May 7, 2026

Keller and Heckman, LLP
Attention: Ms. Evangelia C. Pelonis
Counsel
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Re: GRAS Notice AGRN 79 – Dried *Saccharomyces cerevisiae* expressing an ovine protein

Dear Ms. Pelonis:

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 April 16, 2025, submitted on behalf of your client Bond Pet Foods, Inc. (the notifier). The subject of the notice is Dried *Saccharomyces cerevisiae* expressing an ovine protein (hereafter referred to as Lamb Protein Yeast or the notified substance) for use as a source of protein in adult maintenance diets for dogs at a maximum level of 15% of the diet. The submission informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. You were notified in a letter dated May 21, 2025, that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 79. On December 22, 2025, and February 25, March 13, March 31, and May 5, 2026, CVM received amendments from the notifier containing additional information. We have completed our evaluation of AGRN 79 and have no questions at this time regarding the conclusion of the use of the notified substance for its intended use.

To address the manufacturing method and specifications of the notified substance, the notifier provided details regarding manufacturing process and controls, the composition and potential contaminants analysis, and the analytical methods to establish the specifications. The notified substance is produced through fed-batch fermentation. After the fermentation process, the biomass is harvested by centrifugation. The concentrated biomass is then heat inactivated and spray dried. The production strain is absent in the finished product. The notifier provides the specifications for the finished product, which include: crude protein (≥ 50%, on dry matter basis), lipocortin 3 protein from *Ovis aries* (≥15% of total protein, on dry matter basis), total dietary fiber (+ 35%, on dry matter basis), crude fiber (+ 3%, on dry matter basis), moisture (+10%), ash (+ 9%), non-protein nitrogen (+1.2%), total aerobic plate count (+ 25,000 CFU/g), yeast (+1,000 CFU/g), and mold (+1,000 CFU/g). The notifier also provides stability information for the notified substance.

To support identity and microbial safety, the notifier provides a narrative based on scientific data and literature that addresses history of use and regulatory status for human and animal food, to

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Center for Veterinary Medicine
CPK1, Room 1B068
5001 Campus Drive
College Park, MD 20740-3835
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support its conclusion that *S. cerevisiae* strain sB1466 is safe as the source organism to produce the notified substance for the intended use.

To address the pre-fermentation manufacturing processes of the intended use of the notified substance, the notice includes a description of genetic modifications that were performed during development of the source strain, *S. cerevisiae strain* sB1466, to produce the notified substance for the intended use. The notifier also addresses genetic stability, potential new open reading frames, and absence of any antibiotic resistance markers.

To address utility and the safety of the notified substance, the notifier provides data on the composition of the notified substance, including the amino acid composition, and data on potential contaminants. Pivotal data to support both utility and safety come from published information in adult dogs. Safety was assessed in a 26-week feeding study and digestibility was assessed in a 19-day digestibility study. In the studies, the inclusion of the notified substance progressively replaced egg protein and cellulose.

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 Bond Pet Foods, and other information available, the FDA has no questions at this time regarding the notifier's conclusion that Dried *Saccharomyces cerevisiae* expressing an ovine protein is GRAS for use as a source of protein in adult maintenance diets for dogs at a maximum level of 15% of the diet. 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 Bond Pet Foods 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 79 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