PET SCHOOLED

The Educated Community

December 30, 2020

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 Issue An Official Regulation On The Matter Of Animals That Have Died Other Than Slaughter, For Use In FDA Regulated Animal Feed, Dog, & Cat Foods

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), to request the FDA-CVM to issue an official regulation on the matter of *Animals That Have Died Other Than Slaughter, For Use In FDA Regulated Animal Feed, Dog, & Cat Foods*

A. Action Requested

Petition requests FDA-CVM to issue an official regulation on the matter of *Animals That Have Died Other Than Slaughter, For Use In FDA Regulated Animal Feed, Dog, & Cat Foods*

B. Statement of Grounds

FDA-CVM is a subagency of the FDA. The FDA is an agency within the Department of Health and Human Services, and is subject to both the Federal Food, Drug, and Cosmetic Act (the Act), and § 553 of the Administrative Procedure Act (5 U.S.C. Subchapter II).

FDA has stated that "pentobarbital is routinely used to euthanize animals." FDA has also stated "the most likely way it could get into dog food would be in rendered animal products." Additionally, FDA has stated, "Rendered products come from a process that converts animal tissues to feed ingredients. Pentobarbital seems to be able to survive the rendering process. If animals are euthanized with pentobarbital and subsequently rendered, pentobarbital could be present in the rendered feed ingredients."

According to federal law, animals which have died other than slaughter are illegal to use. Per Section 402 of the Federal Food, Drug, and Cosmetic Act, adulterated food is stated to be "A food shall be deemed to be adulterated – (a) Poisonous, insanitary, or deleterious ingredients." "(a)(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter."

In the final response for citizen petition FDA-2016-P-3578, FDA stated, "we do not believe that the use of diseased animals or animals that have died other than by slaughter to make animal food poses a safety concern." Specifically, FDA continued by stating "we intend to continue to exercise enforcement discretion" on the matter at hand.

Given that FDA remains firm on the position of allowing illegal ingredients to be used in FDA regulated animal feed and pet food products, I request that FDA promulgate an official FDA federal regulation on the matter of *Animals That Have Died Other Than Slaughter, For Use In FDA Regulated Animal Feed, Dog, & Cat Foods*, and ensure this regulation be 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.

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