U.S. FOOD & DRUG ADMINISTRATION

April 16, 2025

Mr. Harry Duty
(b) (6)

Re: Docket No. FDA-2022-P-0405

Dear Mr. Duty:

This letter responds to your citizen petition (FDA-2022-P-0405), dated March 22, 2022, requesting that FDA "open the regulatory term 'corn protein meal' for public comment." In support of your petition, you assert that FDA employees "engaged in rulemaking functions via a private corporation [American Association of Feed Control Officials] AAFCO, but not in compliance with § 553 of the Administrative Procedure Act, even though FDA-CVM employees fully intend to accept this term federally for use in animal feed ingredients." You claim that "FDA-CVM employees [] performed this rulemaking work for this ingredient definition in private, while being paid by FDA-CVM, and while acting in their official job positions for the agency" and claim that your "right under § 553 of the Administrative Procedure Act, to make a public comment on this ingredient definition prior to FDA-CVM accepting this term and allowing for the ingredient's use in animal feed ingredients, has been violated by FDA-CVM."

We deny your petition for the reasons explained below.

We disagree with your premise that that FDA employees "engaged in rulemaking functions via a private corporation AAFCO, but not in compliance with § 553 of the Administrative Procedure Act."[1] That section of the Administrative Procedure Act (APA), 5 U.S.C. §553, sets out requirements for notice and comment rulemaking. FDA has not established a federal definition for corn protein meal for use in animal food or issued any other regulation specifically for corn protein meal for use in animal food. Therefore, the notice and comment rulemaking provisions in the APA do not apply.

To the extent your petition to "open the regulatory term 'corn protein meal' for public comment" is a request that FDA establish a federal regulation, you do not identify the kind of regulation you are requesting, explain the need for such a regulation, or explain how the proposed regulation will address any identified need. For example, if you are asking us to promulgate a federal regulation establishing a common or usual name for corn protein meal, you should explain why such a regulation is needed.

If, on the other hand, you are asking us to promulgate a regulation establishing a definition

[1] We note that AAFCO first defined the term "corn gluten meal" in 1936. FDA did not participate in the review of that definition. FDA conducted a limited review to support the name change from "corn gluten meal" to "corn protein meal." The Association of American Feed Control Officials (AAFCO) includes a tentative definition of "corn protein meal" in chapter six of its 2024 Official Publication. That definition states, "T48.145 Corn Protein 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. Originally called corn gluten meal. (Published 1936, Amended 1960, Name Amended 2023 re.1)." https://www.regulations.gov/document/FDA-2024-D-2977-0003. .

and standard of identity under section 401 of the FD&C Act, you should also explain why such a regulation is needed. 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." In the past, the Agency has established definitions and standards of identity for certain foods under this authority to protect against economic adulteration, maintain the integrity of food, and ensure that food meets consumer expectations. Definitions and standards of identity are established under the common or usual name of the food and set forth requirements pertaining to the content, composition, and production of the food.

You have not demonstrated that establishing a definition and standard of identity for corn protein meal prevents economic adulteration, maintains the integrity of the food, or ensures that the food meets consumer expectations. Your petition does not present evidence of economic adulteration, let alone how the proposed regulation would remedy any economic adulteration. Nor does your petition explain how the proposed regulation would maintain the integrity of the food. Your petition also does not describe or present evidence of any consumer expectations of the food and how the proposed definition would ensure that the food is produced in accordance with those expectations.

For the reasons explained above, we deny your petition.

Sincerely,

William T. Flynn -S

Digitally signed by William T. Flynn -S
Date: 2025.04.16 12:27:21 -04'00'

William T. Flynn, DVM, MS
Deputy Center Director
Center for Veterinary Medicine