



June 7, 2021

GRAS Notice No. AGRN 38

Kristi O. Smedley, Ph.D.
Center for Regulatory Services, Inc.
5200 Wolf Run Shoals Road
Woodbridge, VA 22192

Dear Dr. Smedley:

The Food and Drug Administration's (FDA, we) Center for Veterinary Medicine (CVM) is granting your request, dated May 27, 2021, to cease our evaluation of AGRN 38, filed on July 13, 2020.

The notice informs FDA of Native Microbials Inc.'s view that the intended use of *Pichia kudriavzevii* ASCUSDY21, is generally recognized as safe (GRAS), through scientific procedures, for use as a direct-fed microbial in diets of dairy cattle at an intended use rate 1×10^8 CFU/cow/day. In a teleconference on May 11, 2021, CVM discussed the issues identified during our evaluation of the notice. Specifically, target animal safety concerns were identified in the notice because there is not sufficient information to address the genetic relationship of strain ASCUSDY21 to a known pathogenic strain. CVM also noted there was not adequate discussion regarding the existing contradictory safety information in the scientific literature. CVM also discussed the opportunity for Native Microbials Inc. to request CVM to cease our evaluation of AGRN 38 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 38 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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