



Amy Clewell, ND, DABT
AIBMR Life Sciences, Inc.
2800 E. Madison Street, Suite 202
Seattle, WA 98112

Re: GRAS Notice No. GRN 000835

Dear Dr. Clewell:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Applied Food Sciences, Inc. (AFS) to cease our evaluation of GRN 000835, which we filed on March 4, 2019. We received this request on May 9, 2019.

The subjects of the notice are *Ilex guayusa* leaf extracts for use as an ingredient in “energy” bars, “energy” drinks, ready-to-drink tea beverages (including kombucha), carbonated drinks, coffee-like beverages, and “enhanced” bottled waters at levels providing 60-125 mg caffeine per serving. The notice informs FDA of AFS’ view that *I. guayusa* leaf extracts are GRAS, through scientific procedures.

On May 7, 2019, we held a teleconference to inform you about our determination that the subjects of the notice, two *I. guayusa* leaf extracts, are distinct substances, each requiring a separate GRAS notice. We discussed the opportunity for AFS to ask us to cease our evaluation of GRN 000835 and we recommended submitting a separate GRAS notice for each of the *I. guayusa* leaf extracts. In a letter dated May 8, 2019, transmitted in an email dated May 9, 2019, you requested on behalf of AFS that we cease our evaluation of GRN 000835.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000835 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan J.
Carlson -S
Date: 2019.05.22 10:32:48
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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