



April 20, 2026

Argenta
Attention: Heather Sedlacek, DVM, MS
Senior Regulatory Affairs Manager
2029 Becker Drive, Suite 222
Lawrence, KS 66047

Re: GRAS Notice AGRN 84 – Yeast Beta-Glucan

Dear Dr. Sedlacek:

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 July 31, 2025, submitted on behalf of your client, Kerry Incorporated (Kerry or the notifier). The subject of the notice is Yeast Beta-Glucan (hereafter referred to as Yeast Beta-Glucan or the notified substance) to be used as a source of yeast beta-glucans for dogs and cats of all ages and classes when included at a maximum level of 0.05% beta-glucan. 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 September 3, 2025, that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 84. On February 13 and March 24, 2026 CVM received amendments from the notifier containing additional information. We have completed our evaluation of AGRN 85 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 for the manufacturing process, composition, and analytical methods used to determine the contents of beta-glucan and other constituents. The notified substance is produced in multiple stages consisting of fermentation of non-genetically engineered *Saccharomyces cerevisiae* (*S. cerevisiae*), autolysis of the cells, purification of the beta-glucan from *S. cerevisiae* cell wall, and spray drying.

The notifier provides specifications for the notified substance as follows: appearance (fine beige/tan powder), gluco polysaccharide (beta 1,3/1,6, $\geq 75\%$ on dry matter basis), ash ($\leq 3\%$), fat ($\leq 10\%$), moisture ($\leq 8\%$), protein ($\leq 3.5\%$), carbohydrates ($\geq 75\%$), aerobic plate count (≤ 10000 CFU/g), *Salmonella* (not detected/25 g), *Staphylococcus aureus* (not detected/10 g), coliform (≤ 3 MPN/g), *E. coli* (not detected/10 g), yeast and molds (≤ 100 CFU/g), arsenic (≤ 0.1 mg/kg), cadmium (≤ 0.05 mg/kg), lead (≤ 0.1 mg/kg), and mercury (≤ 0.05 mg/kg). The notifier also provides stability and packaging information.

The notifier concludes that information on the physical or other technical effect of the notified

substance is not necessary because use of the notified substance as a source of beta-glucans in food for dogs and cats when incorporated at up to 0.05% of the complete food does not impact target animal safety.

To address the target animal safety of the intended use of the notified substance, the notifier describes/provides publicly available information on 1) history of safe use of *S. cerevisiae* in both human and animal food; 2) studies in dogs, cats, and rodents which utilized beta-glucan from diverse sources; and 3) dietary exposure assessment of dogs and cats to Yeast Beta-Glucan. Publicly available studies in cats, dogs, rodents, and other animal species fed yeast wall-based ingredients evaluated the impacts on digestibility, performance parameters, hematological analyses, and/or survivability.

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 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(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, 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 submitted on behalf of Kerry, and other information available to the FDA, we have no questions at this time regarding its conclusion that Yeast Beta-Glucan is GRAS for use as a source of beta-glucans in food for cats and dogs in all life stages when included at levels consistent with good feeding practices. 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 Kerry 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 85 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