January 25, 2022

Via Electronic Submission

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305) Rockville, MD 20852

Re: Citizen Petition- Asking FDA-CVM To Propose Official FDA Regulation For The Ingredient "Dried Black Soldier Fly Larvae" For Use In FDA Regulated Animal Feed & Pet Food Products

To whom it may concern:

The undersigned submits this petition under both the Federal Food, Drug, and Cosmetic Act (the Act), and § 553 of the Administrative Procedure Act (5 U.S.C. Subchapter II), and in accordance with 21 C.F.R. § 10.30(b), to request the FDA-CVM to issue a regulation for the ingredient "Dried Black Soldier Fly Larvae" for use in FDA regulated animal feed and pet food products.

A. Action Requested

Petition requests FDA-CVM to propose and issue a new regulation on this matter, and ensure the regulation is passed in compliance with federal law, § 553 of the Administrative Procedure Act.

Specifically, petition requests the FDA-CVM to issue a regulation for the ingredient "Dried Black Soldier Fly Larvae" for use in FDA regulated animal feed and pet food products. FDA-CVM 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.

This petition allows FDA the opportunity to comply with § 553 of the Administrative Procedure Act, of which FDA has never complied with even though FDA agrees to allow for "Dried Black Soldier Fly Larvae" of feed grade quality to be a widely used ingredient in FDA regulated products.

B. Statement of Grounds

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. According to 21 CFR 502.5(d), a common or usual name may be established by regulation or by common usage. There is no current common usage for the term "Dried Black Soldier Fly Larvae" for animal feed or pet food use. Additionally, there is no current FDA regulation for the term "Dried Black Soldier Fly Larvae".

Instead, FDA is helping develop this term in private, via private rulemaking meetings, with the full intent of ultimately recognizing this new term at the federal level through a memorandum of understanding MOU 225-07-7001.

"Dried Black Soldier Fly Larvae" is an ingredient and definition developed by public regulatory employees, via private meetings. Although the creation of this specific ingredient is intended for products in interstate commerce, and although FDA fully intends to "recognize" this ingredient at the federal level

for products in interstate commerce, the creation of this ingredient and its definition was made in violation of § 553 of the Administrative Procedure Act.

FDA has stated that "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." The privately developed regulation for "Dried Black Soldier Fly Larvae" does not satisfy this requirement under law. "Dried Black Soldier Fly Larvae" and its definition is not a common or usual name by which is known to the American public. "Dried Black Soldier Fly Larvae" is a specific definition created in private with the help of federal regulatory officials, with the full intent of these FDA regulatory officials ultimately "recognizing" the ingredient federally through their ongoing MOU 225-07-7001.

FDA has also stated "most animal food ingredients are declared on the labels of animal food by their common usage names. These names are typically consistent with the names in the AAFCO Official Publication, which have come into common usage through adoption by States, manufacturer compliance, and consumer recognition." For this claim, FDA cites "*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.*"

Again, the privately developed regulation for "Dried Black Soldier Fly Larvae" does not satisfy this claim by FDA, given that this ingredient has not come into common usage through adoption by States, manufacturer compliance, and consumer recognition. Even still, FDA fully intends to accept this ingredient as a "common usage" name via their backdoor rulemaking apparatus identified in both MOU 225-07-7001and in CPG Sec. 665.100. Again, this backdoor process of developing the term and definition for "Dried Black Soldier Fly Larvae" violates § 553 of the Administrative Procedure Act. Additionally, this process of developing tht erm and definition for "Dried Black Soldier Fly Larvae" violates Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which requires that ingredients be declared on the label by their common or usual names, according to 21 CFR 502.5(d).

The exact wording of the existing regulation (if any) and the proposed regulation or amendment regulation: Please find the proposed regulation for this term, "Dried Black Soldier Fly Larvae":

"Dried Black Soldier Fly Larvae" is the dried larvae of the Black Soldier Fly, Hermetia illucens, with or without mechanical extraction of part of the oil, that has been raised on a feedstock composed exclusively of feed grade materials. The ingredient must be labeled with guarantees for minimum crude protein and minimum crude fat on an as-fed basis. If oil is mechanically extracted, maximum crude fat must also be guaranteed on the ingredient label. The ingredient is dried by artificial means to no more than 10% moisture. It is for use in salmonid, poultry and swine feed as a source of protein and fat consistent with good feeding practices.

Statement regarding FDA resources:

Steven Solomon, Director of Center for Veterinary Medicine at FDA, has stated on multiple occasions that FDA has "limited resources" to prepare, draft, and publish a regulation for pet food ingredients and other animal feed ingredients. Mr. Solomon has not provided specific details beyond this vague claim. Dr. Solomon has never provided any detail as to what resources FDA may need in effort to do its job, and pass animal feed definition regulations publicly, in a public forum, so citizens such as myself and others can be involved in compliance with § 553 of the Administrative Procedure Act (5 U.S.C. Subchapter II). Instead, Dr. Solomon continues to cut citizens out of the rulemaking process, by adopting privately developed regulations and definitions.

C. Environmental Impact A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 C.F.R. §§ 25.30 and 25.34.

D. Economic Impact In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by FDA following review of the petition. The undersigned will promptly provide this information if requested.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Harry Duty
U.S. Citizen, Consumer, & Stakeholder
(b) (6)
[redacted]