Madhu Soni, Ph.D.
Soni & Associates, Inc.
749 46th Square
Vero Beach, FL 32968

Re: GRAS Notice No. GRN 000609

Dear Dr. Soni:

The Food and Drug Administration (FDA, we) completed our evaluation of Axiom Foods and SPRIM Strategy & Intelligent Innovation's (Axiom) supplement to GRN 000609. We received the supplement that you submitted on behalf of Axiom on December 13, 2017. The supplement addresses an additional processing step for the texture and quality, resulting in a product that contains less protein than that described in GRN 000609. Axiom submitted clarifying information on January 26, 2018, on their updated literature review. Axiom submitted clarifying information on March 6, 2018, on heavy metal specifications and protein levels, as well as additional information on the protease enzyme preparation used in the manufacturing process. Axiom also submitted additional clarifying information on May 30, 2018, on heavy metal specifications, as well as a discussion on exposure to rice protein.

We previously responded to GRN 000609 on June 5, 2016. We stated that we had no questions at that time regarding Axiom's conclusion that rice protein is GRAS for use as an ingredient, formulation aid, and texturizer in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, dairy product analogs, fats and oils, grain products and pastas, milk products, plant protein products, processed fruits and fruit juices, processed vegetables and vegetable juices, and soups and soup mixes at levels ranging from 0.96% to 34.3%.[1]

In the supplement dated December 8, 2017, Axiom provides its rationale for an additional processing step, which in Axiom's view improves the texture and quality of the rice protein. Axiom states that the manufacturing process described in GRN 000609 can produce rice protein particles that are gritty, which pose formulation challenges. Axiom discusses that hydrolysis by a protease enzyme at levels up to 84 mg total organic solid/kg improves the quality and acceptability of rice protein for the intended uses. Axiom states that the protease enzyme is from a nonpathogenic and nontoxigenic strain of *Bacillus licheniformis*. Axiom further states that the protease enzyme preparation complies with the general specifications for food enzyme preparations regarding heavy metals and microbiological properties as published in the Food Chemicals Codex (FCC,

[1] Axiom stated in GRN 000609 that it does not intend to add rice protein to products under USDA's jurisdiction. Additionally, rice protein will not be added to infant formulas.

9th edition, 2014) and by the Joint Expert Committee of Food and Agriculture Organization/World Health Organization on Food Additives (2006).

Axiom notes that the additional processing step, in which rice protein is subjected to enzymatic hydrolysis by protease enzyme, results in some loss of protein. The products described in GRN 000609 contain 80% and 90% protein; the product described in the supplement contains at least 75% protein. Axiom provides data from the analyses of five non-consecutive lots of rice protein to demonstrate that rice protein manufactured using the process described in the supplement meets food grade specifications.

Axiom states that all other manufacturing steps and the intended uses for rice protein remain the same as in the original GRAS notice except that the product has a decreased protein level. Axiom also states that the specifications for cadmium and lead were increased to < 0.65 mg/kg and < 0.40 mg/kg, respectively, and that the specification for total arsenic was lowered to < 0.12 mg/kg. Axiom discusses that the minor increases in cadmium and lead specifications will not affect the safety of rice protein.

In addition, Axiom conducted an updated literature review on published safety studies of rice protein through November 2017. Axiom confirms that studies published since the submission of GRN 000609 did not reveal any significant safety related information. Axiom also states that there have been no reports of adverse effects from consumption of rice protein.

Based on the totality of evidence, Axiom concludes that the intended use of rice protein is GRAS.

Standards of Identity

In the supplement, Axiom states its intention to use rice protein in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

In describing the content of rice protein and in discussing the human studies that Axiom relies on to conclude that rice protein is GRAS under the intended conditions of use, Axiom raises a potential issue under the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under section 403(a) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. Section 403(r) of the FD&C Act lays out the statutory framework for the use of labeling claims that characterize the level of a nutrient in a food or that characterize the relationship of a nutrient to a disease or health-related condition. If products that contain rice protein bear any claims on the label or in labeling, such claims are the purview of the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety neither consulted with ONFL on this

labeling issue nor evaluated the information in the supplement to determine whether it would support any claims made about rice protein on the label or in labeling.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In its review of Axiom's supplement that rice protein is GRAS for the intended uses, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing rice protein. Accordingly, this response should not be construed to be a statement that foods that contain rice protein if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Axiom provided, as well as other information available to FDA, we have no questions at this time regarding Axiom's conclusion that rice protein is GRAS under its intended conditions of use. This letter is not an affirmation that rice protein is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to the supplement to GRN 000609 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000419015, cn=Susan J. Carlson -S
Date: 2018.06.14 12:44:30 -04'00'

Susan Carlson, Ph.D.
Director
Division of Biotechnology
and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition