U.S. FOOD & DRUG ADMINISTRATION

July 15, 2022

Mr. Harry Duty
[redacted]

Re: Docket No. FDA-2022-P-0095

Dear Mr. Duty:

This letter responds to your citizen petition (FDA-2022-P-0095), dated January 25, 2022, requesting that FDA "issue a regulation for the ingredient 'Dried Black Soldier Fly Larvae' 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."

"Dried Black Soldier Fly Larvae" is an ingredient that may be used in some animal food. Although FDA has not established a definition for "Dried Black Soldier Fly Larvae" for use in animal food, there is no Federal requirement that animal food ingredients be defined. The Association of American Feed Control Officials (AAFCO) defines certain ingredients for use in animal food, which are published in the Official Names and Definitions of Feed Ingredients in the AAFCO Official Publication. Dried Black Soldier Fly Larvae is among the ingredients AAFCO has defined.[1] Although AAFCO itself has no regulatory authority, most States have adopted AAFCO's ingredient names and definitions for use in animal food. Consequently, Dried Black Soldier Fly Larvae, as used as an ingredient in animal food, typically conforms to the AAFCO definition.

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. A common or usual name is the name by which an article is known to the American public. A common or usual name may be established by regulation or by common usage.[2] 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. These names are typically

[1] Definition 60.117, Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions in AAFCO Official Publication, 2022.

[2] See 21 CFR 502.5(d).

consistent with the names in the AAFCO Official Publication,[3] which have come into common usage through adoption by States, manufacturer compliance, and consumer recognition.

Your petition alleges that "dried black soldier fly larvae" is not a common or usual name established by common usage. We disagree that "dried black soldier fly larvae" is not the common usage name for the ingredient described in your petition and defined by AAFCO. Many animal food products are labeled with "dried black soldier fly larvae" in the ingredient statement. We are unaware of another name that is used for the ingredient. In fact, your petition refers to the ingredient as "dried black soldier fly larvae" and does not refer to the ingredient by any other name. Nor does your petition provide evidence that another name is in common usage for the ingredient.

Your petition does 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. Since you discuss section 403(i)(2) in your petition, we questioned whether you might be requesting FDA to establish "dried black soldier fly larvae" as a common or usual name by regulation. Historically, FDA has established common or usual names by regulation when there is an inconsistency in the names used in the labeling of a food that causes consumer confusion or when a name in common usage misleads consumers as to the identity of the food. Your petition has not alleged that consumers are confused or misled by the labeling of the ingredient described in your petition and that requiring the ingredient to be labeled as "dried black soldier fly larvae" would remedy any such problem. As explained above, "dried black soldier fly larvae" is already the name used to declare the ingredient. That the definition you have requested for this name is identical to the AAFCO definition and ingredients on the market tends to conform to the definition casts doubt on the existence of such a problem.

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 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 Dried Black Soldier Fly Larvae would prevent economic adulteration, maintain the integrity of the

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[3] 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.

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. 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. Again, that the definition you have requested is identical to the AAFCO definition and ingredients on the market tends to conform to the definition indicates that these problems do not exist and further regulatory action by the agency is not needed.

Finally, the petition contains additional statements without specific requests for action, including statements about FDA resources and FDA's participation in AAFCO meetings and AAFCO's ingredient definition process. These statements are not addressed in this response because they are not relevant to the action requested in the petition.

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: 2022.07.15 08:07:44 -04'00'

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