Fernando Garcia
Amyris, Inc.
5885 Hollis Street, Suite 100
Emeryville, CA 94608

Re: GRAS Notice No. GRN 000987

Dear Mr. Garcia:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 000987, which we filed on May 21, 2021. We received this request on January 15, 2022.

The subject of the notice is 2′-fucosyllactose (2′-FL) for use as an ingredient in nonexempt infant formula for term infants at a maximum level of 2.4 g/L of formula, as consumed; in toddler formulas and meal replacement drinks for children ages 1 – 3 years at a maximum level of 2.4 g/L, as consumed; in infant and toddler foods at maximum levels of 10.0 g/L in drinks, 10.9 g/kg in ready-to-eat cereals and desserts, 12 g/kg in processed cereal-based food and other foods, and 57 g/kg in dry snacks; in beverages (sports and "energy" drinks, flavored waters, fruit juices and drinks, milk drinks, dairy analogs, and milk-based meal replacements) at maximum levels ranging from 0.8-6 g/L; in oral nutritional supplements and enteral tube feeding products at a level of 20 g/L; and in the following foods, at maximum levels ranging from 4.8-80 g/kg: breakfast cereals; frozen dairy desserts; puddings, fillings, mousses; yogurt and non-dairy analogs; meal replacement and snack bars; syrups; and jams and jellies. The notice informs us of Amyris' (you, your) view that these uses of 2′-FL are GRAS through scientific procedures.

In a letter to you dated September 23, 2021, we identified deficiencies in your notice that included the following key issues: incomplete information about the methods used to purify 2′-FL, the estimated dietary exposure to 2′-FL, and the safety of the genetically engineered strain of *Saccharomyces cerevisiae* used to manufacture 2′-FL; questions about the level and type of impurities present and the potential impact on vulnerable consumers (i.e., infants); questions regarding the compositional differences between the notified substance and the test articles used in published *in vivo* toxicology studies; and concerns that the general recognition of safety standard required for a GRAS conclusion had not been met. In our letter, we recommended that you request we cease our evaluation of GRN 000987 if you could not respond in a timely manner, as we anticipated the notice may require extensive revisions to address the deficiencies.

On October 15, 2021, we received your amendment in response to the deficiencies identified in our September 23, 2021 letter. After reviewing your amendment, we sent an email to you on November 30, 2021, stating that we still had questions about the notice's reliance on data and information that are not generally available in the public domain. We also expressed that we continue to have questions about the notice's reliance on published studies which may not be adequate to establish the safety of the notified substance due to compositional differences between it and the test articles. As such, we recommended that you request that we cease our evaluation of the notice. We also suggested that you meet with us at a later date to further discuss the deficiencies if you wish to resubmit the notice. In a phone call with you on December 1, 2021, we reiterated our recommendations noted in the November 30, 2021 email. In an email dated January 15, 2022, you requested that we cease our evaluation of GRN 000987.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000987 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.02.02 16:21:21 -05'00'

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