

November 3, 2022

Kohl Harrington Director – Pet Schooled

Re: Docket Nos. FDA-2022-P-0107, FDA-2022-P-0121, and FDA-2022-P-0754

Dear Mr. Harrington:

This letter responds to your citizen petitions (FDA-2022-P-0107, FDA-2022-P-0121, and FDA-2022-P-0754), dated January 27, 2022, February 3, 2022, and May 7, 2022, respectively. These petitions request that FDA-CVM hold at least one public regulatory meeting in the years 2023, 2024, and 2025, for the "continued development of animal feed and pet food ingredients FDA intents [sic] to recognize federally, and ensure this public meeting complies with the § 553 of the Administrative Procedure Act."

Section 21 CFR 10.65 governs meetings that may be held between representatives of FDA and interested persons outside FDA on matters within the jurisdiction of the laws administered by FDA. If the Agency concludes that it would be in the public interest to hold an open public meeting to discuss a matter pending before FDA, we inform the public of the time and place for the meeting and the topics to be discussed. Interested persons may attend and participate in the meeting as described in the meeting notice.

FDA-CVM held a public meeting on the oversight of pet food on September 24, 2021, at which you spoke. During calendar year 2023, FDA intends to provide the public with additional opportunities to share input on animal food-related topics, such as the FDA's role in the Association of American Feed Control Officials (AAFCO) animal food ingredient definition process. As details for these opportunities are finalized, FDA will publicize them by posting information on its website, including on the FDA Meetings, Conferences and Workshops webpage at https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops. CVM

¹ <u>https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/fda-virtual-listening-session-oversight-pet-food.</u>

² FDA is in the process of reviewing sixteen citizen petitions submitted to FDA by you and others to date that include requests related to FDA's Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO) and the development of animal food definitions. See FDA-2021-P-0436, FDA-2021-P-0476, FDA-2021-P-0700, FDA-2021-P-0882, FDA-2021-P-0883, FDA-2021-P-0884, FDA-2021-P-0924, FDA-2021-P-0927, FDA-2021-P-0949, FDA-2021-P-0950, FDA-2021-P-0953, FDA-2021-P-1044, FDA-2022-P-0063, FDA-2022-P-0213, FDA-2022-P-0253, FDA-2022-P-0356, available at Regulations.gov. As stated in the tentative response to your petition FDA-2021-P-0436, FDA is considering the concerns raised by these petitions and will provide a final response to you after completing our legal and policy analyses. Similarly, FDA will provide a final response to the other petitioners on these issues at that time.

has not yet determined what, if any, additional opportunities for public input it intends to provide in 2023, 2024, and 2025. We encourage you to monitor FDA's website for opportunities to participate in meetings of interest to you.

In accordance with 21 CFR 10.30(e)(3), we deny your petition.³ However, we understand that there has been increased public interest in animal food and animal food ingredients over the past several years, and that stakeholders would like the opportunity to provide input on a variety of animal food topics. Although we are denying your requests, FDA intends to hold public meetings pursuant to 21 CFR 10.65 if we conclude that such meetings would be in the public interest. As details for public meetings are finalized, FDA will post information on its website.

Respectfully,

Steven Solomon -S Digitally signed by Steven Solomon -S Date: 2022.11.03 10:03:34

Steven M. Solomon, DVM, MPH Director, Center for Veterinary Medicine

³ Because FDA action on a meeting does not constitute final administrative action subject to judicial review, this response is not reviewable by a court. See 21 CFR 10.45(d)(2)(i) and 10.65(a).