



Jimmy Wang, Ph.D
Summit Life Science, Inc.
45 Adams Ave
Hauppauge, NY 11788

Re: GRAS Notice No. GRN 001141

Dear Dr. Wang:

The Food and Drug Administration (FDA, we, us) is granting the request on behalf of Shenyang Gold Jyouki Technology Co., Ltd (Shenyang) to cease our evaluation of GRN 001141, which we filed on July 28, 2023. We received this request on April 15, 2024.

The subject of the notice is L- α -glycerophosphorylcholine (α -GPC) for use at levels up to 600 mg/serving as a source of choline in soft drinks, sports and “energy” drinks, powdered beverage mixes, coffee and tea, gummy candy, nutritional beverages, protein and nutritional powders, and cereal and nutrition bars.¹ The notice informs us of Shenyang’s view that these uses of α -GPC are GRAS through scientific procedures.

In an email dated April 12, 2024, we informed you that we could not continue our evaluation due to deficiencies identified in the notice. We noted that we still had questions regarding Shenyang’s dietary exposure estimate. Furthermore, we found that there was not sufficient data to support the safety conclusion made by Shenyang. Given the substantive nature of these issues, we recommended that Shenyang request that we cease our evaluation of the notice. We also suggested that Shenyang request a pre-submission meeting with us prior to submitting a revised GRAS notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001141 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

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for

Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

¹ Shenyang states that α -GPC is not intended for use in infant formula or in products under the jurisdiction of the United States Department of Agriculture.