Ray A. Matulka, Ph.D., FACN
Burdock Group Consultants
859 Outer Road
Orlando, FL 32814

Re: GRAS Notice No. GRN 001061

Dear Dr. Matulka:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 001061, which we filed on August 16, 2022. We received this request on May 22, 2022.

The subject of the notice is deactivated alkaline serine protease (DASP) produced by a strain of *Bacillus licheniformis*, for use as a source of low (less than 25 mg phenylalanine per serving) phenylalanine protein in nutritionally complete medical food in the diet of individuals with phenylketonuria (PKU) ages one year and older. The intended use as the primary protein source (up to 15 g/serving) in medical foods would not result in an excess of 80% of the total protein intake per day. The notice informs us of Tanea Medical AB's view that this use of DASP is GRAS through scientific procedures.

In a teleconference on December 13, 2022, we discussed concerns related to: the dietary exposure, which was based on a recommended daily intake value; the identity of the production strain and details on its construction; the lack of scientific basis for consideration that the phenylalanine content (0.25%) would not present a hazard to the targeted consumer population considering that the intended phenylketonuria (PKU) population is inherently sensitive to phenylalanine; the lack of discussion of potential allergenic peptides within the DASP amino acid sequence or allergens in the production media; questions regarding the maintenance of blood phenylalanine levels within a safe tolerable range in sensitive populations; and other deficiencies requiring clarification. We recommended that Tanea Medical AB request that we cease to evaluate GRN 001061. We noted that, following receipt of this request, we would provide a list of deficiencies that were identified during the evaluation of the notice. In an email dated December 20, 2022, you requested on behalf of Tanea Medical AB that we cease our evaluation of GRN 001061.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001061 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2023.01.26 17:30:00 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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Center for Food Safety
and Applied Nutrition