January 5, 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 "Suncured Alfalfa Meal" 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), and in accordance with 21 C.F.R. § 10.30(b), to request the FDA-CVM to issue a regulation for the ingredient "Suncured Alfalfa Meal" 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 "Suncured Alfalfa Meal" 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 "Suncured Alfalfa Meal" to be a widely used ingredient in FDA regulated products.

B. Statement of Grounds

FDA-CVM helped develop the animal feed ingredient term and definition for "Suncured Alfalfa Meal", in violation of § 553 of the Administrative Procedure Act. After developing this animal feed term privately, via private meetings instead of public meetings required by § 553 of the Administrative Procedure Act, FDA now allows the ingredient "Suncured Alfalfa Meal" to be used in animal feed products.

The specific language for this requested FDA regulation:
Suncured Alfalfa Meal: the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, which has been dried by solar means, stored as bales or stacks, and finely or coarsely ground. If it is chopped instead of ground, it must be designated as "Suncured Chopped Alfalfa" or "Chopped Alfalfa Hay."

Please note, the above requested definition is only a suggestion, and obviously the rulemaking process required by § 553 of the Administrative Procedure Act (5 U.S.C. Subchapter II) would develop this suggested regulation further if needed.

FDA-CVM has previously stated that it has "limited resources to prepare, draft, and publish a regulation" for animal feed ingredients. I note that FDA-CVM has not provided specifics regarding what "resources" are needed in order for FDA-CVM to perform their job as required by § 553 of the Administrative Procedure Act (5 U.S.C. Subchapter II). I also note that a broad and vague claim of "limited resources" is not allow for FDA-CVM to violate binding requirements they're subject to under § 553 of the Administrative Procedure Act (5 U.S.C. Subchapter II).

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

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[redacted]