



George A. Burdock, Ph.D.
Burdock Group
859 Outer Road
Orlando, FL 32814

Re: GRAS Notice No. GRN 001153

Dear Dr. Burdock:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Terviva, Inc. (Terviva) to cease our evaluation of GRN 001153, which we filed on November 16, 2023. We received this request on May 2, 2024.

The subject of the notice is pongamia bean oil (PBO) for use as a substitute for existing fats and oils¹ in dairy drinks and alternatives, cheeses (including alternatives and spreads), meat and poultry alternatives, seafood alternatives, egg product alternatives, plant-based protein foods (nuts and seeds, processed soy products), breads and bread products, rolls and tortillas, cooked cereals, crackers, snack and meal bars, sweet bakery products, chips, popcorn, pretzels, cooked vegetables, sweetened beverages, nutritional and smoothie-type beverages, protein and nutritional powders, fats and oils, and condiments and sauces at levels up to 351 g/kg.² The notice informs us of Terviva's view that these uses of PBO are GRAS through scientific procedures.

In an email dated January 29, 2024, we informed you that we identified numerous issues in the safety narrative section of the notice that were not subsequently resolved in the February 16, 2024 amendment. In an email dated April 25, 2024, we informed you that the amendment, which contains 91 new citations, represents a substantial change in the safety narrative originally provided in GRN 001153 and raises additional concerns such as an indication that PBO consumption may have pharmacological or physiological effects, potentially beneficial or otherwise, at the intended use level, which is not conducive to a conclusion of safety for its use as a food ingredient regardless of an affirmation statement that Terviva makes no drug claims for PBO. Given the substantive nature of these issues, FDA recommended that Terviva request that we cease our evaluation of GRN 001153. We also recommended that Terviva request a meeting with us prior to preparing any future submission for use of this ingredient in food.

¹ Terviva states that fats and oils are defined as in 21 CFR 170.3(n)(12).

² Terviva states that PBO is not intended for use in infant formula or in products under the jurisdiction of the U.S. Department of Agriculture.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001153 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

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