August 31, 2026

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

Re: GRAS Notice AGRN 87 – Nonanoic Acid

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 12, 2025, and received on August 25, 2025, submitted on behalf of your client, Anitox Corporation (Anitox or the notifier). The subject of the notice is Nonanoic Acid (hereafter referred to as Nonanoic Acid or the notified substance) which is intended to be used as a flavor in food for poultry and swine when incorporated at up to 100 mg/kg of complete feed containing preservative agents. The submission informs us of Anitox's conclusion that the subject of the submission is GRAS through scientific procedures. You were notified in a letter, dated December 4, 2025, that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 87. CVM received an amendment, dated April 10, 2026, from the notifier containing additional information. We have completed our evaluation of AGRN 87 and have no questions at this time regarding the conclusion of the use of the notified substance.

To address the identity, method of manufacture, and specifications of the notified substance, the notifier provides a description of the composition, manufacturing process and controls, and analytical methods used to establish the specifications of the notified substance. Nonanoic Acid is manufactured by a non-catalytic continuous oxidation process followed by purification using distillation. The notifier provides the following specifications for the notified substance: nonanoic acid ≥98%, moisture ≤0.10%, acid value 345-355 mg potassium hydroxide (KOH)/g, arsenic ≤0.5 mg/kg, lead ≤0.5 mg/kg, mercury ≤0.2 mg/kg, and cadmium ≤0.5 mg/kg. Based on the provided batch analysis, the notified substance also contains 2-methyloctanoic acid ≤1.5%, nonanal ≤0.1%, iodine value ≤0.4 g iodine (I_2)/100g, iron ≤0.07 mg/kg, the sum of dioxins ≤0.309 toxic equivalency (TEQ)/kg, dioxin-like polychlorinated biphenyls (PCBs) ≤0.128 TEQ/kg, and non-dioxin-like PCBs ≤0.480 ng/g. The notifier also provides stability and packaging information for the notified substance.

To address the utility of the intended use of the notified substance, the notifier provides information on the composition of the notified substance and three published journal articles in

U.S. Food and Drug Administration
Center for Veterinary Medicine
CPK1, Room 1B068
5001 Campus Drive
College Park, MD 20740-3835
www.fda.gov

which the notified substance was added in the feed of poultry and swine. The publications assessed the consumption of feed by the target animal species when the notified substance was incorporated in a typical complete feed.

To address target animal safety of the intended use of the notified substance, the notifier provides data and information on potential impurities and contaminants, estimated exposure assessments, and three published journal articles evaluating the safety of the notified substance when added in the feed of broiler chickens, laying hens, turkeys, and swine.

To address the human food safety of the intended use of the notified substance, the notifier provides scientific rationale based on the presence of the notified substance in common human food sources, a history of use as a flavor agent in human food, and the ability of the notified substance to be metabolized in the same manner as other fatty acids.

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, as amended, submitted by Anitox Corporation, and other information available to the FDA, we have no questions at this time regarding its conclusion that Nonanoic Acid is GRAS for use as a flavor in food for poultry and swine when incorporated at up to 100 mg/kg of complete feed containing preservative agents. 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 Anitox 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 87 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. Lauren Howell at animalfood-premarket@fda.hhs.gov.

Sincerely,

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