U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

James Akingbasote, Ph.D., DABT
Intertek Assuris
2233 Argentia Rd Suite 201
Mississauga, ON L5N 2X7
CANADA

Re: GRAS Notice No. GRN 000239

Dear Dr. Akingbasote:

The Food and Drug Administration (FDA, we) completed our evaluation of Kerry Group Plc (Kerry)'s supplement to GRN 000239, which is dated November 1, 2023.[1,2] We received the supplement on November 7, 2023. The supplement addresses additional uses for the subject of GRN 000239. Kerry submitted information on May 15, June 13, July 23, and August 25, 2025, clarifying the intended uses, specifications, dietary exposure, and safety.

We previously responded to GRN 000239 on July 22, 2008, stating that we had no questions at that time regarding Kerry's conclusion that bakers yeast beta-glucan is GRAS for use as an ingredient in cookies, meal replacement beverages, nutritional bars (including soy protein bars), soy milk, yogurt and yogurt beverages, "probiotic" beverages, fruit drinks, juices, and smoothies, chocolate confections, and soups at a level of up to 200 mg/serving. In addition, our July 22, 2008, response letter discussed and included an appropriate name for the substance that is the subject of the notice (i.e., bakers yeast beta-glucan).

In the supplement dated November 1, 2023, Kerry informs us of its view that bakers yeast beta-glucan is GRAS, through scientific procedures, for use as an ingredient in the foods and at the use levels specified in Table 1. Kerry does not intend bakers yeast beta-glucan to be used in infant formula or products under the jurisdiction of the U.S. Department of Agriculture.

[1] Kerry acquired Biothera's Healthcare Group; Biothera, Inc. was the original notifier of GRN 000239. Thus, FDA's letter refers to Kerry as the notifier for GRN 000239.
[2] In a letter of August 7, 2024, Bill Turney of Kerry stated that Dr. Akingbasote is appointed to represent Kerry with the FDA and to receive and respond to correspondence regarding this supplement. Thus, FDA's letter is addressed to Dr. Akingbasote.

Table 1. Intended uses of bakers yeast beta-glucan.

Food	Maximum use level (%)[a]	Maximum use level, on beta-glucan basis (g/100 g)[b]
Cakes: Light weight cakes (including coffee cake) Medium weight cakes Heavy weight cakes	 0.454 0.313 0.200	 0.363 0.250 0.160
Cookies[c] and crackers	0.833	0.667
Brownies[c]	0.625	0.500
"Energy" drinks, sport or electrolyte drinks, and fluid replacement drinks	0.069	0.056
Enhanced, flavored, carbonated, or fortified water beverages	0.069	0.056
Hot breakfast cereals	0.417-0.625	0.333-0.500
Ready-to-eat breakfast cereals: Puffed cereals High-fiber cereals Biscuit-type cereals	 1.667 0.625 0.417	 1.333 0.500 0.333
Ready-to drink (RTD) coffee beverages and RTD tea beverages	0.069	0.056
Vinegar	1.667	1.333
Snack dips	0.833	0.667
Condiments	1.667	1.333
Non-dairy milk	0.104	0.083
Non-dairy cream	1.667	1.333
Non-dairy yogurt	0.147	0.118
Non-dairy sour cream	0.833	0.667
Frozen yogurt	0.278	0.222
Pudding	0.192	0.154
Breakfast, granola, protein, "energy", and meal replacement bars	0.625	0.500
Milk- and non-milk-based nutrition drinks/shakes; meal replacement beverages; fortified milk beverages and powders; and probiotic beverages	0.104	0.083
Yogurt	0.147	0.118
Yogurt beverages	0.121-0.269	0.097-0.215
Fruit juices, nectars, drinks, and ades (including smoothies)	0.104	0.083
Snack mixes, chips, pretzels, popcorn, and extruded puff snacks	0.833	0.667
Chocolate confections	0.833	0.667
Gummy candies and gelatin fruit snacks	0.833	0.667
Soup and soup mixes	0.102	0.082

[a] Equivalent to 250 mg of bakers yeast beta-glucan/serving
[b] Equivalent to 200 mg of beta-glucan/serving based on the average beta-glucan content of 80%
[c] Includes mixes and powdered forms

Kerry discusses changes in the manufacturing process and specifications for bakers yeast beta-glucan relative to GRN 000239. In this supplement to GRN 000239, Kerry states that there is a minor change in the manufacturing process to decrease the time for cell lyses from several days to 24 hours. In addition, Kerry states that the specification for beta-1,3/1,6-glucan was changed from ≥70% to ≥75%. Kerry also updates the specifications for heavy metals to lead (≤0.1 mg/kg), arsenic (≤0.1 mg/kg), cadmium (≤0.05 mg/kg), and mercury (≤0.05 mg/kg). Kerry provides results from the analyses of five non-consecutive batches (three for heavy metals) to demonstrate that bakers yeast beta-glucan can be manufactured to meet the specifications.

Kerry estimates the eaters-only dietary exposure to beta-glucan from the intended uses of bakers yeast beta-glucan to be 0.67 g/person (p)/d at the mean and 1.39 g/p/d at the 90th percentile for the U.S. population aged 2 years and older based on food consumption data from the 2017-2018 National Health and Examination Survey (NHANES). Kerry also provides an estimated cumulative dietary exposure to beta-glucan from the uses in GRNs 000239, 000309, 000413, and 000995,[3] along with the intended uses in this supplement to GRN 000239.[4] Kerry estimates the mean and 90th percentile eaters-only cumulative dietary exposure to beta-glucan to be 0.91 g/p/d and 1.73 g/p/d, respectively, for the U.S. population aged 2 years and older.

Kerry states that it relies on the Dietary Reference Intake levels for dietary fiber as reported by the Institute of Medicine (IOM). The IOM reports the adequate intake of dietary fiber is in the range of 30 to 38 g/p/d and 21 to 26 g/p/d for adult males and females, respectively; IOM does not establish an upper limit for dietary fiber. Kerry considers unpublished studies with bakers yeast beta-glucan to be corroborative of safety and that based on an updated literature search through May 2025, there are no new publications that would contradict their GRAS conclusion.

Based on the available data and information, Kerry concludes that bakers yeast beta-glucan is GRAS under the intended conditions of use.

Standards of Identity

In the supplement, Kerry states its intention to use bakers yeast beta-glucan in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. 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.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is

[3] We evaluated GRNs 000239, 000309, 000413, and 000995; and responded in letters dated July 22, 2008, June 14, 2010, September 28, 2016, and June 14, 2022, respectively, stating that we had no questions at those times regarding the notifier's GRAS conclusions.

[4] Kerry states the subjects of these GRAS notices are *beta*-glucans derived from yeast, with branched 1,3 and 1,6 glycosidic linkages. In its cumulative dietary exposure estimate, Kerry does not include uses described in GRAS notices where the subject of the notice is plant-derived beta-glucans with linear 1,3 and 1,4 glycosidic linkages.

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 bakers yeast beta-glucan 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 Nutrition Center of Excellence. The Office of Pre-Market 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.

Section 301(ll) 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 Kerry's supplement concluding that bakers yeast beta-glucan 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 bakers yeast beta-glucan. Accordingly, our response should not be construed to be a statement that foods containing bakers yeast beta-glucan, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Kerry provided, as well as other information available to FDA, we have no questions at this time regarding Kerry's conclusion that bakers yeast beta-glucan is GRAS under its intended conditions of use. This letter is not an affirmation that bakers yeast beta-glucan 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 000239 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.12.08 16:56:24 -05'00'

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