



Jeff Fine
AAK USA Inc.
499 Thornall Street
Edison, NJ 08837

Re: GRAS Notice No. GRN 000892

Dear Mr. Fine:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 000892, which we filed on January 22, 2020. We received this request on May 18, 2020.

The subject of the notice is refined shea butter for use at levels not to exceed good manufacturing practices as an ingredient in baked goods and baking mixes; beverages and beverage bases; breakfast cereals; cheeses; cheese analogs; condiments and relishes; confections and frostings; dairy product analogs; fats and oils; fish products (excluding catfish); frozen dairy desserts and mixes; gelatins, puddings, and fillings; grain products and pastas; gravies and sauces; hard candy; herbs, seeds, spices, seasonings, blends, extracts, and flavorings; milk products; nuts and nut products; plant protein products; processed vegetables and vegetable juices; snack foods; soft candy; soup and soup mixes; and sweet sauces, toppings and syrups.¹ The notice informs us of AAK's view that these uses of refined shea butter are GRAS through scientific procedures.

In a telephone conversation on April 22, 2020, and reiterated in a telephone conversation on May 13, 2020, FDA presented the issues identified during our review of the notice. In general, our questions related to the subject of the GRAS conclusion. The substance was described in the notice as "refined shea butter," but also referred to as "its fractionated derivative products." We noted that the identity of the notified substance was not clear and would need to be clarified. Therefore, we recommended that you request that we cease our evaluation of GRN 000892 and submit a GRAS notice for one defined substance with all seven sections of the GRAS notice revised accordingly. We also discussed that in the new submission the safety information and narrative should state which safety studies were considered pivotal and which were corroborative for the notified substance. Furthermore, any extrapolations of safety information from related components and/or the starting material to the notified substance would require a scientific basis, which should be clearly discussed in the notice.

¹ AAK states that refined shea butter is not intended for use in infant formulas or products under the U.S. Department of Agriculture's jurisdiction.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000892 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

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Susan J. Carlson -S
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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