January 1, 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 Propose Official FDA Regulation on Salmonella In Animal Feed (Pet Food), In Compliance With § 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 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 issue a regulation for salmonella in animal food. FDA's current interpretation of 21 U.S. Code § 342, titled "Compliance Policy Guide Sec. 690.800 Salmonella in Food for Animals", violates § 553 of the Administrative Procedure Act.

A. Action Requested

Petition requests FDA-CVM to issue a regulation on this matter, and ensure the regulation is passed in compliance with federal law, § 553 of the Administrative Procedure Act.

B. Statement of Grounds

21 U.S. Code § 342 states "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

FDA-CVM further interpreted this law, in violation of § 553 of the Administrative Procedure Act. Specifically, FDA-CVM has interpreted and considers "all" salmonella strains in "any" quantity to be "adulterants". 21 U.S. Code § 342 states clearly does not deem "all" salmonella strains to be considered adulterants, given that salmonella is not an "added" substance. FDA-CVM's further interpretation of 21 U.S. Code § 342 is FDA-CVM's is masked as a "compliance policy "Sec. 690.800 Salmonella in Food For Animals."

FDA-CVM regulates industry with this compliance policy where they have interpreted federal law in violation of § 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.

