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Food

Agency Additional Correspondence Letter: GRAS Notice No. GRN 000044

CFSAN/Office of Food Additive Safety

June 1, 2007

Luke R. Kazmierski
GTC Nutrition
600 Corporate Circle, Suite H
Golden, CO 80901

Re: GRAS Notice No. GRN 000044

Dear Mr. Kazmierski:

The Food and Drug Administration (FDA) is responding to your correspondence dated January 26, 2007, that you sent regarding additional uses for GRAS Notice No. 000044. Environ Corporation initially submitted GRN 000044, on behalf of GTC Nutrition, in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received this notice on May 2, 2000, and designated it as GRAS Notice No. GRN 000044. In a letter dated November 22, 2000, FDA informed GTC Nutrition that the agency had no questions at that time regarding the conclusion of GTC Nutrition that fructooligosaccharide, the subject of the notice, is GRAS under the intended conditions of use.

In a letter dated January 26, 2007, GTC Nutrition informed FDA of their determination that the addition of fructooligosaccharide is GRAS for use in foods in general, excluding meat and poultry products and infant formula, at levels up to 20 grams (g) per day in the general population and at levels up to 4.2 g per day in infants less than one year of age. GTC Nutrition provided a table of the typical use levels of fructooligosaccharide (Table 1).

Table 1
Typical Use Levels of Fructooligosaccharide*

Food Category	Standard Serving Size	Level of Use/Serving (per cent)
Acidophilus Milk	240 milliliters (ml)	0.4
Analogues and Substitutes for Meat, Poultry or Fish	15-85 grams (g)	1.2-6.7
Bars	40-70 g	1.4-2.5
Breakfast Cereals	40-55 g	1.8-2.5
Beverages and Juices	240 ml	0.4
Cakes	55 g	1.8
Cheese	30-110 g	0.9-3.3
Cream	15-30 g	3.3-6.7
Confectionery	40 g	2.5
Cookies	30 g	3.3
Crackers	15-30 g	3.3-6.7
Dessert Toppings and Fillings	30 g	3.3
Hard candy	15 g	6.7
Ice cream	68 g	1.5
Infant Foods ** (0-12 months)	7-60 g	0.4-3.6
Jams and Jellies	20 g	5.0
Milk, flavored and unflavored	240 ml	0.4
Milk, evaporated and condensed	30 ml	2.6-3.1
Muffins and Quick Bread	50-55 g	1.8-2.0
Sauces, Gravies, and Condiments	30-125 g	0.8-3.3
Snacks	30 g	3.3
Sorbet and Sherbet	85 g	1.2
Soup	245 g	0.4
Toddler Foods (12-24 months)	15-125 g	0.8-6.7

Yogurt

225 ml

0.4

*Use levels may be different from the intended use in the original notice.

** This category excludes infant formula.

GTC Nutrition states its intention to use fructooligosaccharide in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Based on the information provided by GTC Nutrition in GRN 000044, the supplement dated January 26, 2007, and other information available to FDA, the agency has no questions at this time regarding GTC Nutrition's conclusion that fructooligosaccharide is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of fructooligosaccharide. As always, it is the continuing responsibility of GTC Nutrition to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to the additional information submitted regarding GRN 000044, as well as a copy of the information in this notice that conforms to the information in the proposed GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at <http://www.cfsan.fda.gov/~lrd/foodadd.html>).

Sincerely,

Antonia Mattia, Ph.D.

Director

Division of Biotechnology and GRAS Notice Review

Office of Food Additive Safety

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