DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740-3835

Carlos Irizarry
Pharmachem Laboratories, Inc.
265 Harrison Avenue
Kearny, NJ 07032

Re: GRAS Notice No. GRN 000480

Dear Mr. Irizarry:

The Food and Drug Administration (FDA) is responding to the notice, dated July 15, 2013, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on July 19, 2013, filed it on August 14, 2013, and designated it as GRAS Notice No. GRN 000480.

The subject of the notice is dried aqueous extract of white kidney bean (*Phaseolus vulgaris*) (white kidney bean extract). The notice informs FDA of the view of Pharmachem Laboratories, Inc. (Pharmachem) that white kidney bean extract is GRAS, through scientific procedures, for use as an ingredient for general use in foods, excluding meat and poultry products and infant formula, at a level no greater than 10 percent in any food and providing no more than 10 grams per person per day (g/p/d) of the white kidney bean extract.

In its notice, Pharmachem includes a statement from a panel of individuals (Pharmachem's GRAS panel) that evaluated the data and information that are the basis for Pharmachem's GRAS determination. Pharmachem considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Pharmachem's GRAS panel evaluated the identity and composition, method of manufacture and specifications, intended dietary exposure, and published data and information supporting the safety of white kidney bean extract. Based on this review, Pharmachem's GRAS panel concluded that white kidney bean extract produced in accordance with current good manufacturing practice (cGMP) and meeting established specifications is GRAS under the conditions of its intended use.

Pharmachem describes white kidney bean extract as an off-white to beige, free-flowing powder. Pharmachem also provides general information about the composition and describes the macronutrient content of white kidney bean extract. Pharmachem states that white kidney bean extract may inhibit the activity of the digestive enzyme α-amylase when consumed as an ingredient in food.

Pharmachem describes the manufacturing process for white kidney bean extract, noting that it is manufactured using standard equipment and procedures widely used in the food industry. Raw, whole white kidney beans are ground and extracted in deionized water. The extract is then filtered and the liquid concentrated by heat. The concentrate is pasteurized and then spray-dried. Pharmachem states that the thermal processing conditions employed inactivate antinutrients found in *P. vulgaris*, such as hemagglutinins and trypsin inhibitors. The product is sampled at various stages in the manufacturing process to ensure quality. Pharmachem notes that the processing steps, the facility, and the controls used

in the manufacture of white kidney bean extract conform to cGMP for human food in accordance with the applicable regulations.

Pharmachem provides specifications for white kidney bean extract that include identity and an assay for α-amylase inhibiting units. Specifications for the composition of white kidney bean extract include total fat (< 0.5 %), saturated fat (< 0.2 %), cholesterol (< 0.001 %), sodium (2 %), total carbohydrates (60 %), and protein (20 %). Specifications also include limits on acacia gum,[1] which is added as a formulation aid (≤ 10 %), moisture (< 10 %), lead (< 5 milligram per kilogram (mg/kg)), arsenic (≤ 1 mg/kg), mercury (≤ 1 mg/kg), aflatoxins (< 5 micrograms (µg) per kg), pesticide residues, and microbial contaminants. Pharmachem provides data from analyses confirming compliance with these specifications for three batches of white kidney bean extract. Pharmachem states that tests confirm the stability of white kidney bean extract for up to two years.

Pharmachem conducted an exposure assessment based on multiple food examples of the intended use of white kidney bean extract, including baked goods and baking mixes (breads, rolls, pizzas, muffins, frozen waffles and pancakes, tortillas, pre-mixed baking products, bagels, crackers, and cookies) and toppings (parmesan cheese, butter-flavored topping, spice topping, and sugar sprinkles). In this calculation, Pharmachem considered exposure at a level of 750 mg per reference amount customarily consumed for the mean and 90th percentile (users-only) would be 1.57 and 2.99 g/p/d, respectively. Pharmachem states that as new food uses are identified, additional exposure assessments will be performed to confirm that the aggregate exposure remains below 10 g/p/d.

Pharmachem discusses published information supporting the safety of white kidney bean extract. Pharmachem states that acute oral toxicity study in rats showed no mortality or adverse effects at levels up to 5000 mg/kg body weight (bw). No adverse effects were seen in 28-day and 90-day oral toxicity studies performed in rats consuming up to 2500 mg/kg bw/d (approximately 150 g/d in a 60 kg individual). Moreover, Pharmachem cites published and unpublished studies in human subjects consuming dietary supplements containing white kidney bean extract at levels up to 3 g/p/d for 24 weeks and no adverse effects were reported.

Standards of Identity

In the notice, Pharmachem states its intention to use white bean extract 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 use of white kidney bean extract and in describing the information that Pharmachem relies on to conclude that white bean extract is GRAS under the conditions of its intended use, Pharmachem raises a potential issue under the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This issue consists of describing the potential health benefits of consumption of white kidney bean extract. 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 white kidney

[1] Pharmachem notes that acacia gum will be present at levels less than 1% in any food containing white kidney bean extract.

bean extract bear any claims on the label or in labeling, such claims are the purview of the Office of Nutrition, Labeling and Dietary Supplements (ONLDS) in the Center for Food Safety and Applied Nutrition (CFSAN). The Office of Food Additive Safety neither consulted with ONLDS on this labeling issue nor evaluated the information in your notice to determine whether it would support any claims made about white kidney bean extract on the label or in labeling.

Section 301(ll) of the FD&C Act

The Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amends the FD&C Act to, among other things, add section 301(ll). 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 Pharmachem's notice that white kidney bean extract is GRAS for the intended uses, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing white kidney bean extract. Accordingly, this response should not be construed to be a statement that foods that contain white kidney bean extract, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information provided by Pharmachem, as well as other information available to FDA, the agency has no questions at this time regarding Pharmachem's conclusion that white kidney bean extract is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of white kidney bean extract. As always, it is the continuing responsibility of Pharmachem to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000480, as well as a copy of the information in this notice that conforms to the information in the GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying at www.fda.gov/grasnoticeinventory.

Sincerely,

Michael A. Adams -S

Digitally signed by Michael A. Adams -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300042713, cn=Michael A. Adams -S
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Dennis M. Keefe, Ph.D.
Director
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