Katrina Emmel
KemmelCal, Inc.
947 Martina Circle
Corona, CA 92879

Re: GRAS Notice No. GRN 001012

Dear Dr. Emmel:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Japan Bio Science Laboratory-USA, Inc. ("JBSL-USA") to cease our evaluation of GRN 001012, which we filed on September 16, 2021. We received this request on March 23, 2022.

The subject of the notice is powdered sap from *Angelica keiskei* (ashitaba) containing 8% chalcones (ashitaba sap) for use as an ingredient in soft drinks, jellies and jams, candy containing chocolate, and butter at levels up to 0.834% per serving. The notice informs us of JBSL-USA's view that these uses of powdered ashitaba sap (8%) are GRAS through scientific procedures.

In a teleconference on March 23, 2022, we informed you that we identified issues during our evaluation of GRN 001012. We noted that JBSL-USA did not provide sufficient data regarding chemical identity, safety, and dietary exposure. In addition, we noted issues with the interpretation of the findings of key studies.

Given the substantive nature of these issues, we recommended that JBSL-USA request that we cease our evaluation of the notice. We also offered to provide a list of the issues that we identified during our evaluation of the notice and suggested that JBSL-USA request a pre-submission meeting with us prior to the submission of a new GRAS notice for this substance. In an email dated March 23, 2022, you requested that we cease our evaluation of GRN 001012.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001012 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by
Susan J. Carlson -S
Date: 2022.04.07
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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