

Jennifer Miller Renmatix, Inc. 660 Allendale Road King of Prussia, PA 19406

Re: GRAS Notice No. GRN 000973

Dear Ms. Miller:

The Food and Drug Administration (FDA, we) is granting the request filed on Renmatix Inc.'s (you, your) behalf by Ramboll U.S. Corporation (Ramboll) to cease our evaluation of GRN 000973, which we filed on January 26, 2021. We received this request on April 19, 2021.

The subject of the notice is maple wood fiber for use as a bulking agent, emulsifier, humectant, stabilizer, and texturizer in bread and bakery products; mayonnaise-based spreads, dips, and dressings; tomato-based sauces; dairy products; pasta; flour tortillas and flatbreads; granola and granola bars; batters; phyllo pastry, eggroll/dumpling wraps and similar products; margarine and emulsified spreads; icing; confectionery; chocolate and chocolate products; and nut butters and spreads¹ at levels ranging from 1.4 to 34%. The notice informs FDA of your view that maple wood fiber is GRAS through scientific procedures.

In a teleconference with Ramboll on March 25, 2021, and in a follow-up email on April 1, 2021, we summarized the key issues that we identified in the notice, including: lack of clarity on which maple wood fiber forms are the subject(s) of the notice, incomplete information on methods of manufacturing, specifications, and dietary exposure, and inadequate justification for the relevance of some of the safety information, including that for nanomaterials. Given the substantive nature of these deficiencies, we recommended to Ramboll that you request that we cease our evaluation of the notice. We also suggested that you request a pre-submission meeting with us prior to submitting a revised notice. In an email dated April 19, 2021, Ramboll requested on your behalf that we cease our evaluation of GRN 000973. In an email dated April 22, 2021, you notified us of a change in the point of contact for the notice from Ramboll to you.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to

<sup>&</sup>lt;sup>1</sup> You clarified via email on December 8, 2020, that maple wood fiber is not intended for use in products under the jurisdiction of the U.S. Department of Agriculture.

GRN 000973 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

Digitally signed by Susan J.
Carlson -S

Date: 2021.05.13 13:19:00
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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