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FDA Breaks Its Silence on CBD

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After much anticipation, the FDA has begun, once again, to address its policies on cannabidiol (CBD) via:

1. FDA's issuance of a second report to Congress regarding data collected about CBD products on the market (July 9, 2020);
2. Draft guidance regarding clinical development of cannabis-derived compounds (July 21, 2020); and
3. Draft guidance on its much-anticipated and long-awaited CBD enforcement policy (sent to the Office of Management and Budget (OMB) July 22, 2020).

To date, FDA's movement has not officially changed the agency's existing position on the legal status of various CBD-containing consumer products (cosmetics, dietary supplements, etc.), and more is expected, but the recent report to Congress and draft guidance on investigations involving CBD and other cannabis-derived compounds do shed light on FDA's current thinking about cannabis and CBD.

I. The Report

On July 9, 2020, FDA issued a Report to Congress (the "Report") identifying key takeaways from previous CBD product testing and disclosing the agency's plans for the further evaluation of such products, with a specific focus on the mislabeling and adulteration of products in the CBD marketplace. FDA indicates that the Report was necessary for two reasons: (1) to satisfy a recent congressional directive[1] and (2) to develop a deeper understanding of CBD products currently available on the market, which FDA asserts "is critical to making informed decisions about how best to protect public health in the current marketplace."[2] Although previous FDA testing did not indicate a harmful presence of heavy metals in CBD products, results did reveal significant inconsistencies between the amount of cannabinoids advertised on product labeling and the actual amount contained in products. Because of the limited scope of previous testing, FDA cautions that such results cannot be used to draw definitive conclusions, but rather should be used to inform testing that is scheduled to begin later this year. To this point, FDA specifically indicates that "***nothing in [the Report] is intended to change or otherwise alter FDA's prior statements regarding the legal or regulatory status of products containing CBD***."[3]

A. Research Conducted Prior to the Congressional Directive

The Report catalogs the methodology and results of FDA's previous sampling studies on CBD products marketed for human consumption, including oils, tinctures, capsules, powders, tablets, gummies, vape liquids, conventional foods, beverages, and certain topicals (*e.g.,* salves, balms, gels).[4] Studies predating the passage of the 2018 Farm Bill[5] selected products for laboratory analysis based on four risk factors: (1) the presence of serious disease claims; (2) production or distribution in several states, reflecting interstate variation; (3) online sale; and/or (4) consumer complaints or adverse reports.[6] The study conducted after passage of the 2018 Farm Bill narrowed the

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scope of testing by focusing only on products that were: (1) marketed with disease claims and/or (2) intended for vulnerable populations.[7]

All of the studies detailed in the Report tested for the presence of cannabinoids, including CBD and THC.[8] In response to public comment from industry, the study conducted after passage of the 2018 Farm Bill also tested for the presence of certain heavy metals and other contaminants.[9] Results indicated trace amounts of heavy metals and other contaminants that the FDA ultimately found "do not raise significant health concerns."[10] However, data from all studies suggest a trend of widespread inconsistency between the amount of CBD specified on product labeling and the amount of CBD *actually* detected, as well as the presence of undisclosed THC and other cannabinoids.[11]

The Report limits the effect of these studies by noting that the selection of test products based on targeted risk factors, as opposed to randomized market samples, prevents FDA from understanding the extent to which such testing was representative of the overall market and thus cannot be used to draw any definitive conclusions.[12] FDA has also conducted studies on CBD-containing cosmetic products, the results of which indicate greater consistency between product labeling and cannabinoid content than the sampling studies conducted on CBD products marketed for consumption.[13] These results likely indicate that FDA will continue to focus its enforcement efforts on CBD products intended for consumption and marketed as unapproved new drugs.

B. Research Conducted in Accordance with the Congressional Directive

In response to FDA's directive under the Joint Explanatory Statement, FDA has developed a more comprehensive sampling plan, which is divided into two phases: near-term and long-term.[14]

i. 2020 "Near-Term" Evaluations

For its near-term sampling study, which was conducted earlier this year, FDA selected CBD and hemp products for laboratory analysis through a comprehensive narrowing process, randomly selecting products sold online across seven categories: (1) tinctures; (2) oils; (3) capsules; (4) gummies; (5) edibles; (6) beverages; and (7) pet products (*e.g.* tinctures, oils, and drops). Products were analyzed for the presence of CBD, THC, nine additional cannabinoids,[15] and heavy metals (*e.g.*, lead, cadmium, arsenic, and mercury).[16]

Of the 147 products tested, 138 were determined to contain CBD. Of those that did not contain CBD, 7 either indicated "zero CBD" or made no reference to CBD on the product labeling. 102 products indicated the presence of a specified amount of CBD in labeling. Of this category, 18 products contained less than 80% of the amount of CBD indicated; 46 products contained CBD within 20% of the amount of CBD indicated; and 38 products contained more than 120% of the amount of CBD indicated. 72 products were found to contain THC or THCA at concentrations above the permissible 0.3% threshold. 133 products were analyzed for the presence of heavy metals, and 132 did not contain heavy metals at a level that FDA considers a risk to public health.[17] FDA plans to resume testing on 53 other product samples that were unable to be analyzed due to the pandemic and 14 additional samples that were unable to be tested for heavy metals once it resumes normal operations.[18]

ii. Future "Long-Term" Evaluations

The Report expressly identifies certain limitations of the near-term study and indicates that FDA intends for the near-term methodology to inform its long-term sampling plans, rather than to provide conclusive evidence on its own. Product sampling for FDA's long-term plan will be conducted by a third party and is expected to commence in 2020.[19] In selecting CBD and hemp products for laboratory analysis for the long-term study, FDA intends to leverage purchased data on brands, product categories, and distribution channels with its own comprehensive data on brands operating in the CBD marketplace. According to the Report, the sample-selection process will favor hemp and CBD products with a "higher market share" across a wide variety of product categories.[20] FDA intends to analyze all sampled products for the presence of CBD, THC, and the nine other cannabinoids and heavy metals analyzed in the near-term study. Further, FDA also intends to test a subset of products, which is not specified in the Report, for the presence of pesticides, residual solvents, and microbial substances.[21]

II. The Research Guidance

On July 21, 2020, FDA issued draft guidance to encourage cannabis-related clinical research, entitled "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research" (the "Guidance").[22] FDA's Principal Deputy Commissioner, Amy Abernethy, M.D., Ph.D. explained that the "agency is committed to supporting the development of these new drugs through the investigational new drug, drug review, and drug approval processes – and one key element of this support involves development of guidance, like this one."[23]

First, FDA noted that the Guidance restates basic principles of regulation by the agency, given the sometimes different stakeholders that may be pursuing cannabis research. As such, FDA reiterated that any product marketed with a claim of therapeutic benefit (or with any other disease claim) is considered a drug and that those that are not generally recognized among experts as safe and effective for the intended use are "new drugs" under the federal Food, Drug & Cosmetic Act (FDCA) and must be approved by FDA for such use before they may be introduced into interstate commerce. Sponsors who wish to develop new drugs may do so by conducting clinical trials under an investigational new drug (IND) application to determine if the product candidate is safe and effective for the intended use(s). The data obtained from IND studies may later become a part of a new drug application (NDA), which, if approved, authorizes the sale of the drug in the United States.

In addition to outlining the drug-approval process, the Guidance also clarifies permissible sources of cannabis (*see* Section A of the Guidance); provides a list of principles and recommendations that are particularly relevant for the development of drugs containing cannabis, CBD, or other cannabis-derived compounds (*see* Section B of the Guidance); and describes best practices for calculating THC percentage (*see* Section C of the Guidance). The following key points are among the Guidance's highlights:

- **Sourcing:** Historically, the only domestic source of cannabis for legal clinical research purposes was the National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP), but in light of the changes made by the 2018 Farm Bill, hemp may now be used as a source for cannabis drug development, which greatly expands sourcing options for investigational drug sponsors.

- **Quality Principles:** Sponsors of cannabis-derived compounds will be required to provide sufficient information to ensure the identity, quality, purity, and potency of the investigational product, as well as quantitative data regarding phytochemicals that are present in their proposed product, including (without limitation) cannabinoids, terpenes, and flavonoids. Section B of the Guidance lists a number of helpful resources from which sponsors may obtain more information about specific methodologies and other related insight. Importantly, the Guidance clarifies that cannabis is held to the same regulatory standards

as any other botanical raw material, botanical drug substance, or botanical drug product; therefore, any FDA guidances that pertain to such items will also be helpful for those developing new cannabis drugs.

- **Calculating THC:** The Guidance acknowledges some of the challenges of calculating THC on a dry-weight basis and notes the importance of consulting the DEA before commencing drug-development activities. Among other things, the FDA recommends that sponsors calculate the THC level in their product candidates early in the development process to gain insight into its potential control status.

This Guidance represents an important step in FDA's development of practical policies and resources designed to aid and encourage the development of cannabis-containing drug products and, as such, indicates FDA's understanding of the importance of continued innovation in this realm.

III. The Enforcement Guidance

FDA has sent its draft Cannabidiol Enforcement Policy to OMB for review. Industry eagerly awaits information about the draft in the coming weeks or months. While the scope of the FDA's intended enforcement discretion will be clear only when the agency releases the guidance, we anticipate, like many others, that FDA will continue to focus its efforts on those products that pose, either through unlawful promotion as drugs or adulteration, the greatest risk to public health.

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[1] The Joint Explanatory Statement, which accompanied the 2020 Further Consolidated Appropriations Act, specifically directed FDA to conduct a sampling study of the current CBD marketplace to determine the extent to which products are mislabeled or adulterated and provide a report within 180 days of enactment. *See* FDA Report in Response to Further Consolidated Appropriations Act, 2020, dated July 9, 2020, at 1 (hereinafter, "FDA Report").
[2] *See id*. at 2.
[3] *See id*. at FN 6.
[4] *See id*. at 2, 4.
[5] The Agriculture Improvement Act of 2018 (P.L. 115-334).
[6] *See id.* at 2–3.
[7] *See id.* at 4.
[8] *See id.* at 3–4.
[9] All samples in this study were analyzed for arsenic, cadmium, mercury, lead, manganese, nickel, copper, zinc, selenium, molybdenum, antimony, barium, cobalt, lithium, tin, and vanadium.
[10] *See* FDA Report at 4.
[11] *See id.* at 3–4.
[12] *See id*.
[13] *See id*. at 5.
[14] *See id.* at 6.
[15] All 147 product samples were tested for the following cannabinoids: CBC, CBD, CBDA, CBDV, CBG, CBGA, CBN, THC, ∆8-THC, THCA, and THCV.
[16] *See* FDA Report at 6.
[17] *Id*. at 6–7.
[18] *See id.* at 21, 22.
[19] *See id.* at 8.

[20] *See id.* at 7–8.
[21] *See id*. at 8.
[22] FDA In Brief: FDA Issues Draft Guidance to Encourage Cannabis-Related Clinical Research (July 21, 2020) (*hereinafter* "FDA In Brief"); FDA Draft Guidance, *Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research* (July 2020) (*hereinafter,* "FDA Guidance").
[23] FDA In Brief.