U.S. FOOD & DRUG ADMINISTRATION

April 16, 2025

Donavan Melton
(b) (6)

Re: Docket No. FDA-2022-P-1589

Dear Ms. Melton:

This is in response to your petition dated July 16, 2022, requesting FDA-CVM "to comply with, §553 of the Administrative Procedure Act, and publish the ingredient definition for the animal feed/pet food ingredient 'corn meal' on the federal register."

In support, you state that, "'[c]orn meal' is an ingredient FDA allows to be used in animal feed and pet food products under FDA regulatory jurisdiction[]" and that, "[v]ia MOU-225-07-7001, FDA-CVM considers the definition for 'corn meal' to be a federal regulation for FDA regulated products. However, FDA-CVM refuses to comply with §553 of the Administrative Procedure Act and publish this ingredient term and definition on the federal register."[1] You also state that, "MOU-225-07-7001 doesn't shield FDA-CVM from federal requirements of § 553 of the Administrative Procedure Act, and FDA-CVM must immediately post this animal feed/pet food ingredient on the federal register."

For the reasons explained below, we deny your petition.

We disagree with your premise that "FDA-CVM refuses to comply with §553 of the Administrative Procedure Act and publish this ingredient term and definition on the federal register." 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 meal for use in animal food or issued any other regulation specifically for corn meal for use in animal food. Therefore, the APA's notice and comment rulemaking requirements do not apply.

You also mention FDA's Memorandum of Understanding with the Association of American Feed Control Officials (AAFCO), which described FDA's previous role in the AAFCO Ingredient Definition Request Process. That MOU (MOU-225-07-7001) expired on October 1, 2024, and FDA no longer participates in the AAFCO Ingredient Definition Request Process. FDA does not consider any AAFCO ingredient definition to be a federal regulation. Because AAFCO's ingredient definitions are not federal law, the APA's rulemaking requirements do not apply.

To the extent your petition is a request that FDA establish a federal regulation for corn meal, 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

[1] We note that there is not an AAFCO ingredient definition for corn meal. There are, however, other ingredients from the corn grain, distinct from "corn meal" (e.g., corn gluten meal) that do have an AAFCO ingredient definition. We reiterate that AAFCO feed ingredient definitions are not federal definitions and do not have the force or effect of federal law.

federal regulation establishing a common or usual name for corn 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 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 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 stated above and in accordance with 21 CFR 10.30(e)(3), we are denying your petition.

Sincerely,

William T. Flynn -S Digitally signed by William T. Flynn -S
Date: 2025.04.16 12:37:40 -04'00'

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