the app. Just place your fingers on the silver sensors and let it record
- If the test ECG is unable to record, try again, with less movement. If it still fails, then your phone is not compatible with the device

Recording an ECG:

- Apply rubbing alcohol (soaked cotton ball will work) to the chest region behind your pet's elbow (where you can feel the heartbeat)
- Enough to wet the regions where both silver boxes will touch the animal
- If your pet is fluffy, you may have to clip a small patch of fur to allow for better contact
- Hold the device against your pet's chest with the silver areas being up and down (vertical) in contact with the animal
- With the app open, hold your phone near (within a few inches) the device.
- There is a signal bar in the upper left corner of the app to show whether it detects the device. If there are no bars then move your phone around/get closer to the device until they appear.
- Once you see a recording, hold everything in place for at least 30 seconds if possible.
- *The human Kardia app will attempt to interpret the ECG; just ignore this as it is not always accurate.*
- *The heart rate that the apps report is also not always accurate.*

Saving an ECG:

- The app will automatically save the ECG as long as the recording is long enough (>20seconds)
- You can click on the ID (box with pencil icon) in the Veterinary AliveECG app to add your pet's name

Emailing an ECG:

- If you are in the recording screen on the Veterinary AliveECG app, click on "ECGs" to see the list of saved ECGs
- If you are in the home screen on the Kardia app, click "History".
- Select the ECG you wish to send. Go to "Share". Select "Email PDF". **SKIP** the Password protect feature and select the email app you wish to send it by (Gmail, outlook, yahoo, etc). **You must have a working email on your phone for this to work.**
- Select an ECG that you wish to send
- Click the mail icon (either a box with arrow or a letter symbol), and select "Email"
- Email to: cardiovet@tufts.edu (*only monitored Monday-Friday 9AM-5PM*)

B6

Patient ID: 436257

B6

Canine

Years Old Male (Neutered) Pit Bull
Brindle/Blue

Cardiology Appointment Report
ENROLLED IN DCM STUDY

Date: 1/3/2019

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student

B6

Presenting Complaint:

Episodes of collapse over past year

Concurrent Diseases:

B6

Kennel cough in September - CXR at rDVM

General Medical History:

First episode occurred about a year ago - owner originally thought that she had given him too much

B6

He takes it in the winter because he is reactive to snow falling off the roof. Dog fight about to break out later that day and he collapsed.

Has had 5-6 episodes in the past year where he collapses - maintains consciousness, gum color is normal and he is alert. He is usually down for 30-60 seconds. Takes around a couple of hours after the event to go back to normal (lethargic).

All of these had been stimulated by a dog or a lot of arousal. Twice in past month.

Most recent episode was on Saturday - weasel in the yard and **B6** got very worked up. Didn't fully collapse but laid down and wouldn't move. This more recent time he was spinning and acting nauseous (lip smacking). Took into the rDVM where they diagnosed an abnormal arrhythmia.

Chest rads from September, 4DX negative.

Diet has been reduced in the past week, will eat if the food is elevated.

Started urinating in the house about a year ago, believed to be behavioral.
Possibly PUPD in the past couple of months.

Diet and Supplements:

For Health grain free diet until 2 weeks ago For Health
Switched to non-grain free For Health 1 cup and 1/4 BID
Nupro powder

B6

Cardiovascular History:

Prior CHF diagnosis? No
Prior heart murmur? No
Prior ATE? No
Prior arrhythmia? Yes
Monitoring respiratory rate and effort at home? No
Cough? No
Shortness of breath or difficulty breathing? Snoring, raspy
Syncope or collapse? yes
Sudden onset lameness? No
Exercise intolerance? No

Current Medications Pertinent to CV System:

None

Cardiac Physical Examination:

B6

B6

Problems:

Collapse

Arrhythmia

Differential Diagnoses:

DCM/CHF vs tachyarrhythmia vs bradyarrhythmia vs non-cardiac cause of collapse

Diagnostic plan:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Echocardiogram | <input type="checkbox"/> Dialysis profile |
| <input type="checkbox"/> Chemistry profile | <input checked="" type="checkbox"/> Thoracic radiographs +/- |
| <input checked="" type="checkbox"/> ECG | <input checked="" type="checkbox"/> NT-proBNP |
| <input type="checkbox"/> Renal profile | <input type="checkbox"/> Troponin I |
| <input type="checkbox"/> Blood pressure | <input type="checkbox"/> Other tests: |

Echocardiogram Findings:

B6

B6

Assessment and recommendations:

Echocardiogram and ECG reveal DCM and frequent ventricular arrhythmia. There is enough cardiac enlargement to be compatible with CHF and radiographs were discussed, but the owners perceive him to be breathing comfortably and will continue to monitor RR at home for now. If RR at home is 35 or higher then thoracic radiographs are recommended to assess for CHF. Holter monitor was discussed, but there was enough arrhythmia today to consider starting antiarrhythmic therapy and owners are planning to obtain a Kardia for at home ECG monitoring. The longstanding occurrence of collapse episodes (~1 year) is less consistent with these episodes being clearly related to his heart disease, but there is significant arrhythmia so it is possible the intermittent VT could be causing collapse. Recommend attempting to obtain a Kardia reading during an event if they continue, and if this is not successful then consider 24h Holter monitor. Recommend diet change to a main-stream brand suggestion from Dr Freeman. Patient was enrolled in DCM study so taurine levels, BNP, troponin, CBC/chemistry were submitted as part of the study. Recheck echo and blood work in 3 and 6 months as part of the study. Recheck sooner if clinical sign occur such as increased RR/RE, repeated collapse, cough, or exercise intolerance. The housemates of this dog who have been eating the same diet are eligible for screening as part of the DCM study.

Start:

B6

Addendum: Blood worked showed significant azotemia and mild increase in ALT. Recommend stopping and submitting u/a +/- culture and the treating with a course of There is concern for the with the increased ALT, but given the limited options and severity of arrhythmia, recommend continuing for now and rechecking liver values in 2-3 weeks. Recheck blood work sooner if patient stops eating. Unfortunately, if the azotemia does not resolve and the cardiac disease continues to worsen then it may become difficult to balance advanced renal disease and CHF in the future.

Final Diagnosis:

DCM

Ventricular arrhythmia (VPCs, couplets, triplets, non sustained R on T VT)

Heart Failure Classification Score:

ISACHC Classification:

- | | |
|--|-------------------------------|
| <input type="checkbox"/> Ia | <input type="checkbox"/> IIIa |
| <input checked="" type="checkbox"/> Ib | <input type="checkbox"/> IIIb |
| <input type="checkbox"/> II | |

ACVIM Classification:

- | | |
|--|----------------------------|
| <input type="checkbox"/> A | <input type="checkbox"/> C |
| <input type="checkbox"/> B1 | <input type="checkbox"/> D |
| <input checked="" type="checkbox"/> B2 | |

M-Mode

IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
EDV(Teich)	ml
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
Ao Diam	cm
LA Diam	cm
LA/Ao	
Max LA	cm
EPSS	cm

M-Mode Normalized

IVSdN	(0.290 - 0.520)
LVIDdN	(1.350 - 1.730) !
LVPWdN	(0.330 - 0.530)
IVSsN	(0.430 - 0.710)
LVIDsN	(0.790 - 1.140) !
LVPWsN	(0.530 - 0.780) !
Ao Diam N	(0.680 - 0.890) !
LA Diam N	(0.640 - 0.900) !

2D

SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
EDV(Teich)	ml
IVSs	cm
LVIDs	cm
LVPWs	cm
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
LV Major	cm
LV Minor	cm
Sphericity Index	
LVLd LAX	cm
LVA d LAX	cm
LVEDV A-L LAX	ml

B6

LVEDV MOD LAX
LVLs LAX
LVA_s LAX
LVESV A-L LAX
LVESV MOD LAX
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX

Doppler

MR Vmax
MR maxPG
MV E Vel
MV DecT
MV Dec Slope
MV A Vel
MV E/A Ratio
E'
E/E'
A'
AV Vmax
AV maxPG
PV Vmax
PV maxPG

B6

ml
cm
cm
ml
ml
BPM
%
%
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ml
l/min
l/min

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mmHg
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mmHg

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

B6

Male (Neutered)

Canine Pit Bull Brindle/Blue
436257

1/4/2019

Dear **B6**

Thank you for referring **B6** with their pet **B6**

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6

DVM (Cardiology)

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 3/26/2019 2:00:39 PM
Subject: Taste of the Wild Venison & Legume die [B6] EON-383371
Attachments: 2064630-report.pdf

A PFR Report has been received and PFR Event [EON-383371] has been created in the EON System.

A "PDF" report by name "2064630-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-383371

ICSR #: 2064630

EON Title: PFR Event created for Taste of the Wild Venison & Legume diet; 2064630

AE Date	03/06/2019	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Unknown		
Age			
District Involved	PFR- [B6] DO		

Product information

Individual Case Safety Report Number: 2064630

Product Group: Pet Food

Product Name: Taste of the Wild Venison & Legume diet

Description: Originally submitted as RFR EON-383367. CVM resubmitting as PFR. The patient has been eating a grain free diet, specifically the Taste of the Wild Venison & Legume diet for years. He presented on 3/6/19 and the owner reported a mild cough but he felt it was resolving and declined a work up at that time. He presented again on 3/12/19 since the cough had not resolved and we started a work up of the patient that included thoracic radiographs. The patient was/is in congestive heart failure with an enlarged heart. The pet's breed is not a common breed for DCM and with the dietary history of a high legume grain free diet I feel that this is dietary induced.

Submission Type: Initial

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

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

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Venison & Legume diet		

Sender information

B6

USA

Owner information

B6

Unknown USA

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

<https://eon.fda.gov/eon//browse/EON-383371>

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=400469>

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