

July 01, 2022

Ms. Donavan Melton



Re: Docket No. FDA-2022-P-0058

Dear Ms. Melton:

This letter responds to your citizen petition (FDA-2022-P-0058), dated January 5, 2022, requesting that FDA "issue a regulation for the ingredient 'Suncured Alfalfa Meal' for use in FDA regulated animal feed and pet food products." Your petition states that FDA 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."

For the reasons stated below, we are denying your request.

Regulations pertaining to the identity of food are usually established as common or usual name regulations or as definitions and standards of identity. Neither type of regulation has been established by FDA for "Suncured Alfalfa Meal." It is unclear from your petition whether you are requesting FDA to promulgate either of these types of regulations. As described below, the information submitted in your petition is insufficient to conclude that either type of regulation is needed.

"Suncured Alfalfa Meal" is an ingredient that may be used in some animal food. Section 403(i)(2) of the FD&C Act requires that ingredients be declared on the label by their common or usual names. A common or usual name is the name by which an article is known to the American public and may be established by regulation or by common usage. FDA has established very few common or usual names for animal food ingredients by regulation. Hence, most animal food ingredients are declared on the labels of animal food by their common usage names.

"Suncured Alfalfa Meal" is among the ingredients defined by The Association of American Feed Control Officials (AAFCO) in the AAFCO Official Publication. Although AAFCO itself has no regulatory authority, most States have adopted AAFCO's ingredient names and definitions for use in animal food. Consequently, Suncured Alfalfa Meal, as used

Definition 3.1, Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions in AAFCO Official Publication, 2022.

as an ingredient in animal food, typically conforms to the AAFCO definition. The names and definitions in the AAFCO Official Publication² have come into common usage through adoption by States, manufacturer compliance, and consumer recognition. "Suncured Alfalfa Meal" appears to be the common or usual name for ingredients conforming to the AAFCO definition.

Although a common or usual name for animal food ingredients may be established by regulation instead of by common usage, there is no Federal requirement to do so. The Agency may use its joint authorities under sections 403(a)(1), 403(i), and 701(a) of the FD&C Act to issue a common or usual name regulation for a food. In the past, the Agency has established common or usual name regulations when a name in common usage misleads consumers or causes consumer confusion. It is unclear how promulgating the regulation you requested would accomplish either of these purposes. Your petition has not provided evidence that consumers are confused or misled by the name "Suncured Alfalfa Meal" and that promulgating your proposed definition would remedy any such confusion.

If, instead of a common or usual name, you are asking us to promulgate a regulation establishing a definition and standard of identity under section 401 of the FD&C Act, we note that the Agency may only promulgate such 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 standard 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 Suncured Alfalfa Meal would prevent economic adulteration, maintain the integrity of the food, or ensure 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. Finally, 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.

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² Compliance Policy Guide Sec. 665.100 Common or Usual Names for Animal Feed Ingredients states that FDA recognizes the AAFCO ingredient definitions to constitute the common or usual name as contemplated by the FD&C Act for animal feed ingredients, including pet food.

For the reasons stated above and in accordance with 21 CFR 10.30(e)(3), we are denying your petition.

Sincerely,

Steven Solomon Digitally signed by Steven Solomon -5 Date: 2022.07.01 09:54:32 -04'00'

Steven M. Solomon, DVM, MPH Director, Center for Veterinary Medicine