U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Kevin O. Gillies
Kevin O. Gillies Consulting Services, LLC
1759 Grape Street
Denver, CO 80220

Re: GRAS Notice No. GRN 001317

Dear Mr. Gillies:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001317. We received the notice that you submitted on behalf of Beijing Scitop Bio-Tech Co., LTD (Scitop Bio) on November 20, 2025, and filed it on May 28, 2026. Scitop Bio submitted an amendment to the notice on July 18, 2026, clarifying the identity, analytical methods, composition, specifications, intended use, dietary exposure, and stability.

The subject of the notice is *Bifidobacterium animalis* subsp. *lactis* CGMCC 18610 (*B. animalis* subsp. *lactis* CGMCC 18610) for use as an ingredient in conventional foods at levels up to 1×10^{11} colony forming units (CFU)/serving (excluding infant formula, alcoholic beverages, and products under the jurisdiction of the United States Department of Agriculture). The notice informs us of Scitop Bio's view that this use of *B. animalis* subsp. *lactis* CGMCC 18610 is GRAS through scientific procedures.

Scitop Bio describes *B. animalis* subsp. *lactis* CGMCC 18610 as a white to yellow powder. Scitop Bio states that *B. animalis* subsp. *lactis* CGMCC 18610 is a Gram-positive, rod-shaped bacterium. Scitop Bio cites a published article describing *B. animalis* subsp. *lactis* CGMCC 18610 as nonsporulating. The strain was isolated from human breast milk colostrum and is deposited in the Chinese General Microbiological Culture Collection Center under the number CGMCC 18610. Scitop Bio describes the taxonomic identity of the strain. Scitop Bio also discusses the results of genomic analyses to confirm the strain's identity and states that the strain is not genetically engineered. Scitop Bio discusses the results of phenotypic and genotypic characterization and states that *B. animalis* subsp. *lactis* CGMCC 18610 lacks genes encoding virulence factors, toxins, and biogenic amines. Scitop Bio also states that *B. animalis* subsp. *lactis* CGMCC 18610 lacks antibiotic resistance genes except for the resistance to tetracycline which is not acquirable or transmissible.

Scitop Bio describes the manufacture of *B. animalis* subsp. *lactis* CGMCC 18610 by fermentation of a pure culture under controlled conditions. After fermentation, the culture is centrifuged to wash and collect the bacterial cells. The bacterial cells are

lyophilized with protective agents, and the resulting powder is ground and mixed to obtain the final product. Scitop Bio states that *B. animalis* subsp. *lactis* CGMCC 18610 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. Scitop Bio states that *B. animalis* subsp. *lactis* CGMCC 18610 does not contain major food allergens.

Scitop Bio provides specifications for *B. animalis* subsp. *lactis* CGMCC 18610 that include viable cell count (≥ 5×10^{11} CFU/g), moisture (≥ 6%), water activity (≤ 0.2), and limits for heavy metals, including lead (< 0.1 mg/kg), and microorganisms, including Enterobacteriaceae (< 10 CFU/g), *Staphylococcus aureus* (not detectable in 25 g), *Listeria monocytogenes* (not detectable in 25 g), *Salmonella* serovars (not detectable in 25 g), *Bacillus cereus* (< 100 CFU/g), and total yeasts and molds, (< 10 CFU/g). Scitop Bio provides results from the analyses of three non-consecutive batches to demonstrate that *B. animalis* subsp. *lactis* CGMCC 18610 can be manufactured to conform with the provided specifications. Scitop Bio states that *B. animalis* subsp. *lactis* CGMCC 18610 is stable for approximately two years when stored at -18°C.

Scitop Bio estimates the dietary exposure to *B. animalis* subsp. *lactis* CGMCC 18610 from the intended uses to be 1×10^{12} CFU/person/d 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* CGMCC 18610 at the maximum use level of 1×10^{11} CFU/serving. Scitop Bio states that the intended uses of *B. animalis* subsp. *lactis* CGMCC 18610 are substitutional to the current uses of other *B. animalis* subsp. *lactis* strains and thus, will not significantly increase the dietary exposure to the species.

Scitop Bio discusses data and information used to support the safety of *B. animalis* subsp. *lactis* CGMCC 18610, including a history of safe use of *B. animalis* subsp. *lactis* strains in fermented foods. Scitop Bio incorporates into their notice and provides summaries of the information pertaining to the safety of live *B. animalis* subsp. *lactis* strains in food discussed in GRNs 000049, 000377, 000445, 000856, 000872, 000952, 001082, and 001092).[1] Scitop Bio summarizes published animal and human studies using *B. animalis* subsp. *lactis* CGMCC 18610 as a test article and states that no adverse effects were observed in these studies. Scitop Bio notes that a literature search through July 2025 revealed no reports that contradict their safety conclusion for *B. animalis* subsp. *lactis* CGMCC 18610.

Based on the totality of the information, Scitop Bio concludes that *B. animalis* subsp. *lactis* CGMCC 18610 is GRAS for its intended use.

[1] *B. animalis* subsp. *lactis* strains are the subjects of GRNs 000049, 000377, 000445, 000856 000872, 000952, 001082, and 001092. We evaluated these GRAS notices and responded in letters dated March 19, 2002, September 29, 2011, April 10, 2013, December 9, 2019, March 17, 2021, October 31, 2023, and June 23, 2023, stating that we had no questions at that time about the notifiers' GRAS conclusions.

Standards of Identity

In the notice, Scitop Bio states its intention to use *B. animalis* subsp. *lactis* CGMCC 18610 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 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 *B. animalis* subsp. *lactis* CGMCC 18610 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 *B. animalis* subsp. *lactis* CGMCC 18610 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* CGMCC 18610. Accordingly, our response should not be construed to be a statement that foods containing *B. animalis* subsp. *lactis* CGMCC 18610, 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 *B. animalis* subsp. *lactis* CGMCC 18610 is GRAS under its intended conditions of use. This letter is not an affirmation that *B. animalis* subsp. *lactis* CGMCC 18610 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 001317 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON -S

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