February 22, 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 Withdraw MOU 225-07-7001 With AAFCO, And Hold PULBIC Meetings For Animal Feed Ingredient Regulations

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 And Hold Public Meetings.

A. Action Requested

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

B. Statement of Grounds

FDA-CVM is a federal agency that should be promulgating regulations for pet food ingredients intended to be used in products in interstate commerce, in compliance with §553 of the Administrative Procedure Act. Instead, FDA-CVM has developed a process where definitions for animal feed and pet food ingredients for products intended for use in interstate products, are created privately, cutting out members of the public, violating many aspects of §553 of the Administrative Procedure Act.

FDA-CVM routinely engages in private meetings with FDA's "state partners", all under a private corporation umbrella they call "AAFCO" (Association Of Feed Control Officials), at least twice per year.. This "private corporation" is where FDA and their state partners create "official definitions" for animal feed and pet food ingredients that FDA fully intends to "recognize" at the federal level as acceptable for use in pet food products in interstate commerce via MOU 225-07-7001.

However, FDA-CVM did not comply with many aspects of §553 of the Administrative Procedure Act.

According to information found on the federal register, https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf, "*The proposed*

rule, or Notice of Proposed Rulemaking (NPRM), is the official document that announces and explains the agency's plan to address a problem or accomplish a goal. All proposed rules must be published in the Federal Register to notify the public and give them an opportunity to submit comments. The proposed rule and the public comments received on it form a basis of the final rule." FDA-CVM does not engage in any "notice of proposed rulemaking" when it comes to animal feed and pet food ingredients FDA-CVM employees help promulgate via private meetings, prior to automatically accepting those same ingredient terms federally via MOU 225-07-7001.

According to the same information document link above found on the federal register, "agencies will specify a comment period ranging from 30 to 60 days in the "Dates" section of the Federal Register document, but the time period can vary." FDA-CVM is not complying with any public comment requirement required by §553 of the Administrative Procedure Act. When FDA "accepts" these pet food ingredients at the federal level that it helped develop in private at this private corporation, FDA is violating §553 of the Administrative Procedure Act because I have not had the opportunity to comment on any regulations FDA-CVM has accepted to become binding federal regulations via MOU 225-07-7001.

FDA has stated that they have no plans to hold public regulatory meetings to develop pet food regulations. Instead, FDA plans to continue to "recognize" ingredients developed in private at this private corporation, AAFCO, for the rest of time. I request FDA to immediately withdraw from MOU 225-07-7001, and instead start holding PUBLIC meetings where regulations for animal feed and pet food 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.

(b) (6)

Leslie Novosel (Feb 22, 2022 10:26 CST)

Leslie Novosel
Citizen and Stakeholder

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