February 3, 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 At Least One Public Regulatory Meeting In The Year 2023, For The Promulgation Of Animal Feed/Pet Food Ingredients And Their Definitions, In Compliance With Requirements § 553 of the Administrative Procedure Act.

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 in accordance with 21 C.F.R. § 10.30(b), to request the FDA-CVM to hold at least one public regulatory meeting in 2023, for the promulgation of animal feed/pet food ingredients and their definitions, in compliance with the public rulemaking requirements of § 553 of the Administrative Procedure Act.

## A. Action Requested

Petition requests FDA-CVM to hold at least one public regulatory meeting in the year 2023, for the continued development of animal feed and pet food ingredients FDA intents to recognize federally, and ensure this public meeting complies with the § 553 of the Administrative Procedure Act.

## **B.** Statement of Grounds

For years, I have been paying to attend private meetings that AAFCO holds, where FDA is engaging in a privatized version of federal rulemaking for animal feed ingredients. FDA holds a MOU with AAFCO, and via that MOU with this private corporation, FDA "recognizes" all ingredients in the AAFCO OP as acceptable for use in animal feed products in interstate commerce. Animal feed products in interstate commerce falls under FDA regulatory jurisdiction. FDA assists and participates with the AAFCO ingredient definition process via MOU 225-07-7001.

FDA-CVM plans to continue to adopt privately developed ingredients and their definitions (regulations) in 2023. FDA-CVM is aware that I am going to have to continue to pay large sums of money to attend these meetings, and view what is essentially a privatized rulemaking process for animal feed ingredients and their definitions.

As a citizen, my being required to pay to attend these meetings where definitions for animal feed ingredients subject to FDA jurisdiction, and each year recognized by FDA as acceptable for use in animal feed in interstate commerce, is a violation of the requirements of § 553 of the Administrative Procedure Act.

Due to FDA having MOU 225-07-7001 with this private corporation AAFCO, which is a collection of public regulatory officials performing rulemaking via a private corporation umbrella, my rights under \$553 of the Administrative Procedure Act are being violated year after year.

FDA-CVM holding a public regulatory meeting in 2023 and ensuring this regulatory meeting for the development of animal feed and pet food ingredients is compliant with the requirements of §553 of the Administrative Procedure Act, would rectify the ongoing issues of my ability to participate in the rulemaking process without the requirement of a large fee, my ability to participate in the rulemaking process publicly instead of privately, and my ability to comment on all proposed ingredients prior to FDA accepting them federally for use in animal feed products in interstate commerce.

Petition requests FDA-CVM to hold a public regulatory meeting in the year 2023, in compliance with the §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.

