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 001283

Dear Mr. Scaife:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001283. We received the notice that you submitted on behalf of Wecare Probiotics Co., Ltd. (Wecare Probiotics) on May 20, 2025 and filed it on December 1, 2025. Wecare Probiotics submitted an amendment to the notice on February 3, 2026 that provided additional information on the identity as well as clarifications on the analytical methods and batch analyses.

The subject of the notice is *Heyndrickxia coagulans* ATCC PTA-126829 spore preparation (*H. coagulans* ATCC PTA-126829 spore preparation) for use as an ingredient in baked goods and baking mixes; beverages and beverage bases; breakfast cereals; chewing gum; coffee and tea; condiments and relishes; confections and frostings; dairy product analogs; fruit juices; frozen dairy desserts and mixes; fruit and water ices; gelatins, puddings, and fillings; grain products and pastas; hard candy; herbs, seeds, spices, seasonings, blends, extracts, and flavorings; jams and jellies; milk; milk products; nuts and nut products; plant protein products; processed fruits; processed vegetables and vegetable juices; snack foods; soft candy; soups and soup mixes; sugar; and sweet sauces, toppings, and syrups (excluding use in infant formula, infant food products, alcoholic beverages, and products under the jurisdiction of the United States Department of Agriculture) at levels up to 2×10^9 colony forming units (CFU)/serving. Wecare Probiotics states that *H. coagulans* was formerly classified as *Bacillus coagulans*, as reported in Narsing *et. al* (Ref.1). In this notice, Wecare Probiotics uses "*Bacillus coagulans* BC99". The notice informs us of Wecare Probiotics' view that these uses of *H. coagulans* ATCC PTA-126829 spore preparation are GRAS through scientific procedures.

Wecare Probiotics describes *H. coagulans* ATCC PTA-126829 spore preparation as a white to yellowish brown powder. Wecare Probiotics states that *H. coagulans* ATCC PTA-126829 is non-pathogenic and non-toxigenic, as confirmed through a comprehensive set of validated methods. *H. coagulans* ATCC PTA-126829 is a Gram-positive, spore-forming, rod-shaped, facultative anaerobe. The strain was isolated from the stool of a healthy infant and has been deposited in the American Type Culture

Collection (ATCC) with deposit number PTA-126829. Wecare Probiotics discusses the phenotypic and genotypic characterization used to confirm the strain's identity. Wecare Probiotics states that *H. coagulans* ATCC PTA-12682 is not genetically modified and established that it does not contain antibiotic resistance genes based on comprehensive bioinformatic and phenotypic analyses.

Wecare Probiotics describes the manufacture of *H. coagulans* ATCC PTA-126829 spore preparation by batch-fed fermentation of a pure culture under controlled conditions. After fermentation, the cells are separated from the fermentation medium using centrifugation. The biomass is spray dried and then crushed and sieved to obtain a powder. The dried powder is then mixed with excipients as needed. Wecare Probiotics states that *H. coagulans* ATCC PTA-126829 spore preparation is manufactured under current good manufacturing practices using food-grade raw materials. Wecare Probiotics states that all raw materials are used in accordance with applicable U.S. regulations or are GRAS for their intended uses. Wecare Probiotics states that the raw materials used in the manufacturing process are not derived from major food allergens and *H. coagulans* ATCC PTA-126829 spore preparation does not contain any major food allergens.

Wecare Probiotics provides specifications for *H. coagulans* ATCC PTA-126829 spore preparation that include viable cell count (≥ 1 to 500 x 10^9 CFU/g), moisture (≤ 5 g/100 g), limits for heavy metals, including lead (≤0.1 mg/kg), and microorganisms, including coliforms (≤ 10 CFU/g), yeast and mold (≤ 50 CFU/g), *Bacillus cereus* (≤ 1,000 CFU/g), *Salmonella* (not detected in 10 g), *Shigella sp.* (not detected in 25 g), *Staphylococcus aureus* (not detected in 10 g), *Pseudomonas aeruginosa* (≤ 10 CFU/g), and *Listeria monocytogenes* (not detected in 25 g). Wecare Probiotics provides results from the analyses of four non-consecutive batches to demonstrate that *H. coagulans* ATCC PTA-126829 spore preparation can be manufactured to meet these specifications. Wecare Probiotics states that *H. coagulans* ATCC PTA-126829 spore preparation is stable for 36 months at 25°C and 60±5% relative humidity when stored in a dry, dark, and well-closed container.

Wecare Probiotics estimates the dietary exposure to *H. coagulans* ATCC PTA-126829 spore preparation from the intended uses to be 36.4 x 10^9 CFU/person/d based on the assumption that the maximum number of food servings consumed per day by males 51 years and older is 18.2 servings/d and that each serving will contain *H. coagulans* ATCC PTA-126829 spore preparation at the maximum use level of 2 x 10^9 CFU/serving. Wecare Probiotics states that the intended uses of *H. coagulans* ATCC PTA-126829 spore preparation are in the same food categories and at the same use levels as those described in GRN 000399[1] and therefore, an increase in dietary exposure to *H. coagulans* from the intended uses is not expected.

Wecare Probiotics discusses data and information to support the safety of *H. coagulans* ATCC PTA-126829 spore preparation in food, including a history of safe use of *H.*

[1] The subject of GRN 000399 was *B. coagulans* GBI-30, 6086 spore preparation. We evaluated this notice and responded in a letter dated July 31, 2012, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

coagulans in various fermented foods. Wecare Probiotics incorporates into their notice and provides summaries of the information pertaining to the safety of the *H. coagulans* discussed in GRNs 000399,[2] 000526, 000597, 000601, 000660, 000670, 000691, 000725, 000864, and 000949.[2]

Wecare Probiotics summarizes toxicological, genotoxicity, and human clinical studies, concluding that the publications support the safe consumption of *H. coagulans* ATCC PTA-126829 spore preparation and that no treatment-related adverse effects were identified. Wecare Probiotics states that several strains of *H. coagulans* have been safely consumed as part of the human diet and that cases of bacteremia associated with this organism occur rarely and are primarily in immunocompromised populations, and therefore, *H. coagulans* consumption in general poses minimal concern for opportunistic infections.

Based on the totality of the data and information, Wecare Probiotics concludes that *H. coagulans* ATCC PTA-126829 spore preparation is GRAS for its intended use.

Standards of Identity

In the notice, Wecare Probiotics states its intention to use *H. coagulans* ATCC PTA-126829 spore preparation 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, 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 *H. coagulans* ATCC PTA-126829 spore preparation 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

[2] The subjects of 000526, 000597, 000601, 000660, 000670, 000691, 000725, 000864, and 000949 are various *B. coagulans* strains. We evaluated these notices and responded in letters dated March 23, 2015, February 29, 2016, April 28, 2016, January 13, 2017, March 15, 2017, August 28, 2017, February 12, 2018, February 6, 2022, and January 7, 2021, respectively, stating that we had no questions at that time regarding the notifiers' GRAS conclusions.

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's notice concluding that *H. coagulans* ATCC PTA-126829 spore preparation 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 *H. coagulans* ATCC PTA-126829 spore preparation. Accordingly, our response should not be construed to be a statement that foods containing *H. coagulans* ATCC PTA-126829 spore preparation, 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's conclusion that *H. coagulans* ATCC PTA-126829 spore preparation is GRAS under its intended conditions of use. This letter is not an affirmation that *H. coagulans* ATCC PTA-126829 spore preparation 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 001283 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2026.03.18 17:26:08 -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

References:

1. Narsing Rao, M. P., Banerjee, A., Liu, G.-H., & Thamchaipenet, A. (2023). Genome-based reclassification of *Bacillus acidicola*, *Bacillus pervagus* and the

genera *Heyndrickxia*, *Margalitia* and *Weizmannia*. Int J Syst Evol Microbiol, 73(7). https://doi.org/10.1099/ijsem.0.005961.