



November 22, 2022

Dr. Elizabeth Lewis
Scientific & Regulatory Advisor
NutraSteward, Ltd.
Bridge Innovation Centre
Pembrokeshire Science and Technology Park
Pembroke Dock, Pembrokeshire SA72 6UN
Wales, United Kingdom

Re: Animal GRAS Notice No. 56 – Purified Yeast Cell Wall

Dear Dr. Lewis:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM or we) received a generally recognized as safe (GRAS) notice, dated September 3, 2021, submitted on behalf of your client Phileo, Division of S.I. Lesaffre (the notifier). The subject of the submission is purified yeast cell wall fed as a source of fermentable fiber, especially beta-glucans, in food for all animals at a use level depending on the animal species and life stage. The submission informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. The notice was filed on March 8, 2022 and designated as animal GRAS notice number (AGRN) 56. In an October 26, 2022 email to you, CVM informed the notifier of questions regarding their conclusion. Specifically, CVM has questions regarding: 1) the manufacturing process and stability data for the notified substance, 2) missing information for the target animal safety section, and 3) insufficient and inconsistent information pertaining to the intended use of the purified yeast cell wall as a source of fermentable fiber, specifically as a source of beta glucans, for all animals when incorporated at 0.0125 to 0.5% of complete feed.

CVM is granting your request, on behalf of Phileo, Division of S.I. Lesaffre, dated November 10, 2022, to cease evaluation of the AGRN 56.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 56 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>.

U.S. Food and Drug Administration
MPN 4, Room 176
12225 Wilkins Avenue
Rockville, MD 20852
www.fda.gov

If you have any questions about this letter, please contact Ms. Megan Hall at (301) 796-3801 or at megan.hall@fda.hhs.gov.

Sincerely,

/s/

David Edwards, PhD
Director, Division of Animal Food Ingredients
Office of Surveillance and Compliance
Center for Veterinary Medicine