



Dietrich Conze, Ph.D.
Spherix Consulting Group, Inc.
751 Rockville Pike, Unit 30-B
Rockville, MD 20852

Re: GRAS Notice No. GRN 001180

Dear Dr. Conze:

The Food and Drug Administration (FDA, we) is granting the request on behalf of SAVANNA Ingredients GmbH (SAVANNA) to cease our evaluation of GRN 001180, which we filed on May 7, 2024. We received this request on August 21, 2024.

The subject of the notice is cellobiose for use as a substitute for added sucrose and/or lactose in powdered formula intended for young children (ages 1-3 years) at a level up to 1.5%; in sweetened flavored drinks up to 2.5%, in flavored milk drinks up to 4%; in candies containing chocolate up to 8%, in savory sauce dry mixes, fondant and icing, and powdered table-top sweeteners up to 60%; and as a substitute for dextrose in a variety of meat products up to 2%. The notice informs us of SAVANNA's (you, your) view that these uses of cellobiose are GRAS through scientific procedures.

In an email dated August 19, 2024, we informed you that we identified extensive deficiencies during our review of your notice. As examples, we noted missing details about the manufacturing process, questions about the intended uses and dietary exposure estimates, and concerns about the adequacy of the data and information used to support tolerability and safety of cellobiose in young children. Given the substantive nature of the identified deficiencies, we recommended in our email dated August 19, 2024, that you request that we cease our evaluation of GRN 001180. We also offered to provide a list of the deficiencies we identified during our evaluation of the notice in a separate correspondence to you, and we suggested that you request a pre-submission meeting to discuss the resolution of the deficiencies if you plan to resubmit the notice. On August 21, 2024, we received an email requesting that we cease our evaluation of GRN 001180.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001180 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

 Digitally signed by Susan J.
Carlson -S
Date: 2024.09.09 10:49:23
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition