

# Questions & Answers: FDA Center for Veterinary Medicine's Investigation into a Possible Connection Between Diet and Canine Heart Disease

Updated June 27, 2019

*The FDA is investigating reports of canine dilated cardiomyopathy (DCM) in dogs eating certain pet foods. While it is an ongoing investigation, the Center for Veterinary Medicine recognizes that you may have questions. Below we have compiled answers to address some of the frequently asked questions raised by pet owners and veterinarians.*

## **1. What potential connection is the FDA investigating?**

FDA is investigating a potential dietary link between canine dilated cardiomyopathy (DCM) and dogs eating certain pet foods containing legumes like peas or lentils, other legume seeds (pulses), or potatoes as main ingredients. We began investigating after FDA's Center for Veterinary Medicine (CVM) received a number of reports of DCM in dogs eating these diets.

DCM itself is not considered rare in dogs, but these reports are unusual because many of the reported cases occurred in breeds of dogs not typically genetically prone to the disease. Additionally, most of the cases ate diets that appear to contain high concentrations/ratios of certain ingredients, such as peas, chickpeas, lentils and/or various types of potatoes. Some of these were labeled as "grain-free," but grain-containing diets were also represented.

## **2. What is the FDA doing to learn more about this possible connection?**

The FDA's Center for Veterinary Medicine (CVM) is working with the Veterinary Laboratory Investigation and Response Network, a collaboration of government and veterinary diagnostic laboratories to investigate several avenues. Our veterinarians, animal nutritionists, epidemiologists and pathologists are working with board certified veterinary cardiologists and veterinary nutritionists to better understand the clinical presentation of the cases and potential ties to diet. The agency has also been in contact with pet food manufacturers to learn more about product formulation and concentration of certain ingredients in order to help further the investigation. In addition, we are analyzing information from case reports submitted by pet owners and veterinarians. We will continue to work with all of these stakeholders to help advance our ongoing investigation. For more information see FDA Investigation into Potential

[Link between Certain Diets and Canine Dilated Cardiomyopathy \(/animal-veterinary/news-events/fda-investigation-potential-link-between-certain-diets-and-canine-dilated-cardiomyopathy\).](#)

### **3. What additional information would help further the FDA's investigation?**

FDA is encouraged by the response of both pet owners and veterinary professionals in providing information about dogs diagnosed with DCM. As we delve further into the role that diet may play in these cases, we plan to explore additional avenues about ingredient concentration, bioavailability, sourcing, and processing to determine if there are any common factors. We encourage pet food companies with reports of DCM for their products to assist the investigation with information to help us better understand how the proportion of certain ingredients may affect the disease.

### **4. What is canine dilated cardiomyopathy (DCM)?**

DCM is a disease of a dog's heart muscle and results in an enlarged heart. As the heart and its chambers become dilated, it becomes harder for the heart to pump, and heart valves may leak, which can lead to a buildup of fluids in the chest and abdomen (congestive heart failure). If caught early, heart function may improve in cases that are not linked to genetics with appropriate veterinary treatment and dietary modification.

### **5. Why did the FDA notify the public about the possible connection if the agency doesn't have definitive answers?**

The FDA's Center for Veterinary Medicine (CVM) felt a responsibility to shed light on a signal that we have been made aware of and to solicit reports from pet owners and vets that may know of related cases. The data provided through reports will help inform the investigation.

### **6. How many cases have been reported to the FDA?**

Between January 1, 2014 and April 30, 2018, the FDA received 524 case reports of diagnosed dilated cardiomyopathy. Some of these cases involved more than one animal from the same household. In the reported cases, there were 560 individual dogs diagnosed with DCM and 119 of those dogs died. There were 14 individual cats, 5 of which died. The agency received additional reports of cardiac symptoms in dogs, however, the reports did not include a confirmed DCM diagnosis.

### **7. What brands of food have been included in the reports to the FDA?**

There is a range of different brands and formulas included in the reports and some reports named multiple brands and/or formulas. The FDA has compiled a spreadsheet of all DCM case reports submitted through April 30, 2019 (</media/128303/download>). Brands named most frequently in reports submitted to the FDA (as of April 30, 2019) that had at least ten reports, include Acana (67), Zignature (64), Taste of the Wild (53), 4Health (32), Earthborn Holistic (32), Blue Buffalo (31), Nature's Domain (29), Fromm (24), Merrick (16), California Natural (15), Natural Balance (15), Orijen (12), Nature's Variety (11), NutriSource (10), Nutro (10), and Rachael Ray Nutrish (10). These include both grain-free and grain-containing diets in all forms (kibble, canned, raw, home-cooked). The common thread appears to be legumes, pulses (seeds of legumes), and/or potatoes as main ingredients in the food. This also includes protein, starch and fiber derivatives of these ingredients, (e.g., [source] protein, [source] starch, or [source] fiber). Some reports we have received also seem to indicate that the pets were not eating any other foods for several months to years prior to exhibiting signs of DCM.

## **8. Has the FDA asked any of these brands to recall?**

The FDA has not yet determined the nature of the possible connection between these foods and canine DCM, so we do not have definitive information indicating that the food needs to be removed from the market. We have shared case report information with these firms so they can make informed decisions about the marketing and formulation of their products. We are also sharing this information with the public, but encourage pet owners to work with their veterinarians, who may consult with a board-certified veterinary nutritionist, prior to making diet changes.

## **9. What are legumes? What are pulses?**

Legumes are part of the Fabaceae plant family and are the fruit or seed of these plants. Common legumes include peas, beans, lentils, chickpeas, soybeans and peanuts. Pulses are dry edible seeds of certain legume plants. Examples include dried beans, dried peas, chickpeas and lentils. Not all legumes are pulses, but all pulses are legumes. Legumes/pulses are used as an ingredient for both human and animal food and have become a common plant-based source of protein. Many of these ingredients have long been included in pet food. Recently, the proportion of legumes and/or pulses has increased significantly in certain diets, including many labeled as "grain-free" or "zero-grain."

## **10. Does the FDA think this possible link includes diets with rice?**

Rice is a grain, not a legume. The current reports mostly involve diets labeled as "grain-free", however the small number of reports received for foods that contain rice (including brown rice) do not suggest there is any link between diets with rice and DCM in dogs.

## **11. Are sweet potatoes and red potatoes classified as potatoes?**

Yes.

## **12. What does the FDA consider a “main ingredient”?**

There is formal definition for what qualifies as a “main ingredient.” We generally consider a “main ingredient” to be the first 10 ingredients listed in a food’s ingredient list before the first vitamin or mineral ingredient.

## **13. Does the FDA know what it is about these foods that may be connected to canine DCM?**

At this time, it is not clear what it is about these diets that may be connected to DCM in dogs. There are multiple possible causes of DCM. Taurine deficiency is well-documented as a potential cause of DCM, but it is not the only cause of DCM. Nutritional makeup of the main ingredients or how dogs process them, main ingredient sourcing, processing, amount used, or other factors could be involved.

## **14. How do I know if my pet’s food is one of the diets discussed in the FDA’s public notification?**

We suggest reviewing the ingredient list on your pet’s food to see whether legumes, pulses and/or potatoes are listed as one of the main ingredients. You may also wish to review the compilation of all the DCM reports submitted to the FDA through April 30, 2019 (</media/128303/download>), to see what pet owners and veterinarians have reported to the FDA. FDA encourages pet owners to work with their veterinarians, who may consult with a board-certified veterinary nutritionist, prior to making diet changes.

## **15. Should I avoid grain-free diets?**

High levels of legumes, pulses or potatoes appear to be more common in diets labeled as “grain-free,” but it is not yet known how these ingredients may be linked to cases of DCM. Additionally, legumes/pulses and potatoes may appear as ingredients in foods that are not labeled as “grain-free.” Changes in diet, especially for dogs with DCM, should be made in consultation with a licensed veterinarian.

The prevalence of reports in dogs eating a grain-free diet might correlate also to market share: these products have become exceedingly popular over the last several years. Although there are significantly fewer reports of dogs who ate diets containing grains, the FDA has received some complaints associated with grain-containing diets.

## **16. Do I need to change my dog's diet?**

At this time, we are not advising dietary changes based solely on the information we have gathered so far. If you have questions or concerns about your dog's health or its diet, we suggest that you consult your veterinarian, who may consult a board-certified veterinary nutritionist, for individualized advice that considers your dog's specific needs and medical history.

## **17. What's the safest diet for my dog?**

Different dogs have different nutritional needs based on a number of factors, so nutrition advice is not one-size-fits-all. The FDA recommends asking your veterinarian, who may consult a board-certified or veterinary nutritionist, for advice about what to feed your dog.

It's important to note that the reports include dogs that have eaten grain-free and grain containing foods and also include vegetarian or vegan formulations. They also include all forms of diets: kibble, canned, raw and home-cooked. Therefore, we do not think these cases can be explained simply by whether or not they contain grains, or by brand or manufacturer.

To put this issue into proper context, the American Veterinary Medical Association estimates that there are 77 million pet dogs in the United States. As of April 30, 2019, the FDA has received reports about 560 dogs diagnosed with DCM suspected to be linked to diet. Tens of millions of dogs have been eating dog food without developing DCM. If you are concerned about the diet you are currently feeding your dog, FDA recommends working with your veterinarian, who may consult a board-certified veterinary nutritionist, to determine the best diet for your dog's need.

## **18. Is there a list of firms that have not had any DCM cases reported in connection with their food?**

No, for the simple reasons that FDA does not have a comprehensive list of all foods on the market and because the investigation has not yet identified a root cause for the reports of DCM.

Additionally, any reports of illness thought to be connected to food products are voluntary. We rely on pet owners and veterinarians to provide reports of illness, as well as clinical evidence to help document the case. Unlike in human health, there is no centralized reporting system comparable to the Centers for Disease Control and Prevention, which utilizes reports through medical professionals, consumers, and state, local and tribal health agencies.

## **19. Does FDA approve pet food before it can be marketed?**

FDA does not have pre-market authority over pet foods generally, with the exception of food additives, meaning that pet food manufacturers can market products without FDA review or approval but that those products must be safe and properly labeled. Generally, FDA must

establish that a food presents a potential hazard to human or animal health or is otherwise in violation of applicable laws before taking any regulatory or enforcement action.

## **20. Is FDA doing any inspections of the manufacturers of foods reported in possible connection with DCM cases?**

At this time, the FDA is still investigating. While we have identified a potential relationship between consumption of these diets and DCM, additional information is needed to understand how these animals developed DCM. For most inspections of the pet food industry, FDA currently uses a hazard prevention approach, as described by our Food Safety Modernization Act (FSMA) food safety regulations, and we will utilize that approach as appropriate.

## **21. What is it about Golden Retrievers that seems to make them more prone to diet-related DCM?**

One thing to keep in mind is that the Golden Retriever is the second most popular breed of dog in the United States, according to the American Kennel Club. Another note is that the Golden Retriever community has been sharing information via social media about this potential link for some time and many people with connections to the breed are more aware of the issue (and likely more inclined to submit reports).

Golden Retrievers are known to have taurine deficiencies and heart issues that the FDA does not believe are representative of the overall population of dogs.

## **22. What should I do if my dog is experiencing symptoms of DCM?**

If your dog is showing possible signs of DCM or other heart conditions, including decreased energy, cough, difficulty breathing and episodes of collapse, you should contact your veterinarian. Your veterinarian may ask you for a thorough dietary history of all the foods (including treats) the dog has eaten.

## **23. How do vets and consumers submit reports to the FDA?**

CVM encourages pet owners and veterinary professionals to report cases of DCM in dogs suspected of having a link to diet by using the electronic Safety Reporting Portal (<http://www.safetyreporting.hhs.gov/>) or calling their state's FDA Consumer Complaint Coordinators (</safety/report-problem/consumer-complaint-coordinators>).

## **24. What information does the FDA need included in the reports?**

Please see “How to Report a Pet Food Complaint (</animal-veterinary/report-problem/how-report-pet-food-complaint>)” for additional instructions and information.

## **25. I submitted my report to FDA. When will I hear back from them about my complaint, and will they collect any samples for testing?**

FDA will determine whether there is a need to conduct follow-up contact or to obtain diagnostic samples (e.g. tissue, blood, leftover food) for possible testing. While FDA does not necessarily respond to every individual complaint submitted, each report becomes part of the body of knowledge that helps to inform the FDA on the situation or incident.

## **26. How long will the FDA’s investigation take?**

There is no way to know how long the investigation will take, but CVM is hopeful that as we gather more data from case reports, we will gain a better understanding of this possible connection. We will continue to convey our observations publicly as the investigation progresses.