Gavin Thompson
Environ International Corporation
1702 E. Highland Ave., Suite 412
Phoenix, AZ 85016

Re: GRAS Notice No. GRN 000571

Dear Dr. Thompson:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of Jennewein Biotechnologie, GmgH (Jennewein) to GRN 000571. We received the supplement on July 10, 2019. The supplement addresses a change in the production organism for the production of 2'-fucosyllactose (2'-FL).

We previously responded to GRN 000571 on November 6. 2016. We stated that we had no questions at that time regarding Jennewein's conclusion that that 2'-FL is GRAS for use as an ingredient in non-exempt, milk-based infant formulas for term infants and in toddler formulas at a maximum use level of 2 g/L of reconstituted formula.

In the supplement received July 10, 2019, Jennewein informs us of its view that changing the organism for the production of 2'-FL from the genetically engineered *Escherichia coli* BL21 (DE3) #1540 strain to its parent strain (the genetically engineered *E. coli* BL21 (DE3) #1242 strain) and also including the addition of food-grade lactase at the end of the process if there is excess lactose present at the end of the production run is GRAS, through scientific procedures, for use as an ingredient in non-exempt, milk-based infant formulas for term infants and in toddler formulas at a maximum use level of 2 g/L of reconstituted formula.

Jennewein provided information on the genetic engineering of *E. coli* BL21 (DE3) #1242 in the original submission, GRN 000571. The single difference between strains #1540 and #1242 is a high-temperature expressed lactase used to remove excess lactose from the manufacturing process. In the supplement, Jennewein states that the substitution of extraneously added food-grade lactase will have no effect on the identity and safety of 2'-FL.

Based on the totality of the data and information available, Jennewein concludes that 2'-FL produced using the modified manufacturing process using the progenitor *E. coli* strain #1242 is GRAS for its intended use as an ingredient in non-exempt, milk-based infant formulas for term infants and in toddler formulas at a maximum level of 2 g/L of reconstituted formula.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing 2'-FL bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Intended Use in Infant Formula

Under section 412 of the FD&C Act, a manufacturer of a new infant formula must make a submission to FDA providing required assurances about the formula at least 90 days before the formula is marketed. Our response to Jennewein's supplement does not alleviate the responsibility of any infant formula manufacturer that intends to market an infant formula containing 2'-FL to make the submission required by section 412. Infant formulas are the purview of ONFL.

Section 301(ll) of FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of Jennewein's supplement concluding that 2'-FL is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing 2'-FL. Accordingly, our response should not be construed to be a statement that foods containing 2'-FL, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Jennewein provided, as well as other information available to FDA, we have no questions at this time regarding Jennewein's conclusion that 2'-FL is GRAS under its intended conditions of use. This letter is not an affirmation that 2'-FL is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to the supplement to GRN 000571 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2019.11.08 13:53:50 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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