May 09, 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 For The Ingredient "Cracked Pearled Barley" For Use In FDA Regulated Animal Feed & Pet Food Products

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 a regulation for the ingredient "Cracked Pearled Barley" for use in FDA regulated animal feed and pet food products.

A. Action Requested

Petition requests FDA-CVM to propose and issue a new regulation on this matter, and ensure the regulation is passed in compliance with federal law, § 553 of the Administrative Procedure Act. Specifically, petition requests the FDA-CVM to issue a regulation for the ingredient "Cracked Pearled Barley" for use in FDA regulated animal feed and pet food products. FDA-CVM should define this term, hold public meetings on this term, take public comments on this term, conduct scientific review for this term, and post this official regulation both on the FDA website and on the federal register.

This petition allows FDA the opportunity to comply with § 553 of the Administrative Procedure Act, of which FDA has never complied with even though FDA allows for "Cracked Pearled Barley" to be a widely used ingredient in FDA regulated products.

B. Statement of Grounds

"Cracked Pearled Barley" is an ingredient FDA allows to be used in animal feed and pet food products under FDA regulatory jurisdiction.

FDA has never issued any official federal regulation for the ingredient or definition of "Cracked Pearled Barley" in compliance with § 553 of the Administrative Procedure Act.

Although "Cracked Pearled Barley" is a widely used ingredient FDA allows to be used in products in interstate commerce, there is no regulatory definition on the FDA website or in/on the federal register for this specific ingredient.

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.

Donavan Melton (May 9, 2022 12:59 CDT)

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