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FDA CBD Roundup: Agency Continues Existing Enforcement Approach While Reviewing Public Comments and Considering Future Policy Approaches

On May 31, 2019, the U.S. Food and Drug Administration ("FDA") held a much-anticipated public hearing regarding "Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds." Since that time, FDA has reiterated its existing regulatory and enforcement approach to products containing cannabidiol ("CBD") while also evaluating other science-based policy approaches for CBD products. The agency has emphasized that it is aiming to protect patients and the public health, foster innovation for safe and appropriate products, and promote consumer confidence.

FDA's actions follow the enactment of the 2018 Farm Bill. As Ropes & Gray previously reported (see Alert and podcast), the 2018 Farm Bill removed hemp—defined as cannabis and cannabis derivatives with concentrations of THC no more than 0.3%—from the definition of marijuana in the Controlled Substances Act ("CSA"). This legislation meant that hemp, including CBD derived from hemp, was no longer unlawful under the CSA. However, the 2018 Farm Bill expressly preserved FDA's authority to regulate such products.

This Alert summarizes the following recent developments related to FDA's regulation of CBD products:

1. Public Comments: The closing of the comment period on July 16, 2019 for FDA's public hearing docket, with nearly 4500 comments submitted;

2. Recent FDA Warning Letter: FDA's issuance of a warning letter on July 22, 2019, to a firm marketing CBD products with unsubstantiated disease claims; and

3. FDA Testimony: Testimony of FDA's Principal Deputy Commissioner, Amy Abernethy, before the Senate Committee on Agriculture, Nutrition, and Forestry on July 25, 2019.

1. Public Comments Reveal Diversity of Perspectives and Range of Significant Policy Issues

FDA's public hearing docket received 4,492 comments from a diverse range of stakeholders. The majority of commenters were individual consumers who support FDA regulation that promotes broad availability of CBD and other cannabis-derived products. Additionally, various trade organizations, patient and consumer advocacy organizations, research organizations, cannabis and cannabis-derived product manufacturers, law firms, and businesses with a stake in the cannabis and cannabis-derived product market submitted comments. The majority of these comments generally supported regulation that would allow for greater accessibility in the marketplace, but with appropriate controls to ensure safety and quality. Most commenters agreed that the FDA must provide additional guidance and clarification as to how products may be legally manufactured and marketed.

Below is a summary of key issues raised by commenters relating to: (a) FDA regulation and policy generally, (b) health and safety risks, (c) manufacturing and product quality, (d) marketing, labeling, and sales, (e) product benefits, and (f) economic and cost considerations.

A. FDA Regulation and Policy Generally

- Many comments highlighted the need for clarity in the regulatory framework, including with respect to labeling and packaging, manufacturing standards, and product testing standards, among other matters.

- Comments noted that the 2018 Farm Bill has led to confusion about which hemp products are legal, and the current patchwork of state laws is difficult for companies and consumers to navigate.

- Numerous comments supported regulations policies that would legalize CBD-containing dietary supplements and foods. Several comments thought FDA's existing new dietary ingredient notification system would provide reasonable assurance that CBD does not present a significant or unreasonable risk in dietary supplements.

- Several comments recommended that FDA exercise enforcement discretion regarding the "exclusionary clause" provisions on which FDA bases its position that CBD cannot legally be added to foods or marketed in dietary supplements.

- Various comments urged FDA to establish policies that would encourage more research on CBD and other cannabis-derived products.

B. Health and Safety Risks

- Comments expressed concern with the unknown impact CBD can have on special populations, such as pregnant women, nursing women, and children. Pharmaceutical companies were concerned about the unknown interaction that CBD may have with different prescription drugs. However, other commenters pointed to a recent World Health Organization ("WHO") report regarding CBD and the clinical studies of Epidiolex, an FDA-approved form of CBD, to emphasize the overall safety of CBD.

- Commenters raised concern with the lack of oversight for the vast array of CBD products on the market and the potential that they may be of low quality. Undocumented pesticides, heavy metals, residual solvents, and microbial contamination were all cited as potential concerns.

C. Manufacturing and Product Quality

- Commenters expressed concern that the lack of uniform regulation and clear oversight by FDA has led to poor quality products on the market and resulted in consumer distrust and confusion.

- Many comments recommended that FDA establish standards for manufacturing CBD and other cannabis-derived products. Several commenters explained that FDA's existing regulatory framework is adequate to address manufacturing and product quality concerns. For example, comments suggested that current good manufacturing practice requirements be applied to manufacturing of CBD products and that FDA inspect manufacturing facilities.

- Testing laboratories recommended that FDA establish standards for product testing (e.g., testing of THC content) to ensure consistency across jurisdictions.

D. Marketing, Labeling, and Sales

- Commenters asserted that the lack of standardized labels and terminology in the CBD industry has led to consumer confusion and distrust. For example, one comment noted that the terms "hemp oil," "CBD," "CBD extract," "hemp extract," and similar words are all being used in the marketplace with no clear standards for what these terms mean.

- Commenters also expressed concern that the labels of CBD-containing products may not accurately reflect the amount of CBD contained in the products.

- Comments also recommended that labels address the potential for adverse events and discuss risks of specific drug interactions with CBD.

E. Product Benefits

- The majority of comments from individual consumers highlighted the benefits of using cannabis and cannabis-derived products. Individuals provided anecdotes about how CBD products had helped with various ailments, including anxiety, depression, PTSD, brain cancer and pain.

- Individual consumers and health care professionals also cited scientific journal articles purportedly demonstrating the efficacy of CBD and other cannabis-derived products in treating various medical conditions.

F. Economic and Cost Considerations

- Some commenters discussed the positive impact that CBD and other cannabis-derived products would have on the national economy if they were more widely available.

- Some individual consumers commented that CBD products are less expensive than prescription drugs and worried that prices may increase if the products are subject to more regulation.

2. New Warning Letter Continues FDA's Existing Approach to CBD Enforcement

During the May 31 public hearing, Acting FDA Commissioner Ned Sharpless reiterated the agency's current policy for products containing CBD. Specifically, FDA takes the position that under current law, CBD cannot lawfully be added to a food or marketed as a dietary supplement. Additionally, FDA's "biggest concern" is the marketing of CBD products with disease claims that put the health of consumers at risk. Nevertheless, FDA has made clear that the agency does not have a policy of enforcement discretion with respect to any CBD products.

A warning letter issued to Curaleaf on July 22 and announced by FDA on July 23 continues this approach. Among other concerns, FDA cited the firm's marketing of a CBD-containing lotion, pain relief patch, tincture, vape pen, and pet food with various disease claims, including claims on the Company's website and social media accounts that the products could treat cancer, Alzheimer's disease, Parkinson's disease, opioid withdrawal, ADHD, chronic pain, and pet anxiety. Because of these disease claims, FDA considered the products to be unapproved drugs in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Additionally, FDA explained that the firm's CBD-containing products could not legally be marketed as dietary supplements.

The new warning letter is similar to numerous prior warning letters the FDA has issued for CBD-containing products since 2015. However, it demonstrates the need for firms marketing CBD-containing products to review all claims and marketing statements carefully. For example, a CBD-containing product that purports to be a cosmetic (e.g., topical lotion) will nevertheless be considered an unapproved drug by FDA if the product is marketed with disease claims. While FDA is evaluating potential changes to its CBD-related policies, FDA will take action against firms based on its current regulatory approach.

3. In Senate Testimony, FDA Emphasizes Caution in Its Efforts to Develop Additional Regulatory Pathways for CBD

On July 25, 2019, FDA's Principal Deputy Commissioner, Amy Abernethy, testified before the Senate Committee on Agriculture, Nutrition, and Forestry to summarize the agency's efforts to develop a CBD regulatory policy. Dr. Abernethy echoed the agency's consistent position regarding the regulatory status of hemp-derived products, including those that contain CBD and other cannabinoid compounds, in the wake of the 2018 Farm Bill.

Dr. Abernethy discussed the goals of FDA's high-level CBD Policy Working Group, which is considering the appropriateness of potential pathways for dietary supplements and/or conventional foods containing CBD to be lawfully marketed. She described the working group's "first priority" as obtaining and assessing safety data unique to including CBD in food and dietary supplement products as opposed to CBD as an active ingredient in a drug product. Specifically, FDA will evaluate the safety of potentially exposing a wide range of consumers to such products, including pregnant or nursing mothers, children, the elderly, those with chronic illnesses, and those taking medications that might interact with CBD. The working group is also concerned with potentially unsafe manufacturing processes for CBD products and product labeling that lists inaccurate concentrations of CBD or fails to list other potentially dangerous compounds contained in the products.

Dr. Abernethy acknowledged that the FDCA permits FDA to adopt regulations that create exceptions to the legal provisions that currently prohibit CBD from being added to foods or marketed as a dietary supplement. However, she noted that even an expedited rulemaking process can take three to five years under the Administrative Procedure Act. Summarizing the agency's concerns, Dr. Abernethy emphasized that "FDA will only consider creating legal pathways for CBD to be marketed as a dietary supplement or in a food if the Agency is confident that it can develop a framework that addresses safety concerns." FDA previously stated in its July 23 press announcement that it plans to report on the progress of its CBD Policy Working Group by early fall 2019.

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As these developments demonstrate, FDA has many significant issues to evaluate as it reviews public comments and considers future regulatory pathways for CBD-containing products. Yet in the meantime, FDA will not hesitate to take regulatory action through the issuance of warning letters against firms making unsupported, unapproved disease claims for CBD-containing products.

We will continue to monitor this area for further regulatory developments. If you have any questions, please contact any member of Ropes & Gray's FDA Regulatory team or your usual Ropes & Gray advisor.