



October 27, 2022

Donavan Melton

(b) (6)

Re: Docket No. FDA-2022-P-0777

Dear Ms. Melton:

This letter responds to your citizen petition (FDA-2022-P-0777), dated May 9, 2022, requesting that FDA “issue a regulation for the ingredient ‘Cracked Pearled Barley’ 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 “cracked pearled barley.” 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.

“Cracked pearled barley” is a common ingredient in pet food. Section 403(i)(2) of the Federal Food Drug and Cosmetic (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. “Cracked pearled barley” appears to be a common or usual name that has been established by common usage as it is a name known and recognized by the public for an ingredient used in animal food.

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 a common or usual name regulation for “cracked pearled barley” would accomplish either of these purposes. Your petition has not provided

evidence that consumers are confused or misled by the name “cracked pearled barley” and that a different name should be used. Nor has your petition provided evidence that establishing a common or usual name by regulation would remedy any such confusion.

If, instead of promulgating a common or usual name regulation, 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 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 “cracked pearled barley” 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 or explain how establishing a particular definition and standard of identity would remedy any economic adulteration. Your petition also does not explain how establishing a particular definition and standard of identity would maintain the integrity of the food. Finally, your petition does not describe or present evidence of any consumer expectations of the food and how establishing a particular definition and standard of identity would ensure that the food is produced in accordance with those expectations.

Moreover, you have not provided the exact wording of the regulation you are requesting. FDA regulations set out the required format of a citizen petition, including that, “If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested”¹ must be provided.

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

Sincerely,

Steven
Solomon -S

Digitally signed by Steven
Solomon -S
Date: 2022.10.27 14:21:24
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Steven M. Solomon, DVM, MPH
Director, Center for Veterinary Medicine

¹ 21 CFR 10.30(b)(3), Section A. Action Requested, paragraph (1)