



December 23, 2021

GRAS Notice No. AGRN 41

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) Center for Veterinary Medicine (CVM or we) is granting your request, dated December 17, 2021, to cease our evaluation of generally recognized as safe (GRAS) notice No. AGRN 41, which was filed on August 18, 2020.

The notice informs FDA of Native Microbials, Inc.'s (formerly known as Ascus Biosciences, Inc.) (the notifier) view that the intended use of *Clostridium beijerinckii* ASCUSDY20, is GRAS through scientific procedures for use as viable microorganism in the diets of dairy cattle at an intended use rate of 1×10^7 colony forming units per cow per day (CFU/cow/day). In a teleconference with the notifier on November 12, 2021, CVM discussed the issues identified during the evaluation of the notice. Specifically, CVM has questions related to microbial, target animal, and human food safety of the notified substance. CVM also discussed the opportunity for Native Microbials, Inc. to request we cease our evaluation of AGRN 41 and to re-submit a new notice in the future.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 41 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