



Stuart Pape
Polsinelli
1401 Eye Street NW, Suite 800
Washington, DC 20005

Re: GRAS Notice No. GRN 000684

Dear Mr. Pape:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000684. We received the notice that you submitted on behalf of Hampton Creek, Inc. (Hampton Creek) on December 19, 2016, and filed it on January 13, 2017. We received amendments to the notice on March 7, 2017, March 9, 2017, and March 24, 2017. These amendments contain additional safety information, a statement that the information in the amendment of March 7, 2017, is not exempt from the Freedom of Information Act, and a description of literature search methods.

The subject of the notice is mung bean protein isolate for use as a protein in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, condiments and relishes, dairy products analogs, frozen dairy desserts and mixes, fruit and water ices, gelatins, puddings, and fillings, grain products and pasta, milk products, plant protein products, and snack foods at levels ranging from 3 to 90% weight/weight (w/w) of the finished product.

Our use of the term, “mung bean protein isolate,” in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA’s labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under 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 (OFAS) did not consult with ONFL regarding the appropriate common or usual name for mung bean protein isolate.

Hampton Creek provides information about the identity and composition of mung bean protein isolate. Hampton Creek describes mung bean protein isolate as a powder isolated from mung bean (*Vigna radiata*) that contains >80% protein on a dry matter basis (DM). Hampton Creek also provides information about the typical amino acid composition, and the vitamin, mineral, carbohydrate, and lipid contents of mung bean protein isolate.

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Hampton Creek describes the method of manufacture for mung bean protein isolate, which is produced using a series of physical and chemical processes. Raw mung beans are de-hulled and milled. The resulting mung bean flour is extracted with water and the resulting slurry is centrifuged to separate the liquid portion containing the protein extract. The extract is then treated with an antioxidant and acidified to precipitate the protein, which is then washed, pasteurized, and spray dried. Hampton Creek states that the manufacturing process does not alter the chemical and functional properties of the proteins in mung bean protein isolate and provides the results of analyses for an amino acid profile to demonstrate its consistency. Hampton Creek states that the results of an ongoing study show that mung bean protein isolate is stable for at least 6 months when stored at room temperature. Hampton Creek states that all chemicals used in the manufacturing process are food grade and are permitted for use in food.

Hampton Creek establishes food grade specifications for mung bean protein isolate including the content of protein (>80% DM), typical fat levels (3 to 5%), limits on moisture (<7%), carbohydrates (<10%), ash (<8%), limits on heavy metals (arsenic ≤ 0.05 mg/kg, cadmium ≤ 0.05 mg/kg, lead ≤ 0.05 mg/kg, and mercury ≤ 0.025 mg/kg), and microbial contaminants. Hampton Creek provides results of four nonconsecutive batch analyses of mung bean protein isolate to demonstrate that it meets these specifications.

Hampton Creek estimates the dietary exposure to mung bean protein isolate using the maximum intended use levels and consumption data from the 2011-2012 National Health and Nutrition Examination Survey. The estimated mean and 90th percentile dietary exposures for the U.S. population (users only) are 10 g/person(p)/day(d) (168 mg/kg body weight (bw)/d for a 60 kg individual) and 23 g/p/day (401 mg/kg bw/d for a 60 kg individual), respectively. Hampton Creek states that the estimated dietary exposure to mung bean protein isolate is comparable to the exposure estimated from consumption of other plant-based protein products.¹ Hampton Creek states that the intended uses of mung bean protein isolate are substitutional for existing proteins and would not be expected to result in increased exposure to proteins.

Hampton Creek addresses the safety of mung bean protein isolate using an approach based on a 2-tier weight of evidence strategy proposed by International Life Sciences Institute for safety assessment of proteins produced in genetically engineered agricultural products. Hampton Creek states that mung bean protein isolate and its intended use satisfy the Tier I criteria and determines that product-specific *in vivo* safety studies are not necessary for the safety assessment. Hampton Creek assesses the safety of mung bean protein isolate utilizing publicly available data and information pertaining to the product-specific compositional analyses, *in vitro* digestibility data, the non-allergenicity potential, and a history of safe use. Based on the product-specific analytical data, Hampton Creek concludes that mung bean protein isolate does not contain any toxicological, nutritional, or microbiological hazards and is compositionally and nutritionally similar to proteins present as a normal constituent of mung beans.

¹ Dietary exposures to pea protein concentrate and rice protein concentrate were estimated in GRN 000609 and GRN 000608, respectively.

Hampton Creek also provides a summary of published reports on protein digestibility of mung bean. Hampton Creek states that mung bean is not considered to be one of the major eight food allergens identified in the United States Food Allergen Labeling and Consumer Protection Act of 2004, and discusses data and information to support its view of the low allergenic potential of mung bean protein isolate.² Hampton Creek provides analytical data to demonstrate that their manufacture method does not appear to significantly alter the relative abundance of four putative allergens compared to mung bean flour, the starting material. Additionally, Hampton Creek states that mung bean is commonly consumed outside the United States and has a long history of safe use in food.

Hampton Creek includes the statement of a panel of individuals (Hampton Creek's GRAS panel). Based on its review, Hampton Creek's GRAS panel concluded that mung bean protein isolate is safe under the conditions of its intended use.

Based on publicly available information discussed above, Hampton Creek concludes that mung bean protein isolate is GRAS for its intended use in food.

Standards of Identity

In the notice, Hampton Creek states its intention to use mung bean protein isolate 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 intended uses of mung bean protein isolate as a source of protein, Hampton Creek lists foods (e.g., meal replacements, nutritional bars) that often contain health or nutrient content claims. Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). The notice raises a potential issue under these labeling provisions. If products containing mung bean protein isolate bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of ONFL. The OFAS did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

² Mung bean seed storage proteins are similar to those from many other legumes. These include legumes considered clinically significant allergens in the United States (e.g., peanut, soy) as well as legumes commonly consumed in the United States that are not considered clinically significant allergens (e.g., pea, kidney beans). At this time, we are not aware of any evidence of clinically significant cross-reactivity in peanut and soy-allergic United States consumers attributable to exposure to mung bean seed storage proteins.

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 our evaluation of Hampton Creek's notice concluding that mung bean protein isolate is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing mung bean protein isolate. Accordingly, our response should not be construed to be a statement that foods containing mung bean protein isolate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Hampton Creek provided, as well as other information available to FDA, we have no questions at this time regarding Hampton Creek's conclusion that mung bean protein isolate is GRAS under its intended conditions of use. This letter is not an affirmation that mung bean protein isolate 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 that 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 GRN 000684 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
**Michael A.
Adams -S**

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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