U.S. FOOD & DRUG ADMINISTRATION

December 22, 2022

Harry Duty
(b) (6)

Re: Docket No. FDA-2022-P-1367

Dear Mr. Duty

This letter responds to your citizen petition, FDA-2022-P-1367, dated June 28, 2022. Your petition requests that FDA respond to two questions submitted through the Center for Veterinary Medicine's AskCVM mailbox in May 2022 regarding "avian influenza poultry being used as ingredients in pet food products under FDA regulatory jurisdiction."

We are denying your petition in accordance with 21 CFR 10.30(e)(3) because your petition does not ask the Commissioner to take a specific administrative action, which is an element of citizen petitions. Our regulations at 21 CFR 10.30(b)(3) require that a petition request the Commissioner to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action. Your petition does not request such action.[1]

The remainder of this letter is a reply to certain statements you made in your petition. In your Statement of Grounds, you criticize AskCVM and contend that CVM does not hold public meetings or ask Congress for adequate funding. With regard to your criticism of CVM's AskCVM mailbox, we refer you to our response to your citizen petition FDA-2022-P-1407, which raised similar issues. In our response to that petition, we explained that "AskCVM is a resource provided by CVM that allows members of the public to submit questions to CVM. AskCVM also may respond on behalf of individual CVM staff members who receive questions directly from the public. CVM requests that stakeholders use the AskCVM mailbox so that inquiries can be properly logged, tracked, and forwarded to the appropriate parties for response. Having one email address that receives questions and disseminates information allows for the best use of CVM resources. It allows CVM to triage inquiries and seek appropriate input from subject matter experts. Moreover, to the extent that AskCVM can provide responses to questions that have already been answered, it frees up CVM staff and management to work on other pressing matters. Although CVM tries to respond to inquiries in full and in an expeditious manner, we are not always able to do so." We went on to explain, in a footnote, that "[F]or example, CVM does not always respond to questions submitted to the AskCVM mailbox that

[1]Furthermore, FDA responded to the referenced AskCVM inquiries on December 2, 2022, saying, "USDA makes decisions about depopulating flocks due to disease, including avian influenza. We intend to continue to work closely with USDA to analyze the appropriate disposition (including rendering) of any such flocks on a case-by-case basis, based on the best information available at that time. Based on our conversations with USDA, it is our understanding that none of the depopulated birds associated with the current outbreaks were sent to rendering."

appear rhetorical in nature, that are duplicate questions already asked and answered, or that involve describing internal practices, discussions, or deliberations."

With regard to your assertion that FDA-CVM refuses to hold public meetings, we disagree and direct you to FDA's webpages on CVM Workshops, Conferences & Meetings, at https://www.fda.gov/animal-veterinary/news-events/workshops-conferences-meetings, and CVM Past Events, at https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/cvm-past-events. There you can find examples of several public meetings we have held and are planning to hold on a variety of issues, including those involving animal food. We specifically want to point out the following FDA webpage, https://www.fda.gov/animal-veterinary/cvm-updates/fda-opens-registration-virtual-public-meeting-fdas-role-aafco-animal-feed-ingredient-definition?utm_medium=email&utm_source=govdelivery, which announces a virtual public meeting to be held on "FDA and the AAFCO Animal Feed Ingredient Definition Process." We encourage your participation in that meeting.

With regard to your assertion that FDA-CVM does not request "additional" funding from Congress, we disagree. As explained in our response to one of your previous citizen petitions (FDA-2022-P-0119), a large part of our work is accomplished using discretionary funds (i.e., funds not otherwise earmarked by Congress or received as part of user fee programs). We continue to request funding to accomplish all of our important public health work. FDA's budget documentation for Fiscal Year 2023, available at https://www.fda.gov/about-fda/reports/budgets, shows a budget request seeking additional funding for CVM, including funding to support essential services and business functions. This specifically includes efforts to increase capacity for responding to FOIA requests.

Sincerely,

Steven Solomon -S

Digitally signed by Steven Solomon -S
Date: 2022.12.22 14:34:35 -05'00'

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