



Dietrich B. Conze, Ph.D.
Spherix Consulting Group, Inc.
751 Rockville Pike Unit 30-B
Rockville, MD 20852

Re: GRAS Notice No. GRN 001135

Dear Dr. Conze:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Vitalus Nutrition, Inc. (Vitalus) to cease our evaluation of GRN 001135, which we filed on May 26, 2023.

The subject of the notice is galacto-oligosaccharides (GOS) for use as an ingredient in powdered, ready-to-feed, and concentrated liquid forms of cow milk-based, non-exempt infant formula for term infants at a maximum level of 7.8 g/L of infant formula, as consumed. GOS is also for use as an ingredient in cereals, pudding, and custards for infants at levels up to 14 g/kg; drinks for infants at levels up to 16 g/L; milk and milk-based drinks, yogurt, meal replacement drinks and bars, imitation milk, milk-based desserts, soups and soup mixes, coconut beverages, baked goods, cereal bars, ready-to-eat breakfast cereals, soft and hard candies, jams, jellies, preserves, fruit juices, fruit drinks, nectars, vegetable juices, coffee and coffee drinks, smoothies, soft drinks, and non-alcoholic fermented drinks at maximum levels ranging from 0.42 to 25%; and chewing gum up to 42.7%.¹ The notice informs us of Vitalus' view that these uses of GOS are GRAS through scientific procedures.


In an email dated October 2, 2023, and a subsequent phone call on October 30, 2023, we informed you that we had concerns regarding data and information that was lacking in the safety narrative and errors we found in the notice, particularly for the dietary exposure estimates, and that we were recommending Vitalus to request that we cease to evaluate this notice. In an email dated October 31, 2023, you requested that we cease to evaluate this notice.

¹ Vitalus states that GOS is not intended for use in products under the U.S. Department of Agriculture's jurisdiction.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001135 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

 Digitally signed by Susan J.
Carlson -S
Date: 2023.11.03 10:14:31
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition