U.S. FOOD & DRUG ADMINISTRATION

January 26, 2026

DSM Nutritional Products, LLC
Attention: William Lewis, M.S.
Senior Regulatory Affairs Manager
250 Plainsboro Road
Plainsboro, NJ 08536

Re: GRAS Notice AGRN 76 – Condensed Algal Residue Solubles

Dear Mr. Lewis:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine refers to a generally recognized as safe (GRAS) notice, dated April 2, 2025, submitted by DSM Nutritional Products, LLC. The subject of the notice is condensed algal residue solubles (hereafter referred to as the notified substance) to be used as a source of energy in the form of protein, fat, and carbohydrates in beef cattle diets when included at up to 3% of dry matter (DM) intake. The submission informs us of your conclusion that the subject of the submission is GRAS through scientific procedures. You were notified in a letter, dated April 30, 2025, that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 76. We have completed our evaluation of AGRN 76 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 information on the identity, manufacturing process, specifications for the notified substance, and analytical methods used to determine composition, impurities and contaminants. The notified substance is produced through fermentation of a *Schizochytrium sp*. strain optimized for oil production. At the end of fermentation, the broth is thermal inactivated followed by cell lysis to release oil, then the biomass is separated from oil and concentrated to become the notified substance with a syrupy consistency. The notifier provides specifications for the finished product which include: Total DM (min. 25%); on DM basis, crude protein (min. 20%), crude fat (min. 6.5%), crude fiber (max. 0.5%), sodium (min. 8% - max. 11%), sulfur (max. 6%); lead (max. 5 ppm), mercury (max. 0.1 ppm), arsenic (max. 3 ppm), cadmium (max. 0.5 ppm); and *Escherichia coli* generic (<10 CFU/g), total coliforms (<10 CFU/g), *Staphylococcus aureus* (<10 CFU/g), *Enterobacteriaceae* (<10 CFU/g), *Salmonella* (not detected/25g), *Listeria* (not detected/25g), and *E. coli* O157:H7 (not detected/25g). The notifier has also provided stability and packaging information.

To address the intended effect of the notified substance, the notifier provides information on the nutrient composition and two published papers utilizing the notified substance to displace a portion of conventional energy sources, such as grain, in the complete diet for finishing beef cattle.

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

To address the target animal safety of the intended use of the notified substance, the notifier provides published and unpublished information and discussion on the 1) safety of the source organism, *Schizochytrium sp.* microalgae, 2) the impact of the ingredient composition on the maximum tolerable limit of essential minerals for beef cattle, 3) mutagenicity, genotoxicity, and sub-chronic toxicity in rats, and 4) feeding studies in which the notified substance was used to supplement the diet of finishing beef cattle for periods of 21 to 148 days.

To address human food safety associated with use of the notified substance, the notifier provides results of genotoxicity battery and repeated-dose toxicity studies and worst-case scenario calculations to demonstrate that there are no significant risks to consumers of the edible tissues of beef cattle consuming the notified substance. The notifier also describes that the notified substance will be metabolized by the target species and, when incorporated in edible tissues, will be indistinguishable from the same components derived from other sources.

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 DSM Nutritional Products, LLC, and other information available to the FDA, we have no questions at this time regarding its conclusion that condensed algal residue solubles is GRAS to be used as a source of energy in the form of protein, fat, and carbohydrates in beef cattle diets when included at up to 3% of DM intake. 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 DSM Nutritional Products, LLC, to ensure that animal food ingredients that it 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 76 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