



November 27, 2024

NutraSteward, Ltd.
Attention: Elizabeth Lewis, PhD
Scientific and Regulatory Advisor
Frederick House, Johnston
Haverford West, Pembrokeshire
SA62 3AQ
United Kingdom

Re: GRAS Notice AGRN 71 – Beta-Glucans from *Ganoderma lucidum* Mycelium

Dear Dr. Lewis:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) refers to a generally recognized as safe (GRAS) notice, dated June 4, 2024, submitted on behalf of your client Alura, Inc. (the notifier). The subject of the notice is beta-glucans from *Ganoderma lucidum* mycelium as a source of beta-glucans in all animal species. 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 July 11, 2024, and designated as animal GRAS notice number (AGRN) 71. In a November 6, 2024 email to you, CVM informed the notifier of questions regarding their conclusion. Specifically, CVM has questions related to the identity of the microencapsulated product, substantiation of the maximum use rates for each of the intended species and the immunomodulatory effects that were presented to reach a conclusion of safety.

CVM is granting the notifier's request dated November 20, 2024 to cease evaluation of the AGRN 71. In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 71 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-notificationprogram/current-animal-food-gras-notices-inventory>.

If you have any questions or comments, please contact Ms. Wasima Wahid at 240-402-5857 or at wasima.wahid@fda.hhs.gov.

Sincerely,

/s/

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