Duncan Turnbull, D.Phil., D.A.B.T.
Ramboll US Corporation
4350 North Fairfax Drive, Suite 300
Arlington, VA 22203

Re: GRAS Notice No. GRN 000830

Dear Dr. Turnbull:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Blue Prairie Brands, Inc. (Blue Prairie Brands) to cease our evaluation of GRN 000830, which we filed on February 25, 2019. We received this request on April 5, 2019.

The subject of the notice is chicory root powder for use as an ingredient in bakery products; beverages; cereals and other grain products; dairy products and dairy substitutes; desserts; snacks; and soups at levels ranging from 1% to 42% (weight (w)/w). The notice informs FDA of Blue Prairie Brands' view that chicory root powder is GRAS, through scientific procedures and through common use in food.

On April 1, 2019, we held a teleconference with you to discuss deficiencies that we identified during our evaluation of GRN 000830. We discussed that, according to the statement in the notice, the GRAS conclusion is based on the two statutory criteria, scientific procedures and common use in food; however, the data and information presented in the notice does not fully support each of those two statutory criteria for a conclusion of GRAS. We also discussed that: 1) the notice lacks sufficient information about the identity, composition, manufacturing process, specifications, batch analyses, and stability of the notified substance, and 2) the notice does not provide an adequate discussion regarding dietary exposure to the notified substance. We also discussed issues with the evidence of safety presented in the notice, including, but not limited to the following: 1) the lack of discussion regarding absorption, distribution, metabolism, and excretion profiles of the components of the notified substance, 2) insufficient and/or unclear description of some of the safety studies, and 3) the lack of the notifier's concurrence with the safety data presented in the notice. We also noted that there is no clear statement in the notice that Blue Prairie Brands accepts the responsibility for a conclusion of GRAS status.

Given the scope of the deficiencies, we discussed the opportunity for Blue Prairie Brands to ask us to cease our evaluation of GRN 000830 and to schedule a pre-submission meeting with FDA before submitting a new notice.

We followed up on our teleconference with emails sent to you on April 3, 2019, and May 8, 2019, that provided a summary of the main points discussed during the teleconference and detailed questions raised during our evaluation of GRN 000830, respectively.

In an email dated April 5, 2019, you requested on behalf of Blue Prairie Brands that we cease our evaluation of GRN 000830.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000830 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 16:46:58 -04'00'

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