June 27, 2019

By Email
Ms. Susan Thixton
Association for Truth in Pet Food
P.O. Box 954
Safety Harbor, FL 34695

Dear Ms. Thixton:

I am the Ombudsman for the Food and Drug Administration's Office of Regulatory Affairs. The Center for Veterinary Medicine (CVM) has asked me to attend and facilitate the upcoming meeting between you, your attorney, and CVM.

It is my understanding that you are available to meet on July 10 or 11, 2019; however, before the date of the meeting is set, it would be helpful to have a better understanding of the topics you would like to discuss with CVM. To that end, please provide me with a proposed agenda specifying the topics you wish to address and your availability during the weeks of July 15th and July 29th. For purposes of developing your agenda, please assume the meeting will be for 60-90 minutes.

On June 17, 2019, after you and CVM began to discuss dates for the meeting, on behalf of the Association for Truth in Pet Food (ATPF), you filed a petition for reconsideration of the April 30, 2019 decision on ATPF's citizen petition (Docket No. FDA-2016-P-3578). As you consider the topics you want to discuss at the upcoming meeting, I want to make sure you are aware that I will not have any role in the agency's review of your petition for reconsideration, and moreover, under FDA's regulations, your petition for reconsideration "may not be based on information and views not contained in the administrative record on which the decision was made." 21 C.F.R. § 10.33(e). Thus, if you wish to present information at the meeting regarding the subject of the citizen petition that was not part of the administrative record at the time the agency responded to the citizen petition, that information will not be considered as part of your pending petition for reconsideration. Instead, if you want "to rely on information or views not included in the administrative record," then you will need to submit "a new petition to modify the [April 30, 2019] decision under §10.25(a)." *See* 21 C.F.R. § 10.33(e); *see also id.* § 10.30(j).

Sincerely,

Jessica Zeller

cc: Tracey Forfa, Deputy Director, CVM

Period of Agreement

This agreement, when accepted by both parties, will have an effective period of performance from date of signature until 10/01/2024 (and may be modified by mutual consent by both parties or may be extended or terminated as agreed upon by FDA and AAFCO). Any notice of termination will be published in the Federal Register.

Approved and Accepted for FDA:
/s/
Steven Solomon, DVM, MPH
Director, Center for Veterinary Medicine
U.S. Food and Drug Administration
Date: June 20, 2019

Approved and Accepted for AAFCO:
/s/
Robert Geiger
2019 AAFCO President
Date: June 25, 2019

1. Some articles added to animal feed fall under the purview of other federal agencies. Feed-through pesticides are regulated by the Environmental Protection Agency (EPA), and vaccines added to animal feed are the responsibility of the US Department of Agriculture (USDA).

Susan Thixton <susan@truthaboutpetfood.com>

Follow Up

31 messages

CVM OMBUDSMAN <CVMOMBUDSMAN@fda.hhs.gov> Thu, Aug 1, 2019 at 3:24 PM
To: "susan@truthaboutpetfood.com" <susan@truthaboutpetfood.com>
Cc: "Zeller, Jessica" <Jessica.Zeller@fda.hhs.gov>

Dear Susan,

We are sorry that it has taken longer than originally anticipated to get back to you about a facilitated conversation. Unfortunately, given the overlap between the issues you would like to discuss, and the recent lawsuit filed by Lystn, LLC against FDA and others, and because it's the Agency's policy to not comment on issues in litigation, it would not be appropriate to participate in a facilitated discussion with you at this time.

However, we are open to having a listening session, where you could present your views on the topics you have identified. We want to make sure you understand, however, that during the session, we will not be able to answer any questions you may have or respond to any information you present. One of the topics you wanted to discuss with FDA was the Memorandum of Understanding (MOU) between FDA and AAFCO, so we wanted to let you know that the MOU with AAFCO has been renewed. The MOU is available at https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001. During the listening session you would have an opportunity to present your views about the MOU and elaborate on the concerns you raised in your prior communications about the MOU.

If you are interested in having a listening session, either in person or by teleconference, we propose scheduling it for some time in late August.

Please let us know how you would like to proceed. Kindest regards, Tracey