



Gavin P. Thompson, Ph.D.
Ramboll U.S. Corporation
2111 Highland Avenue
Suite 402
Phoenix, AZ 85016

Re: GRAS Notice No. GRN 000782

Dear Dr. Thompson:

The Food and Drug Administration (FDA, we) is granting Sensus America Inc.'s (Sensus) request to cease our evaluation of GRN 000782, which we filed on May 31, 2018. We received Sensus' request in an email from you on August 8, 2018.

The subject of the notice is L-arabinose for use as a sweetener in baked goods and baking mixes, beverages, bars (energy, snack, and sports nutrition), cereal-based products, confectionaries and frostings, chewing gum, condiments, dairy products (frozen desserts, ice creams, and yogurts), desserts (gelatins, puddings, etc.), fruit and water ices, spreads, snack foods, and sweet sauces and syrup, at up to 15% by weight. The notice informs us of Sensus' view that this use of L-arabinose is GRAS through scientific procedures.

On July 24, 2018, we held a teleconference with you to discuss the issues we identified during our evaluation of GRN 000782. We discussed issues with the evidence of safety presented in the notice, including unclear descriptions of the design and interpretation of some of the safety studies, the lack of a clear safety assessment in the notice (i.e., in the notice, Sensus did not address how the dietary exposure resulting from the intended use of L-arabinose relates to the safety of L-arabinose under the conditions of its intended use), and the lack of Sensus' concurrence with the safety data presented in the notice. We also discussed issues with the evidence of general recognition presented in the notice, including the unpublished status of some of the safety studies and the lack of English translations for several safety studies. We also discussed the lack of information about literature searches conducted in support of Sensus' GRAS conclusion, and noted the lack of information about the enzymes used in the manufacturing process for L-arabinose.

During the teleconference, we suggested that Sensus request that we cease to evaluate GRN 000782 in order to fully address the issues we discussed during the teleconference (these were provided to you by email on July 25, 2018), and to request a pre-submission meeting with us to discuss their revised notice before resubmitting. In your email dated August 8, 2018, you stated that Sensus agreed with these suggestions.

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

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000782 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan J. Carlson -S
DN: c=US, o=U.S. Government,
ou=HH5, ou=FDA, ou=People,
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15, cn=Susan J. Carlson -S
Date: 2018.08.29 09:34:31 -0400

Susan J. Carlson, Ph.D.
Director
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