



Marc C. Sanchez, Esq.
Contract In-house Counsel
Fresh Hemp Foods, Ltd.
1717 Pennsylvania Ave #1025
Washington, DC 20006

Re: GRAS Notice No. GRN 000771

Dear Mr. Sanchez:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000771. We received Fresh Hemp Foods Ltd.'s notice on March 23, 2018 and filed it on April 25, 2018. Fresh Hemp Foods submitted amendments to the notice on September 14, 2018 and November 2, 2018. The amendments provided additional information on specifications, dietary exposure estimates, analytical methods, historical consumption, anti-nutrients, potential allergenicity, and toxicological studies conducted with (-)-trans- Δ^9 -tetrahydrocannabinol (THC), cannabidiol (CBD), and other cannabinoids.

The subject of the notice is hemp seed protein powder for use as a source of protein in protein powders, dry blend beverages, ready-to-drink beverages, soups, nutritional beverages, smoothies, dairy product analogs, snacks, baked goods, baking mixes, cereals, meat analog products, nutrition bars, crisps, and sauces at levels of 1-100%.¹ The notice informs us of Fresh Hemp Foods' view that these uses of hemp seed protein powder are GRAS through scientific procedures.

Fresh Hemp Foods states that hemp seed protein powder is derived from varieties of *Cannabis sativa* L. with low THC content, known as industrial hemp. Fresh Hemp Foods states that hemp seeds themselves do not produce THC, and that THC present in hemp seed protein powder comes from contact between the seeds and cannabinoid-containing resins from other plant parts during growth, harvest, and processing.

Fresh Hemp Foods describes multiple formulations of hemp seed protein powder. Hemp seed protein powders manufactured using a dry process are fine, light green powders with protein content averaging 50%, 43%, or 33%, depending on the formulation. A hemp seed protein powder concentrate manufactured with an additional water extraction step is a fine, light tan to greenish powder with protein content greater than 64.5%. Other major components of the protein powders include fiber (9-41%), carbohydrates (7-48.5%), fat (9-15%), and moisture (5-8%).

Fresh Hemp Foods describes the manufacture of hemp seed protein powder. Fresh

¹ Excluding products regulated by the United States Department of Agriculture.

Hemp Foods obtains hemp seed grown under license from Health Canada, which requires use of authorized, low-THC varieties. After harvest, plants are dried, and seeds are removed. Seeds are mechanically cleaned to remove foreign material and whole seeds are cold pressed to extract oil. The defatted hemp seed cake is milled and sifted into powders with various particle size and protein grades. The powders can be sold as-is or further processed to make a hemp seed protein powder concentrate by water extraction, pH adjustment, removal of solids, addition of antioxidant, and spray-drying.

Fresh Hemp Foods provides specifications for hemp seed protein powders including protein content (32-38%, 40-46%, 47-53%, or >64.5%). Specifications also include limits for THC (≤ 4 mg/kg), lead (≤ 3 mg/kg), cadmium (≤ 1 mg/kg), mercury (≤ 0.1 mg/kg), arsenic (≤ 1 mg/kg), aflatoxin (< 0.5 μ g/kg), and microorganisms.² Fresh Hemp Foods gives analytical results from multiple batches to show that hemp seed protein powder can be produced to meet these specifications.

Fresh Hemp Foods estimates dietary exposure to hemp seed protein powder from the intended uses based on food consumption data from the National Health and Nutrition Examination Survey (NHANES 2013-2014). Mean and 90th percentile dietary exposure to hemp seed protein powder is estimated to be 6.9 and 13.8 g/person/day for the general population, aged 2 years and older. The notifier states that the level of hemp seed protein powder used in food is limited by sensory and functional properties of the ingredient.

Fresh Hemp Foods summarizes publicly available information about the long history of hemp seed consumption, particularly in Europe and Asia, which supports the safety of hemp seed in a wide variety of food uses. Fresh Hemp Foods states that the estimated level of exposure to protein from hemp seed protein powder does not exceed the FDA Daily Reference Value or the Institute of Medicine Recommended Dietary Allowance for protein. Fresh Hemp Foods discusses a peer-reviewed scientific study showing that hemp seed protein is highly digestible, like other protein rich seeds such as lentils and pinto beans. The study also shows that hemp seed protein is a complete protein source, containing all essential amino acids. Instances of allergic reactions to hemp seed-derived ingredients have been documented in the scientific literature; however, Fresh Hemp Foods notes that hemp seed protein is not a concern for the general population.³ Fresh Hemp Foods measured levels of anti-nutrients in hemp seed protein powder and found them to be consistent with levels in nuts and other seeds. Fresh Hemp Foods cites peer-reviewed scientific studies describing the fatty acid composition of hemp seed, noting that it has a favorable balance of omega-3 and omega-6 fatty acids. The notifier also discusses levels of contaminants in hemp seed-derived ingredients, including THC and CBD, and concludes, based on peer-reviewed scientific literature, that estimated levels of exposure from the intended uses would not affect the safety of the ingredients.⁴

² The specification for THC is a combined specification for THC and its carboxylic acid metabolic precursor, $\Delta 9$ -tetrahydrocannabinol-carboxylic acid (THCA). The analytical method Fresh Hemp Foods uses to quantify THC measures both THC and THCA.

³ FDA notes that sensitive individuals avoid allergenic foods through product labeling.

⁴ Fresh Hemp Food's cumulative dietary exposure estimate to THC, CBD, and other cannabinoids included exposure from intended uses of the following hemp seed-derived ingredients: dehulled hemp

Based on the information provided in the notice, Fresh Hemp Foods concludes that the intended uses of hemp seed protein powder are GRAS.

Standards of Identity

In the notice, Fresh Hemp Foods states its intention to use hemp seed protein powder 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 Requirement for a Color Additive Petition

There is no GRAS provision for color additives. In the notice, Fresh Hemp Foods describes certain formulations of hemp seed protein powder as light green or tan to greenish in color. As such, the use of hemp seed protein powder in food products may constitute a color additive use under section 201(t)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's implementing regulations in 21 CFR Part 70. Under section 201(t)(1) and 21 CFR 70.3(f), a color additive is a material that is a dye, pigment, or other substance made by a synthetic process or similar artifice, or is extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source. Under 21 CFR 70.3(g), a material that otherwise meets the definition of a color additive can be exempt from that definition if it is used (or is intended to be used) solely for a purpose or purposes other than coloring. Our response to GRN 000771 is not an approval for use as a color additive nor is it a finding of the Secretary of the Department of Health and Human Services within the meaning of section 721(b)(4) of the FD&C Act. Questions about color additives should be directed to the Division of Petition Review in the Office of Food Additive Safety.

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 Fresh Hemp Foods' notice concluding that hemp seed protein powder 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 hemp seed protein powder. Accordingly, our response should not be construed to be a statement that foods containing hemp seed protein powder, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

seed (GRN 000765), hemp seed protein powder (GRN 000771), and hemp seed oil (GRN 000778).

Conclusions

Based on the information that Fresh Hemp Foods provided, as well as other information available to FDA, we have no questions at this time regarding Fresh Hemp Foods' conclusion that hemp seed protein powder is GRAS under its intended conditions of use. This letter is not an affirmation that hemp seed protein powder 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 000771 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Dennis M.

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Dennis M. Keefe, Ph.D.

Director

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

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