



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

Re: GRAS Notice No. GRN 000778

Dear Mr. Sanchez:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000778. We received Fresh Hemp Foods Ltd.'s notice on April 12, 2018 and filed it on May 7, 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, 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 oil for use as a substitute for other edible oils in prepared foods, beverages and beverage bases, soups, smoothies, dairy product analogs, dressings, table oils, spreads, sauces, meat analog products, and crisps at levels of 1-15%.¹ The notice informs us of Fresh Hemp Foods' view that these uses of hemp seed oil are GRAS through scientific procedures.

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

Fresh Hemp Foods describes hemp seed oil as a translucent oil with a nutty aroma and taste. Hemp seed oil is comprised, on average, of 77% polyunsaturated fat, 13% monounsaturated fat, and 9.8% saturated fat. Fresh Hemp Foods notes that hemp seed oil consists primarily of linoleic acid (50.9%) and alpha-linolenic acid (16.7%), with notable amounts of gamma-linolenic acid (3.6%) and stearidonic acid (1.2%).²

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

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

² Linoleic and gamma-linolenic acid are omega-6 fatty acids, and alpha-linolenic and stearidonic acid are omega-3 fatty acids.

are removed. Seeds are mechanically cleaned to remove foreign material, and whole seeds are cold pressed to extract the oil. Hemp seed oil is filtered prior to packaging.

Fresh Hemp Foods provides specifications for hemp seed oil that include limits for THC (≤ 10 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.³ Fresh Hemp Foods gives analytical results from multiple batches to show that hemp seed oil can be produced to meet these specifications.

Fresh Hemp Foods estimates dietary exposure to hemp seed oil 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 oil is estimated to be 4.1 and 8.2 g/person/day for the general population, aged 2 years and older. The notifier states that the level of hemp seed oil used in food is limited by sensory and functional properties of the ingredient.

Fresh Hemp Foods discusses published data and information supporting the safety of hemp seed oil. Fresh Hemp Foods states that hemp seed oil is similar in composition to other edible oils, such as canola, flax, walnut, and cottonseed oils. Fresh Hemp Foods states that the intended uses would result in similar levels of exposure to individual fatty acids relative to existing uses of other oils. 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. Fresh Hemp Foods also notes that hemp seed contains notable amounts of the essential fatty acids linoleic acid and alpha-linolenic acid. 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

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

Standards of Identity

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

³ 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.

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).

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 oil 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 oil. Accordingly, our response should not be construed to be a statement that foods containing hemp seed oil, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

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 oil is GRAS under its intended conditions of use. This letter is not an affirmation that hemp seed oil 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 000778 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**

Digitally signed by Dennis
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