



Alan Richards, PhD
Vanguard Regulatory Services, Inc.
1311 Iris Circle
Broomfield, CO 80020

Re: GRAS Notice No. GRN 001004

Dear Dr. Richards:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Hayashibara Co., Ltd. (Hayashibara) to cease our evaluation of GRN 001004, which we filed on July 23, 2021. We received this request on December 16, 2021.

The subject of the notice is maltosyltrehalose syrup for use as a carbohydrate source in various foods and beverages at levels up to 60%. The notice informs us of Hayashibara's view that the use of maltosyltrehalose syrup is GRAS through scientific procedures.

In an email dated November 23, 2021, we informed you that we could not continue our evaluation due to deficiencies identified in the notice. We noted that we still had questions regarding Hayashibara's dietary exposure estimate. Furthermore, we found that there are not sufficient data presented from studies on maltosyltrehalose syrup to support the safety conclusion made by Hayashibara. Given the substantive nature of these issues, we recommended that Hayashibara request that we cease our evaluation of the notice. We also suggested that Hayashibara request a pre-submission meeting with us prior to submitting a revised GRAS notice for evaluation without prejudice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001004 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by
Susan J. Carlson -S
Date: 2022.01.20
16:48:12 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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

Page 2 – Dr. Richards

cc: Melvin Carter, Ph.D.
Director
USDA/FSIS/●PPD/RIMS
Stop Code 3782, Patriots Plaza III
1400 Independence Ave. SW
Washington, DC 20250-3700