



December 21, 2021

GRAS Notice No. AGRN 43

Dr. Vincent Sewalt  
Head of Regulatory Science & Advocacy  
Global Regulatory Affairs Department  
Danisco US Inc.  
925 Page Mill Road  
Palo Alto, CA 94304

Dear Dr. Sewalt:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM, we) is granting your request, dated November 8, 2021, to cease our evaluation of the generally recognized as safe (GRAS) notice No. (AGRN) 43, filed on February 18, 2021.

The notice informs FDA of Danisco US Inc.'s view that the intended use of phytase from *Trichoderma reesei* expressed as variant of consensus bacterial phytase is GRAS, through scientific procedures, fed to increase phosphate availability at a use rate not to exceed 4000 FTU/kg in swine and poultry. In a teleconference on November 5, 2021, CVM discussed the issues identified during our evaluation of the notice. Specifically, CVM has questions relating to target animal safety, and about the functionality of the notified substance. CVM also has other questions related to chemistry, manufacturing, and controls and molecular biology that ultimately affect the assessment of the safety conclusion. CVM also discussed the opportunity for Danisco US Inc. to request we cease our evaluation of AGRN 43 and to re-submit a new GRAS Notice in the future.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 43 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>.

Sincerely,

/s/

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

**U.S. Food and Drug Administration**  
**Center for Veterinary Medicine**  
**Division of Animal Feeds, HFV-220**  
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