



September 30, 2025

Center for Regulatory Services, Inc.
Attention: Kristi Smedley, Ph.D.
Consultant
1536 Canoe House Road
Jamaica, VA 23079

Re: GRAS Notice AGRN 81 – Dried L-Isoleucine Fermentation Product

Dear Dr. Smedley:

The Food and Drug Administration's Center for Veterinary Medicine (CVM) refers to a generally recognized as safe (GRAS) notice, dated May 8, 2025, submitted on behalf of your client, CJ CheilJedang Corporation (the notifier). The subject of the notice is dried L-isoleucine fermentation product to be used as a source of L-isoleucine in poultry and swine feed. The submission informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. The notice was filed on June 13, 2025, and designated as animal GRAS notice number (AGRN) 81. In a September 19, 2025 email to you, CVM informed the notifier of questions regarding their conclusion. Specifically, CVM had questions regarding a lack of target animal safety data in the intended species. In addition, CVM had questions regarding information on the genomic sequence of the source organism that could potentially impact safety.

CVM is granting your request, dated September 24, 2025, to cease evaluation of the AGRN 81. In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 81 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 or comments, please contact Ms. Megan Hall at animalfood-premarket@fda.hhs.gov.

Sincerely,

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