



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

Re: GRAS Notice No. GRN 001303

Dear Mr. Gillies:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001303. We received the notice that you submitted on behalf of Beijing Scitop Biotech Co., Ltd (Scitop Bio) on September 2, 2025, and filed it on March 04, 2026. Scitop Bio submitted amendments to the notice on April 20, 2026 and April 27, 2026, that clarified the analytical methods, manufacturing process, specifications and safety information.

The subject of the notice is *Bifidobacterium animalis* subsp. *lactis* CGMCC5470 (*B. animalis* subsp. *lactis* CGMCC5470) for use as an ingredient in conventional foods at levels up to 1×10^{11} colony forming unit (CFU)/serving (excluding use in infant formula, alcoholic beverages, and in 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* CGMCC5470 is GRAS through scientific procedures.

Scitop Bio describes *B. animalis* subsp. *lactis* CGMCC5470 as a white to yellow powder and states that *B. animalis* subsp. *lactis* CGMCC5470 is a non-pathogenic, non-toxicogenic, Gram-positive, rod-shaped, anaerobic bacterium. Scitop Bio notes that the strain was isolated from the intestinal tract microflora of a healthy Mongolian child and has been deposited in the China General Microbiological Culture Collection Center with the depository number CGMCC5470. Scitop Bio describes the taxonomic analysis for the 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 modified. Scitop Bio discusses the results of phenotypic and genotypic characterization and states that *B. animalis* subsp. *lactis* CGMCC5470 lacks virulence genes, pathogenicity, biogenic amine production and antibiotic resistance characteristics, except for the resistance to tetracycline which is not acquirable or transmissible.

Scitop Bio describes the manufacture of *B. animalis* subsp. *lactis* CGMCC5470 by fermentation of a pure culture under controlled conditions. After fermentation, the fermentate is subjected to centrifugation. The washed and collected bacterial cells are lyophilized with protective agents. The resulting powder is ground and mixed with formulation ingredients to obtain the final product. Scitop Bio states that *B.*

animalis subsp. *lactis* CGMCC5470 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. Scitop Bio states that *B. animalis* subsp. *lactis* CGMCC5470 does not contain any major allergens.

Scitop Bio provides specifications for *B. animalis* subsp. *lactis* CGMCC5470 that include total cell count ($\geq 5.0 \times 10^{11}$ CFU/g), and limits for water activity (≤ 0.2), moisture ($\leq 6\%$), heavy metals, including lead (< 0.1 mg/kg) and microorganisms, including *Escherichia coli* (< 3 most probable number (MPN)/g), *Salmonella* (not detectable in 25 g), *Listeria monocytogenes* (not detectable in 25 g), and *Staphylococcus aureus* (not detectable in 25 g). Scitop Bio provides the results from the analyses of three non-consecutive batches to demonstrate that *B. animalis* subsp. *lactis* CGMCC5470 can be manufactured to meet these specifications.

Scitop Bio estimates the dietary exposure to *B. animalis* subsp. *lactis* CGMCC5470 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* CGMCC5470 at the maximum use level of 1×10^{11} CFU/serving. Scitop Bio states that the intended uses of *B. animalis* subsp. *lactis* CGMCC5470 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* CGMCC5470, including a history of safe use of *B. animalis* subsp. *lactis* 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* in food discussed in GRNs 000049, 000377, 000445, 000855, 000856, 000872, 000952, 001082 and 001092.¹ Scitop Bio summarizes published animal and human studies using *B. animalis* subsp. *lactis* CGMCC5470 as a test article and states that no adverse effects were observed in these studies. Scitop Bio notes that a literature search through April 2026 revealed no evidence of opportunistic infections caused by *B. animalis* subsp. *lactis* strains.

Based on the totality of the data and information, Scitop Bio concludes that *B. animalis* subsp. *lactis* CGMCC5470 is GRAS for its intended use.

Standards of Identity

In the notice, Scitop Bio states its intention to use *B. animalis* subsp. *lactis* CGMCC5470

¹ 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.

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 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* CGMCC5470 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* CGMCC5470 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* CGMCC5470. Accordingly, our response should not be construed to be a statement that foods containing *B. animalis* subsp. *lactis* CGMCC5470, 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* CGMCC5470 is GRAS under its intended conditions of use. This letter is not an affirmation that *B. animalis* subsp. *lactis* CGMCC5470 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 001303 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON Digitally signed by SUSAN J.
CARLSON

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Date: 2026.05.11 09:50:44 -0400'

Susan J. Carlson, Ph.D.
Director
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