



Susan Cho, Ph.D.
NutraSource, Inc.
6309 Morning Dew Ct.
Clarksville, MD 21029

Re: GRAS Notice No. GRN 00859

Dear Dr. Cho:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Advanced Protein Technologies, Corp. (APTech) to cease our evaluation of GRN 000859, which we filed on June 13, 2019. We received this request on August 21, 2019.

The subject of the notice is 2'-fucosyllactose (2'-FL) for use as an ingredient in whey, milk, and soy-based, non-exempt infant formula for term infants at a level of 2.4 g/L of formula as consumed; infant and toddler foods at levels ranging from 0.24-1.2 g/serving; and in beverage and beverage bases; breakfast cereals; dairy product analogs; frozen dairy desserts and mixes; gelatins, puddings, and fillings; grain products and pastas; jams and jellies; milk and milk products; processed fruits and fruit juices; and sweet sauces, toppings and syrup at levels ranging from 0.28-1.2 g/serving. The notice informs FDA of APTech's view that these uses of 2'-FL are GRAS through scientific procedures.

In an email dated August 21, 2019, we informed APTech that we could not continue our evaluation due to the poor quality of the notice. In general, the notice had the following deficiencies: inaccurate or missing information on the intended use, identity, manufacturing, specifications, and exposure; inaccurate conclusions from cited references; poor quality images that impacted the readability of the notice; the use of incorrect scientific terminology; and incorrect scientific claims. Additionally, we recommended that APTech request that we cease our evaluation of the notice. In an email dated August 21, 2019, APTech requested that we cease our evaluation of GRN 000859. In a follow-up email on August 22, 2019, we provided APTech with a detailed list of the deficiencies we identified in the notice.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000859 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan
J. Carlson -S
Date: 2019.09.06 11:17:27
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
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