Donald F. Schmitt, MPH
ToxStrategies, Inc.
931 W. 75th St.
Suite 137, PMB 255
Naperville, IL 60565

Re: GRAS Notice No. GRN 000893

Dear Mr. Schmitt:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Tate & Lyle (T&L) to cease our evaluation of GRN 000893, which we filed on January 14, 2020. We received your request on May 6, 2020.

The subject of the notice is D-allulose (allulose) for use as a bulk sweetener in alcoholic beverages (e.g., premixed cocktails, wine coolers, and malt beverages); meat and poultry (glazed meat and poultry (e.g., ham), luncheon and formed deli meats, dried products (e.g., jerky)); grain based cereal bars and protein bars; dried cranberries (e.g., craisins); condiments (ketchup and barbecue sauce); cereal bars; and presweetened breakfast cereal (> 5% sugar) at levels ranging from 2-25%. The notice informs us of T&L's view that these uses of allulose are GRAS through scientific procedures.

In response to our questions seeking clarification on manufacturing specifications and the data used to estimate the dietary exposure of allulose, T&L provided an amendment received on March 29, 2020 that included clarification on manufacturing specifications.

In a telephone conversation with T&L on April 16, 2020, we discussed our concerns regarding the GRAS notice. We advised that the notifier conduct a cumulative dietary exposure assessment using the most recent food consumption data. We recommended that the notifier consider their intended uses and how additional uses would impact the overall cumulative dietary exposure estimates. During the meeting, we recommended that T&L request that we cease our evaluation of GRN 000893. After our teleconference, we followed up with emails on April 22, 2020, April 30, 2020 and May 4, 2020. These emails provided summaries of the main points discussed during the teleconference, detailed guidance about performing a revised cumulative dietary exposure assessment and subsequent safety narrative, as well as answers to your follow-up questions regarding your proposal for the revised cumulative dietary exposure assessment.

In an email dated May 6, 2020, you requested on behalf of T&L that we cease our evaluation of GRN 000893.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000893 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2020.06.05 12:08:52 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
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cc: Melvin Carter, Ph.D.
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