REGULATIONS REMAIN HAZY AROUND CBD USE IN SUPPLEMENTS

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On December 20, 2018, President Trump signed the Agricultural Improvement Act of 2018, known as the Farm Bill, into law. Of the many provisions of this legislation, the "Hemp Legalization Amendment" received by far the most public attention.[1] As a result "industrial hemp," defined as Cannabis Sativa plants that contain less than 0.3 percent THC (tetrahydrocannabinol, which is the psychoactive ingredient in marijuana), has been removed from the Drug Enforcement Administration's definition of Marijuana Extract. Industrial hemp is, therefore, no longer a controlled substance, and is legal to cultivate for commercial purposes everywhere in the United States.

The new status granted industrial hemp is expected to open a wealth of legitimate business opportunities for not only the farming sector, but for businesses interested in what can be manufactured from the byproducts of the plant, from healthy oils and protein for use in food to textiles and durable goods. The one notable exception may be the market for CBD (cannabidiol), a constituent of virtually all species of hemp, which has been flourishing in the grey areas of the dietary supplement industry. The problem for CBD, the companies that market it and the consumers who are looking to purchase it is that the farm bill did nothing to alter the status of industrial hemp under the Federal Food Drug and Cosmetic Act (FDCA) as enforced by the Food and Drug Administration (FDA).

FDA AND CBD

FDA's position on CBD is straightforward: CBD is not a legal ingredient for use in foods or dietary supplements. This was expressly stated in a June 2018 Guidance Document, "FDA and Marijuana Questions and Answers," in which the Agency poses the question, "Can products that contain THC or cannabidiol (CBD) be sold as dietary supplements?" According to the agency:

Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the FD&C Act), or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the

limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to sections 201(ff)(3)(B)(i) and (ii) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD. For more information on this provision, including an explanation of the phrase "marketed as," see, Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues. (citation omitted)

The Q&A supports FDA's conclusion that CBD is excluded from the dietary supplement definition under 21 USC §331 by citation to public disclosure by GW Pharma of "substantial clinical investigations" pursuant to an Investigational New Drug Application for its cannabidiol drug, Epidiolex, in a May 7, 2014, press release and a November 26, 2007, press release concerning GW's approval of an Investigational New Drug Application for its drug Sativex, which contains a mixture of CBD and THC.

More recently, at the Council for Responsible Nutrition Annual Conference in October 2018, Steve Tave, director of the FDA's Office of Dietary Supplements, explained, "Just because we (FDA) have not taken enforcement action (against CBD products that do not make claims), people seem to think it is OK." However, "anyone who thinks it is lawful is mistaken."[2]

CBD-FREE HEMP FOODS?

The FDA's position does not mean that companies wishing to market hemp-based supplements or food must remove all traces of CBD from their products. As long as food or supplement ingredient suppliers do not manipulate the CBD content of the products, use "traditional" extraction methods, and marketers do not "call out" CBD content, FDA will have no regulatory concerns. Hemp products containing trace amounts of CBD are on the same footing as Chinese red yeast rice products containing trace amounts of the naturally occurring constituent monacolin K, which is also known as lovastatin.

As explained by the FDA and the 10th Circuit Court of Appeals in *Pharmanex, Inc. v. Shalala* in 2000, there was no question that traditionally prepared red yeast rice had been marketed as a food and used in traditional Asian medicine for its cardiovascular benefits for many years and that it naturally contained monacolin K, which is chemically identical to the active ingredient lovastatin in the prescription drug, Mevacor®. In fact, Merck discovered the efficacy of lovastatin after studying red yeast rice. Traditional red yeast rice, however, does not contain more than trace amounts of lovastatin, and there is no evidence that it was marketed for consumption because of the presence of lovastatin prior to Merck's marketing of Mevacor®. Thus, while it remained possible to market traditionally prepared red yeast rice following the approval of Mevacor®, the Court found it within FDA's power pursuant to sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act to prohibit the marketing of red yeast rice with claims relating to lovastatin or where the manufacturing process had been adjusted to manipulate the amount of lovastatin.

BUT WHAT'S HAPPENING IN THE MARKET?

Despite the FDA's seemingly clear pronouncements that CBD is not a legal ingredient, it can be found in many foods and beverages, dietary supplements and even topically applied ointments. Media coverage of these products abounds.

- On October 8, 2018, CNN.com described CBD as "the USA's coolest food and drink ingredient";
- On January 17, 2019, an article on FoodNavigator.com detailed the market launch of New Age Beverages' Marley brand of CBD-infused drinks. While the company described its decision not to make any performance-related claims for CBD, the ingredient is featured prominently in the front panel of the drinks' cans; and
- On January 15, 2019, *The Atlantic* covered CBD-infused cupcakes sold out of Weed World Candies trucks in Manhattan, noting their ready availability despite the significant questions concerning their illegality.
- At New York State Bar Association's annual meeting, speaking at the session presented by the Committee on Cannabis, Dr. Daniel Fabricant, president of the Natural Products Association, stated that his organization believes that there are more than 1,400 foods, beverages and dietary supplements currently being marketed as containing CBD as an ingredient.

Given its absolute statements of illegality, the FDA's response has been surprisingly timid. Since October 2015 it has issued a half dozen Warning Letters to companies marketing foods and supplements for CBD content, but each of these letters has also cited numerous unapproved drug claims[3]. FDA has not taken any enforcement action, however, against CBD products that do not carry such claims.

WHERE TO FROM HERE?

The same part of the FDCA that blocks CBD foods and supplements also allows the Secretary of Health and Human Services to promulgate a regulation permitting their use. FDA has never published any guidance advising of the factors it would consider in issuing such a regulation, and it has rejected the only petition submitted on the subject without addressing the merits of the request, instead citing highly technical reasons as the basis to refuse to even consider the issue.[4]

Given FDA's position that CBD is not permitted as an ingredient in food, beverages or dietary supplements, its hostility to permitting a "drug" ingredient to be used in food, and its simultaneous failure to take any enforcement action against the numerous CBD products on the market, it seems that the market will remain in limbo for some time. Companies with a strict policy of compliance with FDA laws and regulations will continue to decline to manufacture or distribute CBD products, while others who are not as risk-averse will play in the market.

Whether this state of affairs is sustainable seems doubtful, as it is very unusual for a federal regulator to oversee a marketplace that disregards its authority. Where we will end up, however, remains to be seen.

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1 E.g., "Hemp is about to be legal under the 2018 Farm Bill. You can't get high from it — but you can wear it", *LA Times*, December 19, 2018

2 https://www.nutraingredients-usa.com/Article/2018/11/06/Top-FDA-official-Anyone-who-thinks-CBD-is-lawful-is-mistaken

3 E.g, Stanley Brothers Social Enterprises, LLC 10/31/17, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583192.htm

4 Letter to Marc Ullman, Esq. Re: Docket No. FDA 2009-P-0298, February 3, 2011.