

Submitted online

November 13, 2020

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: FOIA Request for all medical records and diet histories for dogs reported to the FDA-CVM as diet associated DCM cases from a timeframe of January 2014 through October 2020.

BSM Partners submits this request for information under the Freedom of Information Act ("FOIA") and the Food & Drug Administration ("FDA") FOIA regulations.

I. Records requested

BSM Partners is requesting all medical records and diet histories in the FDA's possession, custody or control for dogs reported to the FDA-CVM as having DCM and DCM phenotype as reported to the agency by veterinarians and consumers between the dates of January 2014 through October 2020.

II. Request for a fee waiver

BSM Partners requests that FDA waive the fee it would otherwise charge for search and production of the records listed above. Per FOIA, these records must be provided without charge "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii); see also 21 C.F.R. § 20.46. The requested disclosure meets these specific requirements as laid out in the Act.

a. The request concerns the operations or activities of the government

BSM Partners' request concerns data collected by the FDA to inform federal actions concerning a hypothesized link between dilated cardiomyopathy (DCM) and grain-free dog food products.

b. The disclosure is "likely to contribute" to an understanding of government operations and activities

c. Undo harm to the pet can result from misdiagnosis and treatment of dogs with other medical conditions not consistent with DCM as well as unnecessary veterinary costs to the pet owning consumer as a result of this.

This disclosure will allow the public and the scientific community to review the underlying data collected by the FDA that was the basis for multiple public comments by the agency about the magnitude and scale of diet-related cases of DCM. The release of this information could contribute to further ongoing research as a basis for prospective and retrospective studies among cardiology referral practices examining differential diagnoses for “DCM phenotype”. This is a term coined recently by veterinary cardiologists encompassing a signalment of an enlarged heart silhouette.

d. The information will contribute to the understanding of the general public

This disclosure of these government activities will benefit the public as the issue of diet and canine dilated cardiomyopathy (“DCM”), a rare heart condition most often associated with a dog’s genetics/heredity, is of significant concern to the 63.4 million American households with dogs. The release of the medical records and diet histories with individuals’ names redacted would also benefit and lay the ground work for a broader study looking at other hereditary, infectious, environmental and animal management practices that could also contribute to heart conditions such as DCM in dogs.

FDA Actions To-Date

Over the last three years years, the FDA has expressed a concern about a possible link between grain-free dog food, many of which contain peas, lentils, and other legumes, and DCM based on owner-submitted reports they had received. As such, the agency’s Center for Veterinary Medicine (CVM) issued a public communication on [July 12, 2018](#), to make the American people aware of this development.

An additional update was released on [February 19, 2019](#). Here the FDA noted that, between January 1, 2014 and November 30, 2018, they had received 294 reports of owner-submitted reports of canine DCM in dogs whose diet composed of, at least in part, grain-free dog food. Further, based on those reports, the FDA listed 16 brands of grain-free dog food they determined were most frequently associated with adverse events linked to DCM. This understandably led to much public concern. On [June 27, 2019](#), the agency announced they had to-date received a total of 515 owner-submitted reports of canine DCM. To be sure, not all of these reports contained the dog’s complete diet history or long-term health information, including evidence of concurrent illnesses that may have impacted their status.

On [September 29, 2020](#), as part of their presentation at a forum on canine dilated cardiomyopathy hosted by Kansas State University, FDA noted that, as of July 2020, they had now received more than 1,100 owner-submitted reports of DCM in dogs. At the time, the

agency presented additional data on only 150 of those reports, what they described as a “small subset” – less than 14% – of the overall cases they have received to-date.

There was no mention if the FDA is reviewing the information such as medical records and diet histories of the other dogs that it has in its possession as a result of the FDA’s public request that veterinarians and consumers report cases of suspected diet-associated DCM to the agency.

We would also note that the FDA has continued to request reports of dogs with DCM that are eating grain-free dog food. However, they have not requested reports of dogs with DCM not eating grain free dog food. This decision has inevitably led to the creation of biased data from which the FDA is basing its public communications.

The Need for Public Release of the FDA’s Underlying Data

In order to determine whether a link exists between canine DCM and grain-free dog food, and to better protect the health of millions of dogs, we are requesting the release of the entirety of the FDA’s data set of owner-submitted cases to-date based on the following:

The FDA indicated during the Kansas State forum that to determine the 150 owner-submitted reports that warranted further study, their scientists “used a multidisciplinary investigational approach” to “separate out general cardiac cases from DCM.” If the FDA utilized this process to identify where they believe DCM is present, and then only released investigatory data on just 150 cases, it is unclear how many of the 1,100 reports they have received – a number that has generated significant media attention – are actual cases of DCM that can be analyzed to determine whether this condition is in any way related to grain-free dog food.

Further, the complete histories of the dogs described in the 150 cases discussed by the FDA on September 29th were reviewed but not released to the public.

Access to the FDA’s underlying data is important given research presented by BSM Partners as part of the same Kansas State DCM forum, and included in a [publicly available](#) manuscript currently under peer-review for publication in a scientific journal. BSM Partners found that data collected from 14 cardiology services over 20 years did not support a significant change nationally in canine DCM incidence over time, nor a correlation with grain-free pet food sales. The average incidence rate of DCM at participating cardiology referral practices from 2000 to 2019 was 3.86% and ranged between 2.41% and 5.65%. At the same, time grain-free pet food sales increased at least 500% from 2011 to 2019 according to market data from GFK Nielsen. In other words, one would expect a rise in veterinary cardiologist-diagnosed DCM cases as grain-free pet food surged in popularity, but this data indicates otherwise.

V. Expedited Processing Request

Aggregating expertise to protect canine health

FOIA provides federal agencies must provide for expedited processing of requested records where a “compelling need” is present. 5 U.S.C. § 552(e)(i). Such a need exists here, so BSM Partners requests expedited processing.

The FDA, by providing access to the underlying data on cases it has already referenced publicly, will allow the scientific community to quickly harness its vast capabilities and augment the finite resources of the agency, so that we can more quickly determine whether fears about grain-free dog food are grounded in fact, to protect the health of millions of pets currently eating grain-free diets, and allay the concerns of dog owners.

Detrimental health effects to canine population and undue costs to pet owners

Currently, without definitive evidence to support the link between grain-free diets and DCM, many dogs have been switched from diets that may have been more beneficial for their specific nutritional needs, such as dogs with previously diagnosed food allergies and intolerances that had been eating grain-free and novel protein diets. Additionally, due to the fear of grain-free diets resulting in DCM, some dogs are being misdiagnosed by primary care veterinarians. For example, Dr. Eva Oxford has evaluated dogs with pericardial effusion, in which fluid accumulates within the sac surrounding the heart, thus impeding cardiac output. The dogs were treated inappropriately for congestive heart failure, under the assumption that the clinical signs were due to grain-free diet related DCM. Instances like these lead to undue suffering to the pet and unnecessary veterinary costs to the owner.

VI. Conclusion

Our request is consistent with the FDA’s overall communications efforts regarding DCM. In both private and public settings, the FDA has attributed the statements about its DCM investigation to the need to be transparent with stakeholders. Furthermore, the FDA has indicated that its receipt of Freedom of Information Act (FOIA) requests obligated the agency to release adverse event data and portions of individual dogs’ medical records, and the statements were intended to provide context for the release of that case information. However, this primary case information has not been made available widely or comprehensively, and to the extent that it establishes the basis for the FDA’s statements, it should be released forthwith for further scientific evaluation.

Note remarks by Dr. Steven Solomon, Director of the FDA’s Center for Veterinary Medicine, at the Kansas State forum: “We subsequently received multiple requests under the Freedom of Information Act [FOIA] for this adverse event data that we are obligated to release upon request. And while I acknowledge that this generated angst, it is in keeping with another one of my guiding principles, that we should act openly and transparently with all parties. It is typical that whenever we raise awareness of an issue as we did with these advisories, we get more reports coming in to us.”

We are also encouraged by Dr. Solomon's public [comments](#) that the agency sees this broad look into the causes of DCM "as an ongoing, collaborative, multidisciplinary scientific venture", and concur with his [observation](#) at the Kansas State forum, "that scientific work and exchanges among this community will hopefully continue and expand, especially identifying any scientific gaps and collaborating to fill those gaps." We feel that it is vitally important to review in detail the medical records and diet histories of each of the 1,100 cases categorized by FDA as being categorized by Dr. Solomon as meeting the FDA-CVM's case definition of having DCM and specifically DCM related to diet. This sharing of vital information is consistent with Dr. Solomon's statement that the "FDA will continue to collaborate with ongoing scientific endeavors".

To that end, we will continue to publish our work on this matter in peer-reviewed journals, both to inform the public and help our research colleagues in the fields of veterinary medicine, veterinary nutrition and veterinary cardiology as they undertake studies that produce appropriately controlled, original research.

Thank you for your assistance with this request. If you have any questions, please contact me via email or phone.

Sincerely,



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