March 7, 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 "Corn Gluten 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 "Corn Gluten 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, and in accordance with 21 C.F.R. § 10.30(b). Specifically, petition requests the FDA-CVM to issue a regulation for the ingredient "corn gluten 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 "corn gluten meal" to be a widely used ingredient in FDA regulated products.

Under section 401 of the FD&C Act, the Agency may promulgate regulations to establish definitions and standards for food to "promote honesty and fair dealing in the interest of consumers." For the reasons identified below in the "statement of grounds", FDA-CVM should promulgate a new regulation for "corn gluten meal".

B. Statement of Grounds

On regulations.gov, a final response from FDA-CVM to a citizen petition with the tracking number FDA-2021-P-0912, states the following information from FDA-CVM:

- "Corn gluten meal" is a common ingredient in pet food.
- FDA has not established a definition for "corn gluten meal" for use in animal food, and there is no Federal requirement that animal food ingredients be defined.
- Corn gluten meal is among the ingredients AAFCO has defined.
- Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that ingredients be declared on the label by their common or usual names.

- "Corn gluten meal" appears to be the common or usual name for ingredients conforming to the AAFCO definition and is declared in the ingredient statement on the labels of animal food in compliance with 21 CFR 501.4(a).

Actually, "corn gluten meal" is not a "common or usual name" in compliance with 21 CFR 501.4(a). The ingredients sulfur dioxide and anhydrous ammonia, required for the production of "corn gluten meal", are registered as a toxic chemical substance with EPA, and continues to be regulated under the 1990 toxic substances control act (TSCA), Inventory Update Rule (IUR).

Both ingredients each have their own, privately developed definitions in the AAFCO book. The anhydrous ammonia definition gives the limit for the level allowed in the product, which is equal to the toxicity limit on the MSDS (material safety data sheet). There are also antibiotics used in the production of corn gluten meal, which are specifically forbidden for use in animals. They include virginiamycin and erythromycin.

In FDA-2021-P-0912, FDA-CVM "notes" *corn gluten is listed as a substance affirmed as generally recognized as safe (GRAS) for use in human food in 21 CFR 184.1321*. It is confusing why FDA-CVM noted the human food definition for "corn gluten", given that "corn gluten meal" is not a human food definition. "Corn gluten meal" is a privately developed feed grade ingredient which contains toxic substances, while "corn gluten" is a human grade ingredient. Is FDA-CVM saying that the human food definition for "corn gluten" in 21 CFR 184.1321 is the same as "corn gluten meal", an ingredient privately developed by "public" regulators via a private corporation umbrella called AAFCO?

It is clear that the current definition for "corn gluten meal" is not GRAS. FDA-CVM is attempting to say that any ingredient published by AAFCO, is considered by FDA-CVM to be GRAS, because "which have come into common usage through adoption by States, manufacturer compliance, and consumer recognition." That simply is not true. This specific case with the ingredient "corn gluten meal", the definition violates 21 CFR 501.4(a). An animal feed ingredient can not be both GRAS and potentially a toxic substance as per current regulations of EPA.

Under section 401 of the FD&C Act, the Agency may promulgate regulations to establish definitions and standards for food to "promote honesty and fair dealing in the interest of consumers." FDA-CVM's current definition for "corn gluten meal", although FDA has not established a definition for "corn gluten meal" for use in animal food, is not an honest or fair definition in the interest of consumers. If animal feed and pet food ingredients contain toxic substances as per EPA, the regulatory definition should reflect those facts and the potential health consequences associated with such an ingredient.

Proposed Regulation Definition:

Corn Gluten Meal: is the dried residue from corn after the removal of the larger part of the starch and germ, and the separation of the bran by the process employed in the wet milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm. It may contain fermented corn extractives and/or corn germ meal. The ingredients sulfur dioxide and anhydrous ammonia, required for the production of "corn gluten meal", are registered as a toxic chemical substance with EPA, and continues to be regulated under the 1990 toxic substances control act (TSCA), Inventory Update Rule (IUR). There are also antibiotics used in the production of corn gluten meal, which are specifically forbidden for use in animals. They include virginiamycin and erythromycin.

Summary

Under section 401 of the FD&C Act, the Agency may promulgate regulations to establish definitions and standards for food to "promote honesty and fair dealing in the interest of consumers." For the reasons identified above, FDA-CVM should promulgate a new regulation for "corn gluten meal". Although "corn gluten meal" 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. FDA has the ability and the resources to issue this regulation in compliance with § 553 of the Administrative Procedure Act, under the Federal Food, Drug, and Cosmetic Act (the 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.

Chelsea Kent

Chelsea Kent (Mar 8, 2022 11:32 MST)

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