U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Kevin Scaife
Intertek Health Sciences Inc.
2233 Argentia Road, Suite 201
Mississauga, Ontario, L5N 2X7
CANADA

Re: GRAS Notice No. GRN 001239

Dear Mr. Scaife:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001239. We received Wecare Probiotics Co., Ltd. (Wecare Probiotics)'s GRAS notice on December 19, 2024, and filed it on February 26, 2025. Wecare Probiotics submitted amendments to the notice on April 29, 2025, that clarified the manufacturing process, specifications, intended uses and safety information.

The subject of the notice is *Bifidobacterium animalis* subsp. *lactis* PTA-126817 (*B. animalis* subsp. *lactis* PTA-126817) for use as an ingredient in conventional foods at levels up to 5 x 10^{11} colony forming units (CFU)/serving.[1] The notice informs us of Wecare Probiotics' view that these uses of *B. animalis* subsp. *lactis* PTA-126817 are GRAS through scientific procedures.

Wecare Probiotics describes *B. animalis* subsp. *lactis* PTA-126817 as a white to brown colored powder and states that *B. animalis* subsp. *lactis* PTA-126817 is a non-pathogenic, non-toxigenic, Gram-positive, rod-shaped, anaerobic, non-spore-forming, lactic acid-producing bacterium. Wecare Probiotics notes that the strain was isolated from the breast milk of a healthy woman and has been deposited in the American Type Culture Collection with the depository number PTA-126817. Wecare Probiotics describes the taxonomic analysis for the identity of the strain. Wecare Probiotics also discusses the results of genomic analyses to confirm the strain's identity and states that the strain is not genetically modified. Wecare Probiotics discusses the results of phenotypic and genotypic characterization performed on *B. animalis* subsp. *lactis* PTA-126817 and states that *B. animalis* subsp. *lactis* PTA-126817 has no genes for pathogenicity and virulence, and lacks antibiotic resistance characteristics.

Wecare Probiotics describes the manufacture of *B. animalis* subsp. *lactis* PTA-126817 by fermentation of a pure culture under controlled conditions. After fermentation, the fermentate is subjected to centrifugation. The collected bacterial cells are mixed with a cryoprotectant, freeze-dried and sieved. The resulting powder is mixed with excipients to obtain the final

product. Wecare Probiotics states that *B. animalis* subsp. *lactis* PTA-126817 is manufactured under 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 their intended use. Wecare Probiotics states that the raw materials used in the manufacture are not derived from major allergens and *B. animalis* subsp. *lactis* PTA-126817 does not contain any major allergens.

Wecare Probiotics provides specifications for *B. animalis* subsp. *lactis* PTA-126817 that include total cell count (≥ 1 x 10^{11} CFU/g), and limits for heavy metals, including lead (< 0.1 mg/kg) and microorganisms, including *Escherichia coli* (not detected in 1 g), *Salmonella* spp. (not detected in 25 g), *Listeria monocytogenes* (not detected in 25 g), and *Staphylococcus aureus* (< 10 CFU/g). Wecare Probiotics provides the results from the analyses of five non-consecutive batches to demonstrate that *B. animalis* subsp. *lactis* PTA-126817 can be manufactured to meet these specifications. Wecare Probiotics states that *B. animalis* subsp. *lactis* PTA-126817 is stable for 24 months when stored at -18 °C in a well-closed container.

Wecare Probiotics estimates the dietary exposure to *B. animalis* subsp. *lactis* PTA-126817 from the intended uses to be 5 x 10^{12} CFU/person/day based on the assumption that an individual consumes on average 20 servings of food/d in the United States and 10 servings of food would contain *B. animalis* subsp. *lactis* PTA-126817 at the maximum use level of 5 x 10^{11} CFU/serving. Wecare Probiotics states that the intended uses of *B. animalis* subsp. *lactis* PTA-126817 are substitutional to the current uses of other *B. animalis* subsp. *lactis* strains and therefore, an increase in dietary exposure to *B. animalis* subsp. *lactis* is not expected.

Wecare Probiotics discusses data and information used to support the safety of *B. animalis* subsp. *lactis* PTA-126817, including a history of safe use of the *B. animalis* subsp. *lactis* in fermented and non-fermented foods and beverages. Wecare Probiotics incorporates into their notice and provides summaries of the information pertaining to the safety of live *B. animalis* subsp. *lactis* in food discussed in GRNs 000049, 000377, 000445, 000855, 000856, 000872, 000952, 001082 and 001092.[2] Wecare Probiotics also demonstrates over 99% of average protein and nucleotide identity between *B. animalis* subsp. *lactis* PTA-126817 and *B. animalis* subsp. *lactis* strains HN019, BB-12, AD011, and IDCC 4301 that were subjects of previous GRNs. Wecare Probiotics discusses opportunistic infection caused by certain *B. animalis* subsp. *lactis* strains and states that there is no concern for safety and the reported infections only occurred in immunocompromised patients with underlying conditions. Wecare Probiotics summarizes published toxicology studies and human studies on *B. animalis* subsp. *lactis* and states that no adverse effects were observed at the test doses in these studies.

Based on the totality of the data and information, Wecare Probiotics concludes that *B. animalis* subsp. *lactis* PTA-126817 is GRAS for its intended use.

Standards of Identity

In the notice, Wecare Probiotics states its intention to use *B. animalis* subsp. *lactis* PTA-126817 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.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, & Cosmetic (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 *B. animalis* subsp. *lactis* PTA-126817 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 (OPMAS) 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 Federal Food, Drug, and Cosmetic Act (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 *B. animalis* subsp. *lactis* PTA-126817 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 *B. animalis* subsp. *lactis* PTA-126817. Accordingly, our response should not be construed to be a statement that foods containing *B. animalis* subsp. *lactis* PTA-126817, 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 *B. animalis* subsp. *lactis* PTA-126817 is GRAS under its intended conditions of use. This letter is not an affirmation that *B. animalis* subsp. *lactis* PTA-126817 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 001239 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.06.11 09:55:03 -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. Wecare Probiotics states that *B. animalis* subsp. *lactis* PTA-126817 is not intended for use in infant formula, infant food products, products under the jurisdiction of the United States Department of Agriculture, alcoholic beverages, or in foods where standards of identity preclude its use.
2. The subjects of GRNs 000049, 000377, 000445, 000855, 000856, 000872, 000952, 001082 and 001092 are various *B. animalis* subsp. *lactis* strains. We evaluated these notices and responded in letters dated March 19, 2002, September 29, 2011, April 10, 2013, February 5, 2020, December 9, 2019, December 9, 2019, March 17, 2021, October 31, 2023 and June 23, 2023, respectively, stating that we had no questions at the time regarding the notifiers' GRAS conclusions.