



August 18, 2022

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

RE: Animal GRAS Notice No. AGRN 49

Dear Dr. Smedley:

The Food and Drug Administration's (FDA or the agency) Center for Veterinary Medicine (CVM or we) refers to a generally recognized as safe (GRAS) notice, dated August 9, 2021, submitted on behalf of your client Native Microbials, Inc. (Native Microbials or the notifier). The subject of the submission is *Clostridium beijerinckii* ASCUSB67, used as a viable microorganism in poultry feed at an intended use rate of 1×10^4 CFU/cow/day. The submission informs FDA of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. Additionally, we received an amendment, dated September 21, 2021, providing more information for this submission. Following an initial evaluation, you were notified in a letter dated October 1, 2021 that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 49. In a May 23, 2022 email, CVM informed you of questions related to the safety of the notified substance as GRAS.

CVM is granting your request, on behalf of Native Microbials, dated July 11, 2022, to cease evaluation of AGRN 49.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 49 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. Carissa Adams at (240) 402-6283 or carissa.adams@fda.hhs.gov.

Sincerely,

/s/
David Edwards, Ph.D.
Director, Division of Animal Food Ingredients
Office of Surveillance and Compliance
Center for Veterinary Medicine

U.S. Food and Drug Administration
MPN 4, Room 176
12225 Wilkins Avenue
Rockville, MD 20852
www.fda.gov