U.S. FOOD & DRUG ADMINISTRATION

April 16, 2026

NutraSteward Ltd.
Attention: Elizabeth Lewis, Ph.D.
Scientific & Regulatory Adviser
Frederick House
Johnston, Pembrokeshire SA62 3AQ
United Kingdom

Re: GRAS Notice AGRN 85, Dried Black Soldier Fly Larvae

Dear Dr. Lewis:

The Food and Drug Administration's (FDA or the Agency) Center for Veterinary Medicine refers to a generally recognized as safe (GRAS) notice, dated July 25, 2025, submitted on behalf of your client EnviroFlight, LLC (Enviroflight or the notifier). The subject of the notice is Dried Black Soldier Fly Larvae (hereafter referred to as Dried Black Soldier Fly Larvae or the notified substance) with or without mechanical extraction of part of the oil. The substance is intended for use as a source of protein and fat in food for cats and dogs in all life stages when included at levels consistent with good feeding practices. The submission informs us of Enviroflight's conclusion that the subject of the submission is GRAS through scientific procedures. You were notified in a letter, dated September 18, 2025, that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 85. We have completed our evaluation of AGRN 85 and have no questions at this time regarding the conclusion of the use of the notified substance for its intended use.

To address the identity, method of manufacture, and specifications of the notified substance, the notifier provides the black soldier fly (*Hermetia illucens*) taxonomy, breeding, growing, harvesting, and downstream processing of larvae, the composition and potential contaminants analyses, and the analytical methods. The larvae are raised on a feedstock composed exclusively of feed-grade materials. Dried whole black soldier fly larvae is produced by drying harvested larvae without mechanical pressing to remove oil. Defatted black soldier fly larvae meal is produced by mechanical pressing the dried whole black soldier fly larvae to remove a portion of the oil fraction. The notifier provides specifications, stability and packaging information for both forms of finished products.

The specifications for Dried Black Soldier Fly Larvae in an unextracted state are: appearance (dried whole larvae), crude protein (≥35%), crude fat (≥20%), moisture (≤10%), ash (≤10%), crude fiber (≤10%), lead (≤1 mg/kg), arsenic (≤1 mg/kg), cadmium (≤0.5 mg/kg), mercury (≤0.5 mg/kg), total aerobic plate count (≤75,000 CFU/g), yeast (≤10 CFU/g), mold (≤10 CFU/g), and Enterobacteriaceae (≤10 CFU/g).

U.S. Food and Drug Administration
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If the Dried Black Soldier Fly Larvae are defatted, then the specifications are: appearance (light-brown free-flowing powder), crude protein (≥45%), crude fat (≥8%), moisture (≤10%), ash (≤12%), crude fiber (≤10%), lead (≤1 mg/kg), arsenic (≤1 mg/kg), cadmium (≤0.5 mg/kg), mercury (≤0.5 mg/kg), total aerobic plate count (≤75,000 CFU/g), yeast (≤10 CFU/g), mold (≤10 CFU/g), and Enterobacteriaceae (≤10 CFU/g). The crude fat content for defatted black soldier fly larvae from provided batch analysis is in the range 8.4 to 10.6%.

To address the utility of the intended use of the notified substance, the notifier provides data on the amino acid and fatty acid profiles of the notified substance. In addition, the notifier provides digestibility data from in vitro and in vivo feeding studies performed with adult dogs, adult and growing cats, swine, and cecectomized roosters, which show protein and fat digestibility of the notified substance.

To address the target animal safety of the intended use of the notified substance, the notifier notes that the identity of the notified substance is identical to that of the Dried Black Soldier Fly Larvae defined by the Association of American Feed Control Officials, which has been demonstrated to be safe for use in multiple animal species, including adult dogs and adult cats. The notifier states that the larvae are raised exclusively on feed grade materials in strictly controlled environments, which limits the potential for the accumulation of contaminants. The notifier substantiates this statement with analytical data from multiple batches of the notified substance that demonstrate the absence of harmful levels of heavy metals, pathogenic microorganisms, and other potential contaminants. The notifier also describes the absorption, distribution, metabolism, and excretion pathways of protein common to mammals. Pivotal data to support the safety of the notified substance in cats come from two 70-day feeding studies in adult cats and one gestation, lactation, and growth study in queens and kittens, in which diets containing up to 20% dried whole black soldier fly larvae meal were fed. Pivotal data to support the safety of the notified substance in dogs comes from a 28-day study in adult dogs fed diets containing up to 20% defatted black soldier fly larvae meal. The notifier also provides supportive data from additional studies in which Black Soldier Fly Larvae products were fed to dogs and swine.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll) (1)-(4) applies. In our evaluation of this notice, concluding that the notified substance is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing the notified substance. Accordingly, our response should not be construed to be a statement that foods containing the notified substance, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusion

Based on the information contained in the notice submitted on behalf of EnviroFlight, and other information available to the FDA, we have no questions at this time regarding its conclusion that Dried Black Soldier Fly Larvae is GRAS for use as a source of protein and fat in food for cats and dogs in all life stages when included at levels consistent with good feeding practices. The Agency has not made its own determination regarding the GRAS status of the intended use of

the notified substance in animal food under 21 CFR 570.35. Unless noted above, our evaluation did not address other provisions of the FD&C Act. As always, it is the continuing responsibility of EnviroFlight, to ensure that animal food ingredients that the notifier markets are safe and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 85 is accessible to the public on our website for the Current Animal Food GRAS Notices Inventory at https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory.

If you have any questions or comments, please contact Ms. Wasima Wahid at animalfood-premarket@fda.hhs.gov.

Sincerely,

/s/
Jeanette B. Murphy, M.S.
Acting Director
Office of Surveillance and Compliance
Center for Veterinary Medicine