February 28, 2022

Via Electronic Submission

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305) Rockville, MD 20852

Re: Citizen Petition- Asking FDA-CVM To Hold Public Meetings For Animal Feed Ingredient Regulations, And Withdraw MOU 225-07-7001 With AAFCO

To whom it may concern:

The undersigned submits this petition under both the Federal Food, Drug, and Cosmetic Act (the Act), and § 553 of the Administrative Procedure Act (5 U.S.C. Subchapter II), and pursuant to 21 C.F.R. §§ 25.30 and 25.34 and 21 C.F.R. § 10.30(b), to request the FDA-CVM to withdraw MOU 225-07-7001.

A. Action Requested

Petition requests FDA-CVM to withdraw MOU 225-07-7001, an agreement between FDA and private corporation AAFCO. Instead, FDA should develop animal feed terms and definitions publicly and in compliance with §553 of the Administrative Procedure Act.

B. Statement of Grounds

FDA has a MOU with AAFCO, where FDA "recognizes" the "official definitions" of AAFCO. This MOU is MOU 225-07-7001. AAFCO is a private corporation, operated by a board of directors of ***public*** state regulatory employees, and FDA employees sit on AAFCO's board of directors as well.

FDA's Center for Veterinary Medicine (CVM) hosted a virtual listening session on Friday, September 24, 2021, on the Agency's oversight of pet food. FDA-CVM stated in their meeting announcement "FDA regulates the ingredients, manufacturing and labeling of pet food, including treats. Pet food can be for a variety of companion species such as dogs, cats, birds, gerbils, hamsters, snakes and lizards."

During this meeting, Steven Solomon of FDA-CVM referred to the public state regulatory partners as FDA's "state partners", saying "Our state regulatory partners also play a major role in both our inspectional work, our response activities, particularly when there's an issue with pet food."

Mr. Solomon was not entirely truthful with the public regarding "state partners" and the level of involvement FDA-CVM defers to them on federal matters, specifically on animal feed and pet food regulatory work. According to MOU 225-07-7001, "*The Association of American Feed*

Control Officials (AAFCO) is a voluntary membership organization of the states in the United States (US) and Federal government agencies… responsible for the execution of laws and regulations pertaining to the production, labeling, distribution, use, or sale of animal feed and feed ingredients." The word "voluntary" is a twist on words, because most "state partners" are required by their public regulatory jobs to attend AAFCO meetings and to participate in the organization. What Mr. Solomon didn't publicly admit during this "listening session" was how year after year, FDA-CVM recognizes AAFCO ingredients federally, in a process where these ingredients and their definitions are developed privately with the participation of FDA employees. The process violates various aspects of §553 of the Administrative Procedure Act, including the public comment requirement, prior to FDA-CVM recognizes them as binding federal law.

Essentially, FDA-CVM has helped privatize the pet food regulation process, and is consistently engaged in this privatized process, which should instead be an open part of our democracy. Instead, FDA-CVM and their state partners charge citizens exorbitant entry fees to their meetings, and the meetings are not compliant with §553 of the Administrative Procedure Act, even though FDA-CVM fully intends to "recognize" the material being developed in private via MOU 225-07-7001. The most disturbing aspect of these public regulators is how they have "restricted access" to certain members of the public who have dissented against them. FDA-CVM has not had any issue with members of the public being banned from these regulatory meetings, and FDA-CVM plans to indefinitely continue to operate in private partnership with states for pet food regulations.

From a legal argument, states "reference" the AAFCO model regulations and ingredient definitions in their respective state laws. There are many outstanding legal issues there, given that most states are not complying with their own state based administrative procedures act. However, for the purpose of this citizen petition, FDA-CVM takes a similar stance federally via MOU 225-07-7001. The entire process can still exist if FDA-CVM were to hold these pet food regulatory meetings, publicly. States could then "reference" the publicly developed/created federal ingredient. Presently, FDA-CVM refuses to provide copies of animal feed regulations because FDA says the public regulators own the copyright. If ingredients are developed publicly, §553 of the Administrative Procedure Act requires the material to be available for free on the federal register. This would greatly benefit members of the public. This process of FDA-CVM holding public regulatory meetings allows the "state partners" to continue to have a voice in the process. Public meetings simply make the entire process more equitable for all. The process now via MOU 225-07-7001 is not an equitable process, and is violating many rights afforded to citizens under § 553 of the Administrative Procedure Act

I request FDA to immediately withdraw from MOU 225-07-7001, and instead start holding public meetings where regulations for animal feed ingredients are developed publicly, in compliance with § 553 of the Administrative Procedure Act.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 C.F.R. §§ 25.30 and 25.34.

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by FDA following review of the petition. The undersigned will promptly provide this information if requested.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Tyler Burch (Feb 28, 2022 14:16 CST)

Tyler Burch

(b) (6)