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

Re: Animal Generally Recognized as Safe Notice No. 62 – Sodium Salts of Lactylates of Lauric and Myristic Acids

Dear Dr. Lewis:

The Food and Drug Administration's Center for Veterinary Medicine (we) refers to a generally recognized as safe (GRAS) notice dated December 23, 2022, received on March 10, 2023, submitted on behalf of your client, Corbion (Purac Biochem BV) (Corbion or the notifier). The subject of the submission is Sodium Salts of Lactylates of Lauric and Myristic Acids (C12/C14 Lactylates) as a nutritional ingredient (source of lauric and myristic acids) in the food of all categories and species of animals at an intended use rate of 0.7-1.8 g/kg of complete feed. The notice informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. Following an initial evaluation, you were notified in a letter dated August 22, 2023 that the GRAS notice was acceptable for filing, and the notice was designated as AGRN 62. On January 18, 2024, CVM received an amendment from the notifier containing additional chemistry, manufacturing, and controls, and target animal safety information. We have completed our evaluation of AGRN 62 and have no questions at this time.

To address the identity, method of manufacture, and specifications of the notified substance, the notifier provides the common or usual name for the notified substance as Sodium Salts of Lactylates of Lauric and Myristic Acids. The notified substance is formed by esterification of lauric (C12) and myristic (C14) acids with lactic acid in the presence of sodium hydroxide. This esterification reaction produces a mixture of which the primary components are sodium lactylates of lauric acid and myristic acid. It is intended for use as a nutritional ingredient (source of lauric and myristic acids) in food of all categories and species of animals at 0.7-1.8 g/kg complete feed. The C12/C14 Lactylates is a brown substance and marketed as 30-40% C12/C14 Lactylates in its market formulation. The notifier further provides specifications for C12/C14 Lactylates with test methods and the following acceptance criteria: Color brown, Acid Value (AV) 50-70 mg potassium hydroxide (KOH)/g, Ester Value (EV) 130-160 mg KOH/g, Saponification Value (SV) 180-230 mg KOH/g, Sodium 6.0-8.0 %w/w, Arsenic ≤10 mg/kg, Lead ≤5 mg/kg, Mercury ≤0.2 mg/kg, and Cadmium ≤1 mg/kg. The notifier also tests for dioxins and polychlorinated biphenyls in the produced C12/C14 Lactylates. The notifier provides stability and homogeneity information for C12/C14 Lactylates.

To address the target animal safety of the intended use of the notified substance, the notifier provides information demonstrating: 1) C12/C14 Lactylates are absorbed, digested, metabolized, and excreted to substances that are well-documented, 2) C12/C14 Lactylates

dissociate into components (e.g., lauric, myristic, lactic acid, sodium ions) that are ubiquitous and generally understood to be metabolized and excreted through simple and well-understood biological processes, 3) the estimated exposure to C12/C14 Lactylates, and 4) a history of safe use of fat-rich ingredients, individual fatty acids, and organic acids in animal food.

The notifier states intake of C12/C14 Lactylates will be self-limiting on the basis that there are detrimental physiological effects associated with the intake of excessive levels of dietary fat. Additionally, the notifier provides justification for similarities of the notified substance to other lactylates commonly used in animal and human food. The notifier supports the safety of the maximum intended use of C12/C14 Lactylates in all classes and species of animals, regardless of life stage, with a narrative based on the extrapolation of available data and information. The notifier justifies the extrapolation of these data through the physiological similarities of metabolic pathways across the target species.

To address the human food safety of the intended use of the notified substance, the notifier provides information on the metabolism and excretion of C12/C14 Lactylates and similarly structured lactylates in animals. The notifier also provides information on the metabolism of other minor components in C12/C14 Lactylates according to well established pathways. The notifier includes information showing that the maximum intended use of C12/C14 Lactylates is not expected to have any significant impact on the composition or quality of animal products, and no residues of C12/C14 Lactylates or its metabolites will deposit in animal products which may pose a safety concern to humans consuming animal products. Additionally, the notifier provided the studies that had previously been evaluated by the European Food Safety Authority and the FDA as part of novel foods and GRAS notifications, respectively, for fatty acids and lactylates for use in human food(s), showing that salts of lactylates of fatty acids and individual fatty acids and organic acids have an established history of use in human food and in human food production.

The Association of American Feed Control Officials publishes in their Official Publication a list of names and definitions for accepted feed ingredients. FDA recognizes these names as being “common or usual” names for feed ingredients. FDA recognizes the name “Sodium Salts of Lactylates of Lauric and Myristic Acids” as the common or usual name for the notified substance.

Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Under section 403(a) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. The notifier did not provide any information to demonstrate that the notified substance functions as intended because the notifier concluded that the intended use would not be expected to impact safety. Therefore, we did not evaluate whether the notified substance, Sodium Salts of Lactylates of Lauric and Myristic Acids, would achieve the effect claimed for it. However, please note that if products containing the notified substance bear any claims on the label or in labeling regarding the function of the notified substance, these claims should be supported by appropriate data and information. FDA may take enforcement action if any claims on labels or labeling are found to be false or misleading.

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 Corbion's notice, as amended, concluding that Sodium Salts of Lactylates of Lauric and Myristic Acids as a nutritional ingredient (source of lauric and myristic acids) in the food of all categories and species of animals at an intended use rate of 0.7-1.8 g/kg of complete feed 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 Sodium Salts of Lactylates of Lauric and Myristic Acids. Accordingly, our response should not be construed to be a statement that foods containing Sodium Salts of Lactylates of Lauric and Myristic Acids, 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 Corbion (Purac Biochem BV), and other information available to the FDA, we have no questions at this time regarding the notifier's conclusion that Sodium Salts of Lactylates of Lauric and Myristic Acids is GRAS under the intended conditions of use. The Agency has not, however, 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 Corbion 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 62 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 about this letter, please contact Ms. Lauren Howell at 240-402-8012 or at Lauren.Howell@fda.hhs.gov.

Sincerely,

Timothy Schell, Ph.D.
Director
Office of Surveillance and Compliance
Center for Veterinary Medicine