



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

Re: GRAS Notice No. GRN 000765

Dear Mr. Sanchez:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000765. We received Fresh Hemp Foods Ltd.'s notice on March 1, 2018, and filed it on April 5, 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 dehulled hemp seed for use as an ingredient in ready-to-drink beverages, soups, sauces, nutritional beverages, smoothies, dairy product analogs, grain products, baked goods, baking mixes, spreads, dressings, cereals, snacks, and nutrition bars at levels of 1-40%.¹ Fresh Hemp Food states that dehulled hemp seed would be used in a similar way to linseed, poppy seed, sesame seed, sunflower seed, chia seed, and mustard seed. The notice informs us of Fresh Hemp Foods' view that these uses of dehulled hemp seed are GRAS through scientific procedures.

Fresh Hemp Foods states that dehulled hemp seed 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 dehulled hemp seed comes from contact between the seeds and cannabinoid-containing resins from other plant parts during growth, harvest, and processing.

Fresh Hemp Foods describes dehulled hemp seed as having the appearance of small, white nuts with green flecks. Hemp seed consists primarily of fat (48-54%) and protein (31-38%), with lesser amounts of fiber (4.6%) and carbohydrates (3.4%).

Fresh Hemp Foods describes the manufacture of dehulled hemp seed. Fresh 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. Whole seeds are mechanically cleaned to remove foreign material and are dehulled by

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

cracking and removing the seed coat. The dehulled seed is cleaned to remove remaining hulls and foreign materials.

Fresh Hemp Foods provides specifications for dehulled hemp seed that 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 dehulled hemp seed can be produced to meet these specifications.

Fresh Hemp Foods estimates dietary exposure to dehulled hemp seed 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 dehulled hemp seed is estimated to be 7.03 and 14.07 g/person/day for the general population, aged 2 years and older. The notifier states that the level of dehulled hemp seed 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 cites peer-reviewed scientific studies describing the fatty acid composition of hemp seed, noting that it has a favorable balance of omega-3 (e.g. gamma-linolenic acid) and omega-6 (e.g. stearidonic acid) fatty acids. Fresh Hemp Foods also notes that hemp seed contains notable amounts of the essential fatty acids linoleic acid and alpha-linolenic acid. 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 would not be a concern for the general population.³ Fresh Hemp Foods measured levels of antinutrients in dehulled hemp seed and found them to be consistent with levels in nuts and other seeds. The notifier also discusses levels of contaminants, including THC and CBD, in hemp seed-derived ingredients and concludes, based on peer-reviewed scientific literature, that estimated levels of exposure from the intended uses do not affect the safety of the ingredients.⁴

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

Standards of Identity

² The specification for THC is a combined specification for THC and its carboxylic acid metabolic precursor, Δ^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 seed (GRN 000765), hemp seed protein powder (GRN 000771), and hemp seed oil (GRN 000778).

In the notice, Fresh Hemp Foods states its intention to use dehulled hemp seed 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.

Section 301(II) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(II) 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(II)(1)-(4) applies. In our evaluation of Fresh Hemp Foods' notice concluding that dehulled hemp seed is GRAS under its intended conditions of use, we did not consider whether section 301(II) or any of its exemptions apply to foods containing dehulled hemp seed. Accordingly, our response should not be construed to be a statement that foods containing dehulled hemp seed, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).

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 dehulled hemp seed is GRAS under its intended conditions of use. This letter is not an affirmation that dehulled hemp seed 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 000765 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Dennis M.
Keefe -S

Dennis M. Keefe, Ph.D.
Director

Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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