U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Amy M. Sheppard
ToxStrategies LLC
23501 Cinco Ranch Blvd, Suite H210
Katy, TX 77494

Re: GRAS Notice No. GRN 001297

Dear Ms. Sheppard:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Nuritas that we cease our evaluation of GRN 001297. We received this request on May 15, 2026. We received Nuritas' notice on August 29, 2025, and filed it on January 16, 2026.

The subject of the notice is enzyme-hydrolyzed brown rice protein for use as a protein source in nutrition and cereal bars; protein powders, drinks, and smoothies; breads, rolls, high-protein cookies, bagels, English muffins; non-milk-based meal replacements; ready-to-eat breakfast cereals; imitation milks; margarine; salad dressings; imitation meat products; flavored milk drinks, milk-based meal replacements, yogurts, frozen yogurts; fruit juices and nectars, smoothies and drinks; vegetable juices and smoothies; soups and soup mixes; coffee and tea; chocolate candy and other confections; ready-to-drink beverages including carbonated soft drinks, sports drinks, and flavored or enhanced waters; and hard candy at a maximum level of 1 g/serving (excluding use in infant formula and products under the jurisdiction of the United States Department of Agriculture). The notice informs us of Nuritas' view that these uses of enzyme-hydrolyzed brown rice protein are GRAS through scientific procedures.

In a meeting on May 4, 2026, and in a follow up email dated May 8, 2026, we communicated with you as Nuritas' representative regarding deficiencies in the notice. We noted that additional information is needed to support Nuritas' GRAS conclusion, including a description of the enzyme(s) used in the method of manufacture, clarification of the specifications for potential contaminants, additional information on the intended uses with expression of use levels for each food category on a g per 100 g basis, and a revised cumulative estimate of dietary exposure for the ingredient that includes current uses and maximum use levels of enzyme-hydrolyzed brown rice protein.

We have ceased our evaluation of the notice at your request on behalf of Nuritas. We remind Nuritas of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind Nuritas that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive) must have pre-market

approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170).

Your request on behalf of Nuritas does not preclude Nuritas from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that Nuritas address these issues raised in this letter to adequately support a GRAS conclusion. Finally, we remind Nuritas of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which Nuritas agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001297 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON -S

Digitally signed by SUSAN J. CARLSON -S
Date: 2026.06.15 14:23:47 -04'00'

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