U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

November 12, 2019

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

Re: GRAS Notice No. AGRN 28

Dear Dr. Smedley:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of AGRN 28, which we filed on November 11, 2018. We received your request on November 4, 2019.

The subject of the notice is L-threonine (≥75%) produced via fermentation of a genetically engineered strain of *Corynebacterium glutamicum* (or L-Threonine Fermentation Product). The notice informs FDA of CheilJedang's view that L-Threonine Fermentation Product is GRAS, through scientific procedures, for use as a source of the nutrient L-threonine in the diets of livestock and poultry, at an intended use rate dependent on current good manufacturing or feeding practice for the target species.

In teleconferences on July 23 and October 28, 2019, and in our email dated October 18, 2019, we discussed issues identified during our evaluation of the notice. In the teleconference on July 23, 2019, we discussed concerns that the safety of the intended use of the notified substance as a source of the essential amino acid L-threonine depends on demonstrating utility and that the notice did not contain information that is generally available and accepted among qualified experts to support the utility of the notified substance. We also discussed concerns with the molecular techniques used to engineer the production organism, the manufacturing of the notified substance, and target animal safety.

In our October 18, 2019 email, we responded to CheilJedang's questions and stated that in the context of animal food or feed ingredients that are intended to supply an essential nutrient, published or otherwise publicly available utility data is needed in order to establish that the substance is generally recognized as safe under the conditions of its intended use.

In the teleconference on October 28, 2019, we stated that CheilJedang did not have sufficient publicly available data and information at the time of submission to support its conclusion that the notified substance is generally recognized as safe under the intended conditions of use. We

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discussed the opportunity for CheilJedang to request us to cease our evaluation and to re-submit a new GRAS notice in the future to fully address all the identified issues.

In accordance with 21 CFR 570.275(b)(3), the text of this letter responding to AGRN 28 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