U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

William J. Rowe
GRAS Associates, LLC
11810 Grand Park Avenue, Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001169

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) is granting the request on behalf of GeneChem, Inc. (GeneChem) to cease our evaluation of GRN 001169, which we filed on March 5, 2024. We received this request on September 25, 2024.

The subject of the notice is 6'-sialyllactose sodium salt (6'-SL) for use as an ingredient in non-exempt infant formula for term infants at a level of 0.34 g/L of formula as consumed; in formula intended for young children (ages 1-3 years) at a level of 0.34 g/L as consumed; in yogurt and juice drinks for infants and young children at 1.8 g/L and in hot cereals, desserts, dry snacks, and other foods for infants and young children at 1.96 – 10.25 g/kg; in non-alcoholic beverages (sports, isotonic, and "energy" drinks; enhanced or fortified waters; soft drinks; coffee and tea; fruit nectars, juices, and drinks; vegetable nectars and juices; milk, flavored milk drinks, buttermilk, evaporated and condensed milk, and milk substitutes; meal replacements; nutritional drinks for pregnant women; and protein drinks) and in oral nutritional drinks and enteral tube feeding products (for ages 11 years and older) at levels up to 10.68 g/L; and in the following food categories for use at levels from 1.29 - 106.77 g/kg: baked goods and baking mixes; hot cereals; ready-to-eat breakfast cereals; frozen dairy desserts; fruit and water ices; puddings and fillings; cereal and granola bars; protein and meal-replacement bars; jams, jellies, preserves, and fruit butters; yogurt (including non-dairy yogurt); canned fruits; fruit-based desserts; syrups (for flavoring milk beverages); chewing gum and sugar substitutes; and beverage whiteners and cream substitutes. The notice informs us of GeneChem's (you, your) view that these uses of 6'-SL are GRAS through scientific procedures.

In an email dated August 16, 2024, we informed you that we identified extensive deficiencies during our review of GRN 001169 and recommended that you request that we cease our evaluation of the notice. We also offered to provide a list of the deficiencies we identified, in a separate correspondence to you, and we suggested that you request a pre-submission meeting to discuss the resolution of the deficiencies if you plan to resubmit the notice. In an email dated August 20, 2024, you requested a meeting to discuss our recommendation. During a meeting held on September 6, 2024, we

explained our concerns, which included the potential presence of lithium in the finished ingredient, lack of details on the removal of impurities during the manufacturing process, illegibility of figures presented to support the compositional analyses of the ingredient, and questions about the intended uses and resulting estimates of dietary exposure. We noted that the deficiencies were too numerous and substantive to adequately address in an amendment. On September 25, 2024, we received an email requesting that we cease our evaluation of GRN 001169.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001169 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Mical E. Honigfort -S

Digitally signed by Mical E. Honigfort -S
Date: 2024.10.07 13:42:52 -04'00'

for Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program