Timothy Murbach, ND, DABT
AIBMR Life Sciences, Inc.
1425 Broadway, Suite 458
Seattle, WA 98112

Re: GRAS Notice No. GRN 000992

Dear Dr. Murbach:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Phynova Group Limited (Phynova) to cease our evaluation of GRN 000992, which we filed on June 3, 2021. We received this request on November 15, 2021.

The subject of the notice is white mulberry (*Morus alba* Linn) leaf extract for use as an ingredient in a variety of food categories at levels ranging from 120 mg to 294 mg/serving. The notice informs us of Phynova's view that this use of white mulberry leaf extract is GRAS through scientific procedures.

FDA met with the notifier on October 28, 2021. During the meeting, we informed Phynova that we could not continue our evaluation due to issues identified in our review of the GRAS notice that would require additional information. The notice did not adequately address the safety of the intended use of white mulberry leaf extract for subpopulations with diabetes or renal impairment, given the known activity of its principal component, 1-deoxynojirimycin. In addition, the notice did not provide sufficient data and information to support the safety of chronic dietary exposure resulting from the intended use of the notified substance in food. Given the substantive nature of these issues, FDA recommended that Phynova request that we cease our evaluation of GRN 000992. We also recommended that Phynova request a meeting with us prior to preparing any future submission for use of this ingredient in food.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000992 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.05.06 18:02:52 -04'00'

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