



Hempagenix, LLC
2200 N. Commerce Pkwy
Suite 200
Weston, FL 33326

www.hempagenix.com

Summer 2019

Information on the Advertising, Marketing and Sale of Cannanumb®

There is much confusion and ambiguity surrounding the sale and marketing of products that contain "Cannabis Sativa (Hemp) Seed Oil". Hempagenix, LLC, the makers of Cannanumb® have created this product information document to provide information on the legalities that surround the ingredient "Cannabis Sativa (Hemp) Seed Oil" which is contained in Cannanumb®.

On May 28, 2019, Cannanumb® rolled out a nationwide TV campaign on major television networks. During the Summer of 2019, it is our goal for Cannanumb® to be on the shelves of major big box retailers. The TV spot can be viewed here <https://www.youtube.com/watch?v=P-kv11PrXsE>

MARIJUANA, CBD AND HEMP INDUSTRY OVERVIEW

Marijuana is federally illegal and classified as a Schedule 1 substance according to the DEA and the United States Controlled Substances Act (CSA). Even after the passing of the United States Agriculture Improvement Act of 2018 (The 2018 Farm Bill) the legal landscape surrounding CBD is unclear and changing rapidly both at the Federal and State levels. Most major U.S. retailers still will not carry CBD based products, but over ten thousand independent (Mom/Pop) retailers currently have it on their store shelves. U.S Banking is an obstacle for manufacturers and retailers selling CBD ingestible and other CBD products. In December of 2018, the FDA made it clear in a statement by former FDA Commissioner Scott Gottlieb, M.D., ***"it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug."*** Most consumers, even those who are educated, cannot determine the difference between marijuana, CBD or Hemp. On the other hand, many national retailers carry Hemp-based products such as snack chips, lotions and other consumable products. The common denominator with these hemp-based products is the fact that the leaf (which is a worldwide universal symbol) is clearly displayed on the packaging of these products. There are CBD-based pain products on the market, where most of them are hiding their CBD ingredient behind the word "Hemp", and therefore cannot be sold in major retailers or smaller retailers due to the fact that they cannot receive an FDA National Drug Code (NDC) registration, which Cannanumb® has obtained in 2018. Since many CBD manufacturers do not want to display the word "CBD" on their packaging, they are deceiving consumers by listing the number of milligrams (mg) of CBD as milligrams of "Hemp Extract" or "Hemp Oil". Cannanumb® does not contain any CBD... it contains the legal ingredient Cannabis Sativa (Hemp) Seed Oil. We believe there is a need to launch a national topical pain product for the first time that not only effectively relieves pain, but is also a registered FDA OTC drug, branded and marketed in the same fashion as marijuana and CBD products.

Cannanumb® by Hempagenix™ will enter the market with a new, one-of-a-kind revolutionary roll-on formulation. This method of application is the newest and easiest way to apply a pain topical, with no mess. Our proprietary formulation contains Cannabis Sativa (Hemp) Seed Oil, Lidocaine (Drug), Arnica, and Menthol, which all concentrate on muscle aches, with a deeper penetration to the aggravated nerves. Unlike topical CBD products, which cannot penetrate through the Dermis (middle layer of the skin), Cannanumb's proprietary formula can effectively penetrate through the Dermis and target aggravated nerves, relieving pain.

FACTUAL BACKGROUND ON HEMP

Industrial hemp is a commonly used term for a group of varieties of the species *Cannabis sativa* L. that are cultivated for industrial rather than drug purposes.¹ Cannabis Sativa Hemp Seed Oil (hereinafter “Hemp Oil”) is composed almost entirely of fats, which makes it ideal for human food use and the manufacturing of consumer products such as lotions and cosmetics. Hemp seed oil is a great source of omega-3 fatty acids in the desirable alpha-linolenic acid (ALA) form, which the human body can put to immediate use upon consumption. Studies have shown that consumption of fatty acids in a ratio of 4:1 omega-6 to omega-3 results in a reduced risk of cardiovascular disease and cancer.² Hemp seed oil contains omega-6 and omega-3 fatty acids in a ratio of less than 3:1, which means that it is a great source of omega-3 fatty acids and helps to maintain a healthy dietary fatty acid ratio.

Besides the favorable fatty acid composition, hemp seed oil is also rich in vitamins, antioxidants, and phytosterols that make it even more desirable to use as a cooking oil. For example, hemp seed oil contains significant amounts of vitamin E, phytol, and β -sitosterol. The FDA recognizes that phytosterol consumption is linked to lowered blood levels of LDL cholesterol. Thus, including hemp seed oil in the diet could contribute to this effect.

Industrial hemp is a commonly used term for a group of varieties of the species *Cannabis sativa* L. that are cultivated for industrial rather than drug purposes. Regulations in the EU and Canada conservatively mandate less than 0.2 and 0.3% of THC in industrial hemp flowers, respectively. By contrast, marijuana varieties typically contain 3 to 15% THC in their flowers. Due to minimal THC content, flowers from industrial hemp have no potential for drug use.

For seed, hemp is harvested when the seed is mature and ready for combining. See U.S. Dept. of Agriculture, “Industrial Hemp in the United States: Status and Market Potential” 7, 10 (Jan. 2000) (“USDA Study”). Most of the seed’s value is derived from either dehulling the whole seed and/or crushing it for oil. Hemp seeds supply essential amino acids in an easily digestible form with a high protein efficiency ratio; the hemp oil offers a high concentration of the two essential fatty acids in an optimum ratio of the omega 3/omega 6 acids. Because of this nutritional profile, hemp nut and oil are increasingly used in natural food products such as corn chips, nutrition bars, nondairy milks, breads and cereals.

The hemp seed (or nut) itself contains only miniscule traces of THC, usually much less than 0.5 parts per million (ppm) of THC; however “[d]epending on the hemp variety and the degree of seed cleaning, various amounts of THC residues can be found on the outer shells of whole seed and in the products made from hemp seeds.” Hemp oil may contain trace amounts of THC from the trace resin residue on the outer shells. Currently, THC levels in hulled seeds produced in Canada are typically less than 2 ppm and in hemp seed oil, less than 5 ppm.

According to the United States Controlled Substance Act (CSA), the CSA exempts hemp stalk, seed and oil from the definition of “Marihuana”, notwithstanding that such stalk, seed and oil may contain non-psychoactive miniscule trace amounts of residual resin with naturally occurring trace amounts of THC. The express language of the CSA thus provides that hemp stalk, oil, cake and sterilized seed are not controlled as “Marihuana” under Schedule I of the CSA. In fact, the express exclusion of hemp stalk, oil, cake and sterilized seed was adopted by Congress.

The hemp industry still has work ahead to win legal status for hemp-derived cannabidiol, or CBD oil, as an ingredient in food or dietary supplements despite the signing of the big farm bill. This does not change the consumers mindset for the need of Hemp based or CBD products.

As per the 2018 farm bill, provisions of the bill amend the definition of marijuana by removing hemp and all parts of the plant and all derivatives from the definition, according to the American Herbal Products Association, Silver Spring, Md. “This effectively removes all U.S. Drug Enforcement Administration (D.E.A.) authority regarding hemp cultivation, production or commercial activity for products that contain hemp or constituents of hemp,” the association said, adding the rule legalizes the domestic cultivation, production and commercial development of hemp and hemp products at the federal level. The law defines hemp as cannabis (*Cannabis sativa* L.) and derivatives of cannabis that are less than 0.3% on a dry weight basis of the psychoactive compound delta-9-tetrahydrocannabinol (T.H.C.).

¹ This distinction is formally affirmed in Article 28(2) of the United Nations’ Single Convention on Narcotic Drugs, 1961, to which the United States is a signatory party: “This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.”

² The importance of the omega-6/omega-3 fatty acid ratio in cardiovascular disease and other chronic diseases. The Center for Genetics, Nutrition and Health

DECEMBER 20, 2018

FDA RESPONDS TO THREE GRAS NOTICES FOR HEMP SEED-DERIVED INGREDIENTS FOR USE IN HUMAN FOOD

The U.S. Food and Drug Administration has completed its evaluation of three generally recognized as safe (GRAS) notices for hemp seed-derived food ingredients. The GRAS notices were submitted by Fresh Hemp Foods, Ltd. The agency has no questions about Fresh Hemp Food's conclusion that the following ingredients are GRAS under their intended conditions of use: hulled hemp seed (GRN765), hemp seed protein powder (GRN771), and **hemp seed oil** (GRN778).

Foods containing hemp seed and hemp seed-derived ingredients are currently marketed in the US. Hemp seeds are the seeds of the hemp plant, Cannabis sativa. Although hemp is from the same species as cannabis (marijuana), the seeds themselves do not naturally contain tetrahydrocannabinol (THC), the main psychoactive ingredient in cannabis. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high".

The GRAS notices are for three different hemp seed-derived ingredients. The GRAS conclusions can apply to ingredients from other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food. As stated on FDA and Marijuana: Questions and Answers, it is a prohibited act under section 301(l) of the Federal Food, Drug, and Cosmetic Act to introduce into interstate commerce a food to which CBD or THC has been added.

FDA Search

Our product, Cannanumb® Pain Relief Liquid Roll-On is an FDA Registered (NDC Package Code #72614-265-02) "Over the Counter" (OTC) pain drug. (ie. Tylenol, Motrin, IcyHot and Pepto-Bismol). See the FDA website <https://www.accessdata.fda.gov/scripts/cder/ndc/> and search "Canna Numb" under Proprietary Name to view our FDA Registration.

The FDA approved facility in the USA where Cannanumb® is manufactured, also produces several other National Brands.

This document was prepared by Seth A. Hyman – President & CEO – Hempagenix, LLC