



July 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. 51 – Synthetic Sodium Aluminosilicate

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 August 26, 2021, submitted on behalf of your client Protekta, Inc., (Protekta or the notifier). The subject of the submission is synthetic sodium aluminosilicate to be used to maintain calcium balance in periparturient dairy cows at an intended use rate of up to 400 g/head/day for at least 14 days and no more than 28 days. The submission informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. Additionally, we received an amendment, dated October 6, 2021, containing a missing reference for this submission. The notice, as amended, was filed on October 28, 2021, and designated as animal GRAS notice number (AGRN) 51. During the evaluation, we received two additional amendments in response to a request for more information. In a June 22, 2022 email to you, CVM informed the notifier of questions regarding the notifiers conclusion. Specifically, CVM has questions related to chemistry, manufacturing, and controls and human food safety that ultimately affect the assessment of the safety conclusion.

CVM is granting your request, on behalf of Protekta, Inc., dated July 5, 2022, to cease evaluation of the AGRN 51.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 51 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>.

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If you have any questions about this letter, please contact Ms. Megan Hall at +1 (301) 796-3801 or 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