U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Vickie Modica
AIBMR Life Sciences, Inc
1425 Broadway, Suite 458
Seattle, WA 98122

Re: GRAS Notice No. GRN 001263

Dear Ms. Modica:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001263. We received the notice that you submitted on behalf of Jeneil Biotech, Inc. (Jeneil) on February 27, 2025, and filed it on July 3, 2025. Jeneil submitted an amendment to the notice on September 25, 2025, clarifying the manufacturing process, specifications, and safety information.

The subject of the notice is *Heyndrickxia coagulans* PTA-127366[1] spore preparation for use as an ingredient at a maximum level of $2 \times 10^9$ colony forming units (CFU)/serving in baked goods and baking mixes; breakfast cereals; beverages and beverage bases; coffee and tea; milk and milk products; dairy product analogs; fruit juices; condiments and relishes; confections and frostings; frozen dairy desserts and mixes; fruit and water ices; jams and jellies; gelatins, puddings and fillings; grain products and pastas; hard and soft candy; chewing gum; extracts, flavorings, herbs, seeds, spices, seasonings and blends; nuts and nut products; plant protein products; processed fruits; processed vegetables and vegetable juices; snack foods; soups and soup mixes; sugar; and sweet sauces, toppings and syrups (excluding use in infant formula, alcoholic beverages, products under the jurisdiction of the United States Department of Agriculture, or in any food for which standards of identity would preclude its use). The notice informs us of Jeneil's view that these uses of *H. coagulans* PTA-127366 spore preparation are GRAS through scientific procedures.

Jeneil describes *H. coagulans* PTA-127366 spore preparation as a beige to light tan powder. Jeneil states that *H. coagulans* PTA-127366 is a non-pathogenic, non-toxigenic, Gram-positive, spore-forming, motile, rod-shaped bacterium. The strain was isolated from tapioca starch and has been deposited in the American Type Culture Collection (ATCC) with deposit number PTA-127366. Jeneil discusses the results of phenotypic and genotypic characterization used to confirm the strain's identity. Jeneil states that the organism is not genetically modified, and its genome was free of any known antibiotic

[1] Jeneil states that *Heyndrickxia coagulans* was formerly classified as *Bacillus coagulans*, as reported in 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. The notice refers to this organism by its former name, *B. coagulans*.

resistance genes.

Jeneil describes the manufacture of *H. coagulans* PTA-127366 spore preparation by batch fermentation of a pure culture under controlled conditions. After fermentation, the cells are separated from the fermentation medium and concentrated via centrifugation. The biomass is then freeze-dried, milled into a powder, sieved and formulated with diluents to achieve the desired product concentration. Jeneil states that *H. coagulans* PTA-127366 spore preparation is manufactured under current good manufacturing practices using food-grade raw materials and that all raw materials and processing aids used in the manufacturing process are used in accordance with applicable U.S. regulations, are GRAS for their respective uses, or are the subject of an effective food contact notification. Jeneil states that *H. coagulans* PTA-127366 spore preparation does not contain any major allergens.

Jeneil provides specifications for *H. coagulans* PTA-127366 spore preparation that include total viable spore count ($\geq 1.5 \times 10^{10}$ CFU/g), limits for moisture (≤ 6%), heavy metals, including lead (≤ 0.1 mg/kg), and microorganisms, including *Escherichia coli* (absent in 10 g), *Salmonella* species (absent in 25 g), coagulase positive *Staphylococcus* (absent in 10 g), and *Listeria* species (absent in 25 g). Jeneil provides results from the analyses of three non-consecutive batches to demonstrate that *H. coagulans* PTA-127366 spore preparation can be manufactured to meet these specifications. Jeneil states that *H. coagulans* PTA-127366 spore preparation is stable at 20-25 °C and 30-60% relative humidity for 18 months.

Jeneil estimates the dietary exposure to *H. coagulans* PTA-127366 spore preparation to be $3.6 \times 10^{10}$ CFU/person/d based on the assumption that an individual consumes an average of 18.2 servings of food/d in the US and those servings contain *H. coagulans* PTA-127366 spore preparation at the maximum use level of $2 \times 10^{9}$ CFU/serving. Jeneil states that the intended uses of *H. coagulans* PTA-127366 spore preparation are substitutional for those described in other GRNs and therefore, there would be no increase in the dietary exposure to *B. coagulans* as this would be an alternative strain.[2]

Jeneil discusses data and information to support the safety of *H. coagulans* PTA-127366 spore preparation in food, including a history of safe use of *H. coagulans* in various fermented foods. Jeneil incorporates into their notice and provides summaries of the information pertaining to the safety of the *H. coagulans* discussed in GRNs 000240, 000378, 000399, 000526, 000597, 000601, 000660, 000670, 000691, 000725, 000864, and 000949. Additionally, Jeneil performed a literature search to identify studies pertinent to the safety assessment published through September 2024.

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[2] The subjects of GRNs 000949, 000691, 000601, 000597, 000526, 000399 are *Bacillus coagulans* strain DSM 17654 spore preparation, SANK 70258 spore preparation, MTCC 5856 spore preparation, SNZ1969 spore preparation, Unique IS2 spore preparation, and GBI-30, 6086 spore preparation, respectively. We evaluated these notices and responded in letters dated January 7, 2021, August 28, 2017, April 28, 2016, February 29, 2016, March 23, 2015, and July 31, 2012, respectively, stating that we had no questions at that time regarding the notifiers' GRAS conclusions.

Jeneil summarizes relevant toxicological, genotoxicity, and human clinical studies, concluding that the publications support the safe consumption of *H. coagulans* PTA-127366 spore preparation and that no treatment-related adverse effects were identified. Jeneil 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. To this end, Jeneil states that they identified only one documented case of *B. coagulans* bacteremia since the 1950s and therefore, *H. coagulans* consumption in general poses minimal concern for opportunistic infections.

Based on the data and information summarized above, Jeneil concludes that *H. coagulans* PTA-127366 spore preparation is GRAS for its intended use.

**Standards of Identity**

In the notice, Jeneil states its intention to use *H. coagulans* PTA-127366 spore preparation 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 & 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 *H. coagulans* PTA-127366 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 (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 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 Jeneil's notice concluding that *H. coagulans* PTA-127366 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* PTA-127366 spore preparation. Accordingly, our response should not be construed to be a statement that foods containing *H. coagulans* PTA-

127366 spore preparation, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

**Conclusions**

Based on the information that Jeneil provided, as well as other information available to FDA, we have no questions at this time regarding Jeneil's conclusion that *H. coagulans* PTA-127366 spore preparation is GRAS under its intended conditions of use. This letter is not an affirmation that *H. coagulans* PTA-127366 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 001263 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.12.09 17:16:29 -05'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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