



October 12, 2021

GRAS Notice No. AGRN 40

Mr. Melvin S. Drozen
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001

Dear Mr. Drozen:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM or we) is granting your request, dated September 6, 2021, to cease our evaluation of generally recognized as safe (GRAS) notice No. AGRN 40, which was filed on August 13, 2020.

The notice informs the FDA of Calysta, Inc.'s (the notifier) view that the intended use of dried *Methylococcus capsulatus* product, a biomass produced via a continuous fermentation process, is GRAS through scientific procedures for use as a source of protein in the diets of salmonid species at a level up to 18% of the diet. In a teleconference with the notifier on August 18, 2021, CVM discussed the issues identified during the evaluation of the notice. Specifically, the source of, or identity of, or acceptance criteria for the mesophilic bacteria in relation to the heat treatment step intended to inactivate *M. capsulatus*. Additionally, we discussed the appropriateness of small-scale batches to address safe use from large-scale batches with unknown quantities of viable source organisms. Also, CVM discussed the opportunity for Calysta, Inc. to request we cease our evaluation of AGRN 40 and to re-submit a new notice in the future.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 40 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

U.S. Food and Drug Administration
Center for Veterinary Medicine
Division of Animal Feeds, HFV-220
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