



May 6, 2026

Splitrock Regulatory Solutions, LLC
Attention: James La Marta, Ph.D.
Principal Consultant
107 Decker Road
Boonton, NJ 07005

Re: GRAS Notice AGRN 77, Olive Extract

Dear Dr. La Marta:

The Food and Drug Administration's (FDA or the Agency) Center for Veterinary Medicine (CVM) refers to a generally recognized as safe (GRAS) notice, dated March 26, 2025, submitted on behalf of your client, Kemin Industries, Inc., (Kemin or the notifier). The subject of the notice is Olive Extract, (hereafter referred to as Olive Extract or the notified substance). The submission informs FDA of the notifier's conclusion, based on scientific procedures that the notified substance is GRAS for use in foods for dogs and cats as a component of a formulated palatant when incorporated at no more than 200 parts per million (ppm) of finished pet food. You were notified in a letter dated May 20, 2025, that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 77. CVM received an amendment, dated December 18, 2025, from the notifier containing additional information. We have completed our evaluation of AGRN 77 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, and the analytical methods used to determine the levels of total phenols, impurities, and contaminants. The notified substance is produced by filtering, concentrating, and pasteurizing the aqueous phase that is separated from the oil and solid pomace when olives are pressed for oil production. The notifier provides specifications for the notified substance which include a flavor/aroma of green/fruity, an appearance of reddish liquid, moisture >45%, phenolic compounds 5-8%, yeast and mold $\leq 5 \times 10^2$ colony-forming units per gram (CFU/g), total plate count $< 10^3$ CFU/g, *Escherichia coli* < 10 CFU/g, enterobacteria ≤ 100 CFU/g, *Salmonella spp.* absent in 25g, arsenic < 1 mg/kg, cadmium < 1 mg/kg, lead < 0.5 mg/kg, and mercury < 0.1 mg/kg. The notifier provides analysis for pesticides, polyaromatic hydrocarbons, mycotoxins, and dioxins/furans. The notifier also provides stability information.

To address the utility, the notifier provides information on the composition of the notified substance. Additionally, the notifier provides two publications in which the notified substance was incorporated as a component of a multi-ingredient formulation and added to food for dogs and cats. The publications assessed the acceptance of the finished food containing the notified substance.

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 target animal safety of the intended use of the notified substance, the notifier provides information on the metabolism of hydroxytyrosol, the toxicity profile of hydroxytyrosol, and the safety assessment of hydroxytyrosol in dogs and cats. The safety evaluation of the intended use of the notified substance focused on the toxicological profile of hydroxytyrosol as it is the predominant phenolic compound in table olives and other phenolic compounds are rapidly converted to hydroxytyrosol in the intestinal tract.

The toxicity profile of hydroxytyrosol includes publicly available studies on genotoxicity, oral acute and subchronic toxicity (90-day studies), and reproductive/developmental studies in rodents. The No-Observed-Adverse-Effect Level of 250 mg hydroxytyrosol/kg body weight from the subchronic studies in rodents is used to calculate the margin of exposure in dogs and cats. To account for differences in metabolism across species, especially the low glucuronidation ability of cats, the notifier describes estimated safety factors to address the margin of exposure to hydroxytyrosol in puppies and kittens and both small and large adult dogs and cats using the Nutrient Requirements of Dogs and Cats (National Research Council, 2006) energy requirements to estimate food intake.

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

Section 301(II) 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(II) (1)-(4) applies. In our evaluation of this notice, as amended, concluding that the notified substance is GRAS under its intended conditions of use, we did not consider whether section 301(II) 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(II).

Conclusion

Based on the information contained in the notice, as amended, submitted on behalf of Kemin, and other information available to the FDA, we have no questions at this time regarding its conclusion that Olive Extract is GRAS for use in foods for dogs and cats as a components of a formulated palatant, incorporated at no more than 200 ppm. 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 Kemin 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 77 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