U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Kevin Scaife
Intertek Health Sciences Inc.
2233 Argentia Rd
Mississauga, Ontario L5N 2X7
Canada

Re: GRAS Notice No. GRN 001240

Dear Mr. Scaife:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001240. We received the notice that you submitted on behalf of Wecare Probiotics Co., Ltd. (Wecare Probiotics) on December 19, 2024, and filed it on March 12, 2025. Wecare Probiotics submitted an amendment to the notice on May 27, 2025, clarifying the identity, manufacturing process, specifications, and intended uses.

The subject of the notice is *Lacticaseibacillus rhamnosus* ATCC PTA-126815 for use as an ingredient in conventional foods at levels up to 1 x 10^{11} colony forming units (CFU) per serving (excluding use in infant formula, foods formulated for infants, alcoholic beverages, and products under the jurisdiction of the United States Department of Agriculture). The notice informs us of Wecare Probiotics' view that these uses of *L. rhamnosus* ATCC PTA-126815 are GRAS through scientific procedures.

Wecare Probiotics discusses the identity of *L. rhamnosus* ATCC PTA-126815 and describes it as a white to brown powder. Wecare Probiotics states that *L. rhamnosus* ATCC PTA-126815 is a non-pathogenic, non-toxigenic, Gram-positive, rod-shaped, lactic acid-producing bacterium that was isolated from the feces of a healthy infant. Wecare Probiotics discusses the results of genomic and phenotypic analyses to confirm the strain's identity. Wecare Probiotics states that *L. rhamnosus* ATCC PTA-126815 is not genetically modified and is deposited in the American Type Culture Collection (ATCC) under the designation number of ATCC PTA-126815.

Wecare Probiotics describes the manufacturing process for *L. rhamnosus* ATCC PTA-126815, stating that it is produced by fermentation of a pure culture in a sterile, contained environment. Wecare Probiotics states that after fermentation, the *L. rhamnosus* ATCC PTA-126815 biomass is collected by centrifugation, mixed with a cytoprotectant, freeze dried, crushed into a powder, and mixed with excipients to yield the final product. Wecare Probiotics states that *L. rhamnosus* ATCC PTA-126815 is manufactured in accordance with current good manufacturing practices and that all raw

materials are food-grade and are used in accordance with applicable U.S. regulations or are GRAS for the intended use.

Wecare Probiotics provides specifications for *L. rhamnosus* ATCC PTA-126815 that include viable cell count (≥ 1 x 10^{11} CFU/g), limits for heavy metals, including lead (< 0.1 mg/kg), and microorganisms, including *Salmonella* spp. (not detected in 25 g), *Staphylococcus aureus* (< 10 CFU/g), and *Listeria monocytogenes* (not detected in 25 g). Wecare Probiotics provides the results from the analyses of five non-consecutive batches to demonstrate that *L. rhamnosus* ATCC PTA-126815 can be manufactured to meet these specifications. Wecare Probiotics states that *L. rhamnosus* ATCC PTA-126815 is stable for 24 months when stored in a well-closed container at -18 °C.

Wecare Probiotics estimates the dietary exposure to *L. rhamnosus* ATCC PTA-126815 from the intended uses to be 1.0 x 10^{12} CFU/person/d based on the assumption that an individual consumes on average 20 servings of food/d and that 10 servings of food will contain *L. rhamnosus* ATCC PTA-126815 at the maximum use level of 1.0 x 10^{11} CFU/serving. Wecare Probiotics states that the intended uses of *L. rhamnosus* ATCC PTA-126815 are substitutional to the uses described in GRN 001093[1] and therefore an increase in dietary exposure to *L. rhamnosus* is not expected from the intended uses.

Wecare Probiotics discusses the history of safe use of *L. rhamnosus* in human foods, describing its use in food products and the production of fermented foods. Wecare Probiotics states that in addition to being isolated from infant fecal samples, *L. rhamnosus* has also been isolated from human breast milk. Wecare Probiotics incorporates into their notice and provides summaries of the information pertaining to the safety of *L. rhamnosus* in food discussed in GRNs 000231, 000288, 001013, 001083, 001093, and 001130.[2] Wecare Probiotics also provides the results of analyses demonstrating a high degree of genetic and proteomic identity between *L. rhamnosus* ATCC PTA-126815 and *L. rhamnosus* strains GG, HN001, and IDCC3201, which were the subjects of previous GRNs. Wecare Probiotics discusses published toxicity studies supporting the safety of other strains of *L. rhamnosus*, with the studies demonstrating no adverse effects. Wecare Probiotics discusses corroborative unpublished acute and short-term toxicity studies that assessed the safety of *L. rhamnosus* ATCC PTA-126815, with these studies showing no report of adverse effects. Wecare Probiotics discusses the results of bioinformatic analyses and concludes that no genes encoding virulence factors, toxigenicity, or antibiotic resistance were identified in the genome of *L. rhamnosus* ATCC PTA-126815 and the strain is unable to produce biogenic amines or D-lactate.

Based on the data and information provided in the submission, Wecare Probiotics concludes that *L. rhamnosus* ATCC PTA-126815 is GRAS for its intended use.

Standards of Identity

In the notice, Wecare Probiotics states its intention to use *L. rhamnosus* ATCC PTA-126815 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 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 *L. rhamnosus* ATCC PTA-126815 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) of the 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 Wecare Probiotics' notice concluding that *L. rhamnosus* ATCC PTA-126815 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 *L. rhamnosus* ATCC PTA-126815. Accordingly, our response should not be construed to be a statement that foods containing *L. rhamnosus* ATCC PTA-126815, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Wecare Probiotics provided, as well as other information available to FDA, we have no questions at this time regarding Wecare Probiotics' conclusion that *L. rhamnosus* ATCC PTA-126815 is GRAS under its intended conditions of use. This letter is not an affirmation that *L. rhamnosus* ATCC PTA-126815 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 GRN 001240 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.07.08 11:19:46 -04'00'

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

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1. The subject of GRN 001093 was *L. rhamnosus* ATCC BAA-2836. We evaluated this notice and responded in a letter dated June 9, 2023, stating that we had no questions at the time regarding the notifier's GRAS conclusion.
2. The subjects of GRNs 000231, 000288, 001013, 001083, and 001130 are various strains of *L. rhamnosus*. We evaluated these notices and responded in letters dated May 29, 2008, November 1, 2009, December 15, 2021, October 31, 2023, and September 28, 2023, respectively, stating that we had no questions at the time regarding the notifiers' GRAS conclusions.