U.S. FOOD & DRUG ADMINISTRATION

February 2, 2023

Ronald Brock
(b) (6)

Re: Docket Nos. FDA-2022-P-0172 and FDA-2022-P-0174

Dear Mr. Brock:

This letter responds to the following citizen petitions you submitted:

> FDA-2022-P-0172, filed February 14, 2022, requesting "FDA hold a public comment session and opportunity for the animal feed/pet food ingredient 'Suncured Alfalfa Meal' "prior to FDA-CVM recognizing the ingredient federally, in compliance with federal law, § 553 of the Administrative Procedure Act;" and
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> FDA-2022-P-0174, filed February 14, 2022, requesting "FDA hold a public comment session and opportunity for the animal feed/pet food ingredient 'Black Soldier Fly Larvae' "prior to FDA-CVM recognizing the ingredient federally, in compliance with federal law, § 553 of the Administrative Procedure Act."

In accordance with 21 CFR 10.30(e)(3), we deny your petitions.[1]

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.

For example, FDA-CVM held a public meeting on the oversight of pet food on September 24, 2021.[2] During calendar year 2023, we intend 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.[3] As

[1] 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).
[2] https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/fda-virtual-listening-session-oversight-pet-food.

[3] 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-

details for these opportunities are finalized, we will publicize them by posting information on our website, e.g., on the FDA's Meetings, Conferences and Workshops webpage at https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops. We encourage you to monitor the FDA website for opportunities to participate in meetings of interest to you.

With respect to your specific statements that FDA hold public meetings "prior to FDA-CVM recognizing the ingredient[s] federally, in compliance with federal law, § 553 of the Administrative Procedure Act," it appears that you are conflating FDA's participation in the AAFCO Feed Ingredient Definition process with notice and comment rulemaking. AAFCO definitions are not federal definitions and are not subject to 5 U.S.C. § 553, the notice and comment rulemaking requirements of the Administrative Procedure Act.

Although we are denying your petitions, 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. We intend 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, we will post information on our website.

Respectfully,

William T. Flynn -S

Digitally signed by William T. Flynn -S
Date: 2023.02.02 11:50:05 -05'00'

William T. Flynn, DVM, MS
Deputy Director for Science Policy
Center for Veterinary Medicine

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-0884, 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.