



Sherwin Chen
Super Beta Glucan, Inc.
5 Holland, Unit 109
Irvine, CA 92618

Re: GRAS Notice No. GRN 001124

Dear Mr. Chen:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001124, which we filed on May 22, 2023. We received this request on September 26, 2023.

The subject of the notice is β -glucans from *Hericium erinaceus* strain BCRC 35669 (β -glucans) for use as an ingredient at levels up to 150 mg/serving in cookies; non-milk and milk-based meal replacement beverages; cereal bars (breakfast, granola, and protein); soy protein bars; soy milk; yogurt, yogurt beverages, and milk-based beverages containing live microorganisms; fruit juices, drinks, and smoothies; and chocolate confections.¹ The notice informs us of Super Beta Glucan, Inc. (SBG, you)'s view that these uses of β -glucans are GRAS through scientific procedures.

In response to our questions seeking clarification on the identity and safety of the production strain, manufacturing process, and specifications, SBG provided an amendment received on August 4, 2023, that did not sufficiently characterize the identity and safety of the production strain. Given the substantive nature of this issue, in emails sent to you on September 8, 2023, and September 12, 2023, and in a call with you on September 12, 2023, we recommended that SBG request that we cease our evaluation of GRN 001124. We suggested that SBG request a GRAS pre-submission meeting with us prior to submitting a revised GRAS notice. In an email dated September 26, 2023, SBG requested that we cease our evaluation.

¹ SBG states that β -glucans are not intended for use in infant formula or foods formulated for infants, in any products under the jurisdiction of the United States Department of Agriculture, or in foods for which standards of identity do not permit its addition.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001124 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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