



September 29, 2020

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

Re: GRAS Notice No. AGRN 35

Dear Dr. Smedley:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of AGRN 35, which we filed on December 18, 2019.

The subject of this notice is Dried L-valine Fermentation Product ( $\geq 72\%$  L-valine) produced by a bioengineered *Corynebacterium glutamicum* strain, KCCM 80058. The notice informs us of CJ CheilJedang Corporation's view that the intended use of Dried L-valine Fermentation Product is GRAS, through scientific procedures, as a source of the nutrient L-valine in food for livestock and poultry. The intended use level will be decided by animal nutritionists based on good feeding practice for the target species.

In the teleconference on July 1, 2020, we discussed issues identified during our evaluation of the notice. These issues were related to the notified substance's identity, method of manufacturing, specifications, analytical methods, utility, target animal safety, and bioengineering techniques. On July 27, 2020, CJ CheilJedang Corporation provided an amendment to address the issues identified by us during the teleconference on July 1, 2020. In the teleconferences on August 11 and 13, 2020, we discussed inconsistencies identified between the original submission and amendment regarding the descriptions of the genetic modifications. We also identified deficiencies in the biogenic amine analysis provided in the amendment. Additional information is needed to address these issues to support our safety assessment. We discussed the opportunity for CJ CheilJedang Corporation to ask us to cease our evaluation of AGRN 35 and to re-submit a new GRAS notice in the future.

In accordance with 21 CFR 570.275(b)(3), the text of this letter responding to AGRN 35 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