



Victoria Davis  
Prozure, Inc.  
22224 Collington Drive  
Boca Raton, FL 33428

Re: GRAS Notice No. GRN 000957

Dear Ms. Davis:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000957. We received the notice that you submitted on behalf of Prozure, Inc. (Prozure) on June 15, 2020, and filed it on October 29, 2020. We received amendments to the notice on May 11, 2021, May 19, 2021, June 9, 2021, September 7, 2021, and October 6, 2021, providing additional information regarding specifications, dietary exposure, and safety.

The subject of the notice is *Lactobacillus johnsonii* strain ATCC PTA-124205 (*L. johnsonii* ATCC PTA-124205)<sup>1</sup> for use as an ingredient in conventional foods<sup>2</sup> at up to 10<sup>10</sup> colony forming units (CFU)/serving. The notice informs us of Prozure's view that these uses of *L. johnsonii* ATCC PTA-124205 are GRAS through scientific procedures.

Prozure describes *L. johnsonii* ATCC PTA-124205 as a white powder. Prozure states that *L. johnsonii* ATCC PTA-124205 is a Gram-positive, rod shaped bacterium, and is deposited in the strain collection of ATCC. Prozure discusses the results of phenotypic and genotypic characterizations used to confirm the strain's identity.

Prozure describes the manufacture of *L. johnsonii* ATCC PTA-124205 by fermentation of a pure culture under controlled conditions. After fermentation, the culture medium is concentrated by centrifugation. Following this, food-grade cryoprotectants are added to the concentrate, which is then frozen. Prozure states that alternatively the ingredient may be freeze-dried and ground into a powder. Prozure states that *L. johnsonii* ATCC PTA-124205 is manufactured using current good manufacturing practices and food-grade raw materials that are approved for their respective uses.

Prozure provides specifications for *L. johnsonii* ATCC PTA-124205 that include limits for microorganisms, including yeast and mold ( $\leq 100$  CFU/g), total coliforms ( $\leq 100$  CFU/g), *Salmonella* serovars (absent in 25 g), *Listeria monocytogenes* (absent in 25 g),

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<sup>1</sup> Prozure designates *L. johnsonii* ATCC PTA-124205 as *L. johnsonii* strain 456.

<sup>2</sup> Prozure states that *L. johnsonii* ATCC PTA-124205 is not intended for use in infant formulas or products under the jurisdiction of the US Department of Agriculture.

and heavy metals, including lead ( $\leq 0.5$  mg/kg). Prozure provides the results of analyses of three non-consecutive lots to demonstrate that *L. johnsonii* ATCC PTA-124205 can be manufactured to meet these specifications.

Prozure intends to use *L. johnsonii* ATCC PTA-124205 at a maximum level of  $10^{10}$  CFU/serving in conventional foods. Prozure estimates dietary exposure to *L. johnsonii* ATCC PTA-124205 to be up to  $10^{11}$  CFU/person/day based on an estimate that the average person consumes 20 food servings/day and an assumption that ten or more servings/day of food contain the maximum use level of *L. johnsonii* ATCC PTA-124205.

Prozure discusses the safety of lactobacilli, their history of safe use in food, and their presence in the human gastrointestinal microbiome to support the safety of *L. johnsonii* ATCC PTA-124205. Prozure states that *L. johnsonii* ATCC PTA-124205 is non-pathogenic and non-toxicogenic. Prozure discusses the results of unpublished studies demonstrating that *L. johnsonii* ATCC PTA-124205 is susceptible to antibiotics and lacks transferable antibiotic resistance genes. Prozure discusses the results of published animal studies demonstrating that consumption of *L. johnsonii* does not induce toxicity. Prozure discusses the results of a clinical study where *L. johnsonii* was administered to healthy adults and reports that no relevant adverse reactions were observed. Prozure discusses published reports of opportunistic infections in immunocompromised individuals and states that these do not present a safety concern for consumption of *L. johnsonii* ATCC PTA-124205. Prozure notes that the European Food Safety Authority concluded that *L. johnsonii* met Qualified Presumption of Safety status in 2007 and has maintained this status.

Based on the totality of evidence, Prozure concludes that *L. johnsonii* ATCC PTA-124205 is GRAS for its intended use.

### **Standards of Identity**

In the notice, Prozure states its intention to use *L. johnsonii* ATCC PTA-124205 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 & 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. johnsonii* ATCC PTA-124205 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 Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety (OFAS) 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.

### **Allergen Labeling**

The FD&C Act requires that the label of a food that is or contains an ingredient that contains a “major food allergen” declare the allergen’s presence (section 403(w)). The FD&C Act defines a “major food allergen” as one of nine foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame (effective January 1, 2023)) or a food ingredient that contains protein derived from one of those foods. *L. johnsonii* ATCC PTA-124205 may require labeling under the FD&C Act because the fermentation medium may contain protein derived from major food allergens, including wheat, soy, and/or milk. Questions about petitions or notifications for exemptions from the food allergen labeling requirements should be directed to the Division of Food Ingredients in OFAS. Questions related to food labeling in general 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 Prozure’s notice concluding that *L. johnsonii* ATCC PTA-124205 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. johnsonii* ATCC PTA-124205. Accordingly, our response should not be construed to be a statement that foods containing *L. johnsonii* ATCC PTA-124205, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

### **Conclusions**

Based on the information that Prozure provided, as well as other information available to FDA, we have no questions at this time regarding Prozure’s conclusion that *L. johnsonii* strain ATCC PTA-124205 is GRAS under its intended conditions of use. This letter is not an affirmation that *L. johnsonii* strain ATCC PTA-124205 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 000957 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

**Susan J.  
Carlson -S**

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