U.S. FOOD & DRUG ADMINISTRATION

April 7, 2026

Splitrock Regulatory Solutions, LLC
Attention: James La Marta, Ph.D.
Principal Consultant
107 Decker Road
Boonton, NJ 07005

Re: GRAS Notice AGRN 83 – Serine-endopeptidase

Dear Dr. La Marta:

The Food and Drug Administration's Center for Veterinary Medicine (CVM) refers to a generally recognized as safe (GRAS) notice, dated June 23, 2025, submitted on behalf of your client, AB Enzymes GmbH (the notifier). The subject of the notice is serine-endopeptidase to be used as a processing aid to hydrolyze vegetables and animal proteins for use as ingredients in food for all animals. 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 30, 2025, and designated as animal GRAS notice number (AGRN) 83. In a March 13, 2026 email to you, CVM informed the notifier of questions regarding their conclusion. Specifically, CVM has questions related to the utility narrative and supporting information which do not provide adequate data and information on hydrolysis of vegetable proteins. Additionally, the firm did not adequately address transformation of the ProteaseM expression cassette in their production strain *T. reesei* RF8963 from host strain RF4847, molecular biology information that impacts a conclusion of target animal safety.

CVM is granting your request, dated March 26, 2026, to cease evaluation of AGRN 83. In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 83 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. Lauren LaPlace at animalfood-premarket@fda.hhs.gov.

Sincerely,

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

U.S. Food and Drug Administration
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