



September 7, 2022

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

Re: Animal GRAS Notice No. 53 – *Ruminococcus bovis* ASCUSDY10

Dear Dr. Smedley:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM or we) received a generally recognized as safe (GRAS) notice, dated August 19, 2021, submitted on behalf of your client Native Microbials, Inc., (Native Microbials or the notifier). The subject of the submission is *Ruminococcus bovis* ASCUSDY10 to be used to as a viable microorganism in dairy cattle feed at an intended use rate of up to  $1 \times 10^8$  colony forming units (CFU) /cow/day. The submission informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. Additionally, on September 30, 2021 and November 22, 2021, we received amendments to the original submission containing updated sections of the GRAS notice and references. The notice, as amended, was filed on November 23, 2021, and designated as animal GRAS notice number (AGRN) 53. During the evaluation, we received two additional amendments in response to a request for more information. In a July 18, 2022, email to you, CVM informed the notifier of questions regarding the notifier's conclusion. Specifically, CVM has questions related to the microbial safety of the micro-organism, the manufacturing process, and target animal safety that ultimately affect the assessment of the safety conclusion.

CVM is granting your request, on behalf of Native Microbials, Inc., dated August 2, 2022, to cease evaluation of the AGRN 53.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 53 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. Wasima Wahid at (240) 402-5857 or [wasima.wahid@fda.hhs.gov](mailto:wasima.wahid@fda.hhs.gov).

Sincerely,

/s/

David Edwards, PhD  
Director, Division of Animal Food Ingredients  
Office of Surveillance and Compliance  
Center for Veterinary Medicine