



Mr. Ryan Simon
Intertek
2233 Argentia Rd
Suite 308
Mississauga, ON L5N 2X7
CANADA

Re: GRAS Notice No. GRN 000961

Dear Mr. Simon:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Sichuan Synlight Biotech, Ltd. (Sichuan) to cease our evaluation of GRN 000961, which we filed on November 13, 2020. We received this request on April 28, 2021.

The subject of the notice is β -glucan derived from *Agrobacterium* sp. strain CCTCC No. M2010020 (β -glucan) for use as an ingredient in baked goods and baking mixes; beverages and beverage bases; breakfast cereals; dairy product analogs; frozen dairy desserts; grain products and pastas; gravies and sauces; jams and jellies; milk products; processed fruits and fruit juices; and processed vegetables and vegetable juices at levels ranging from 0.1 to 0.9%.¹ The notice informs FDA of Sichuan's view that β -glucan is GRAS through scientific procedures.

In a teleconference on March 11, 2021, and in a follow-up email dated March 29, 2021, we informed you that we could not continue our evaluation due to the deficiencies we identified in the notice. In the teleconference on March 11, 2021, we discussed deficiencies that require clarification and additional information, including those related to: the manufacturing process, the analytical methods, the intended use, and the dietary exposure estimate to β -glucan; the lack of information regarding the description of the production strain and in the discussion of potential allergens in the fermentation media; the timeliness of the literature search, the unpublished status of cited safety information, the lack of a final safety evaluation, and the lack of absorption, distribution, metabolism, and excretion (ADME) information in the safety narrative; and other deficiencies. In the follow-up email dated March 29, 2021, we provided you with a list of these deficiencies. Given the substantive nature of these deficiencies, we recommended that you request that we cease our evaluation of the notice. We also suggested that you request a GRAS pre-submission meeting with us to discuss the deficiencies before resubmitting the notice for evaluation without prejudice. In an email

¹ Sichuan states that β -glucan is not intended for use in infant formula or in any products under the jurisdiction of the United States Department of Agriculture.

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dated April 28, 2021, you requested on behalf of Sichuan that we cease our evaluation of GRN 000961.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000961 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

Digitally signed by Susan
J. Carlson -S
Date: 2021.05.19
16:08:21 -04'00'

Susan Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition