



December 7, 2022

Dr. Andreas Kern
Senior Regulatory Affairs Specialist
BASF Corporation
3550 Johns Hopkins Court
San Diego, CA 92121

Re: Animal GRAS Notice No. 57 – Mannanase 19287

Dear Dr. Kern:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM or we) received a generally recognized as safe (GRAS) notice, dated March 11, 2022, submitted by BASF Corporation (BASF or the notifier). The subject of the submission is mannanase 19287 produced by *Thermothelomyces thermophilus* strain DSM 33149 for use in reducing the viscosity of intestinal digesta in poultry diets. 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 April 29, 2022 and designated as animal GRAS notice number (AGRN) 57. In an October 14, 2022, email to you, CVM informed the notifier of questions regarding their conclusion. Specifically, CVM has questions related to the applicability of the target animal safety data and information that was presented to reach a conclusion of safety, insufficient information addressing the methodologies to identify the source strain in the molecular biology, and microbial safety narratives and supporting information as well as the analysis of the impact of the analyzed enzymatic activity levels in the proposed use rate of the notified substance.

CVM is granting your request dated October 21, 2022, to cease evaluation of the AGRN 57.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 57 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 about this letter, please contact Ms. Wasima Wahid at (240) 402-5857 or at wasima.wahid@fda.hhs.gov.

Sincerely,

/s/

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