



September 24, 2025

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

Re: GRAS Notice AGRN 78 – Dried L-Arginine Fermentation Product

Dear Dr. Smedley:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) refers to a generally recognized as safe (GRAS) notice, dated April 11, 2025, submitted on behalf of your client, CJ CheilJedang Corporation (the notifier). The subject of the notice is dried L-arginine fermentation product to be used as a source of L-arginine 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 May 13, 2025, and designated as animal GRAS notice number (AGRN) 78. In a September 4, 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 host strain that could potentially impact safety.

CVM is granting your request, dated September 8, 2025, to cease evaluation of the AGRN 78. In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 78 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 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

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