



April 2, 2021

GRAS Notice No. AGRN 39

Ms. Diane Shanahan  
BASF Enzymes LLC  
3550 John Hopkins Court  
San Diego, CA 92121

Dear Ms. Shanahan:

The Food and Drug Administration's (FDA, we) Center for Veterinary Medicine (CVM) is granting your request, dated March 16, 2021, to cease our evaluation of AGRN 39, filed on July 14, 2020.

The notice informs FDA of BASF Enzymes LLC's view that the intended use of the phytase enzyme produced by *Pseudomonas fluorescens* strain BD50104 expressing an altered *appA* 6-phytase gene from *Escherichia coli* strain K12 is GRAS, through scientific procedures, to increase the availability of phytin-bound phosphorus in poultry diets at a level of 250-2000 U/kg in complete feed. In a teleconference on March 9, 2021, CVM discussed the issues identified during our evaluation of the notice. Specifically, target animal safety concerns were identified with the lowest proposed use rate. CVM also noted other questions in the chemistry, manufacturing, and controls section that would require clarification. CVM also discussed the opportunity for BASF Enzymes LLC to request CVM to cease our evaluation of AGRN 39 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 39 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,

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**  
**12225 Wilkins Avenue**  
**Rockville, MD 20852**  
[www.fda.gov](http://www.fda.gov)