U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Kevin Gillies
Kevin O. Gillies Consulting Services, LLC
1759 Grape St.
Denver, Colorado, 80220

Re: GRAS Notice No. GRN 001278

Dear Mr. Gillies:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001278. We received Beijing Scitop Bio-tech Co., LTD (Scitop Bio)'s notice on May 7, 2025 and filed it on August 25, 2025. Scitop Bio submitted amendments to the notice on January 27, 2026, February 13, 2026 and March 3, 2026, providing clarifying information about the microorganism, manufacturing process, specifications, analytical methods, safety, and an updated literature search.

The subject of the notice is *Lactiplantibacillus plantarum* CGMCC 6312 (*L. plantarum* CGMCC 6312) for use as an ingredient in conventional foods at a level up to 1×10^{11} colony forming units (CFU) per serving, except in infant formula, products under the jurisdiction of the United States Department of Agriculture, and alcoholic beverages. The notice informs us of Scitop Bio's view that these uses of *L.plantarum* CGMCC 6312 are GRAS through scientific procedures.

Scitop Bio describes *L. plantarum* CGMCC 6312 as a white to yellow powder. Scitop Bio states that *L. plantarum* CGMCC 6312 is a non-pathogenic, non-toxigenic, Gram-positive, rod-shaped, mesophilic, anaerobic bacterium that was originally isolated from sour cow milk. Scitop Bio discusses the results of genomic and phenotypic analyses to confirm the strain's identity. Scitop Bio states that *L. plantarum* CGMCC 6312 is not genetically modified and is deposited in the Chinese General Microbiological Culture Collection Center (CGMCC) with the depository number CGMCC 6312.

Scitop Bio describes the manufacturing process for *L. plantarum* CGMCC 6312, stating that it is produced by fermentation of a pure culture in a sterile, controlled environment. After fermentation, the cells are collected by centrifugation, mixed with cryoprotectants, freeze dried, and ground into a powder to yield the final product. Scitop Bio states that *L. plantarum* CGMCC 6312 is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids used in the manufacturing process are food-grade and are used in accordance with applicable U.S. regulations, are GRAS for their intended use, or are the subject of an effective food contact notification. Scitop Bio states that none of the raw materials

used in the manufacturing process are major allergens or are derived from major allergens and *L. plantarum* CGMCC 6312 does not contain any major allergens.

Scitop Bio provides specifications for *L. plantarum* CGMCC 6312 that include viable cell count (≥ 5.0 x 10^{11} CFU/g), and limits for water activity (≤0.2), moisture (≤ 6%), heavy metals, including lead (< 0.1 mg/kg), and microorganisms, including *Enterobacteriaceae (*< 10 CFU/g), *Salmonella* spp. (not detectable in 25 g), *Staphylococcus aureus* (not detectable in 25 g), and *Listeria monocytogenes* (not detectable in 25 g). Scitop Bio provides the results from the analyses of three non-consecutive batches to demonstrate that *L. plantarum* CGMCC 6312 can be manufactured to meet these specifications.

Scitop Bio estimates the dietary exposure to *L. plantarum* CGMCC 6312 from the intended uses to be 1 x 10^{12} CFU/person/day based on the assumption that an individual consumes an average of 20 servings of food/day in the U.S. and half of those servings contain *L. plantarum* CGMCC 6312 at the maximum level of 1 x 10^{11} CFU/serving. Scitop Bio states that the intended uses of *L. plantarum* CGMCC 6312 are substitutional for other *L. plantarum* strains; therefore, there would be no increase in the dietary exposure to *L. plantarum* as this would be an alternative strain.

Scitop Bio discusses the history of safe use of *L. plantarum* in human foods, describing its use in fermented foods, such as milks, bread, meats, and vegetables. Scitop Bio incorporates into their notice and provides summaries of the information pertaining to the safety of *L. plantarum* in food discussed in GRNs 000685, 000722, 000847, 000946, 000953, 001086, 001108, 001113, 001127, 001158.[1] Scitop Bio discusses the results of bioinformatic analyses and concludes that no genes encoding virulence factors or toxigenicity were identified in the genome of *L. plantarum* CGMCC 6312. While Scitop Bio states that *L. plantarum* CGMCC 6312 is sensitive to most clinically relevant antibiotics, genomic analysis identified genes associated with aminoglycoside resistance, and the results of *in vitro* testing demonstrated resistance to vancomycin. Scitop Bio explains that resistance to aminoglycosides and vancomycin is intrinsic to *L. plantarum* isolates. Scitop Bio discusses data showing that *L. plantarum* CGMCC 6312 is unable to produce biogenic amines.

Based on the totality of the data and information, Scitop Bio concludes that *L. plantarum* CGMCC 6312 is GRAS for its intended use.

Standards of Identity

In the notice, Scitop Bio states its intention to use *L. plantarum* CGMCC 6312 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

[1] The subjects of GRNs 000685, 000722, 000847, 000946, 000953, 001086, 001108, 001113, 001127, 001158 are various strains of *L. plantarum*. We evaluated these notices and responded in letters dated October 31, 2017, February 16, 2018, September 30, 2019, February 5, 2021, February 5, 2021, October 27, 2023, August 16, 2023, July 20, 2023, February 1, 2024, and May 8, 2024, respectively, stating that we had no questions at the time regarding the notifiers' GRAS conclusions.

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 *L. plantarum* CGMCC 6312 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 Scitop Bio 's notice concluding that *L. plantarum* CGMCC 6312 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. plantarum* CGMCC 6312. Accordingly, our response should not be construed to be a statement that foods containing *L. plantarum* CGMCC 6312, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Scitop Bio provided, as well as other information available to FDA, we have no questions at this time regarding Scitop Bio's conclusion that *L. plantarum* CGMCC 6312 is GRAS under its intended conditions of use. This letter is not an affirmation that *L. plantarum* CGMCC 6312 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 001278 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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Susan J. Carlson, Ph.D.
Director
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