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FDA Updates Guidance for CBD Products amid a New Round of Warning Letters and Announcement of Date for Public Hearing

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On April 2, 2019, the U.S. Food and Drug Administration (FDA) issued a sweeping press release from outgoing Commissioner Scott Gottlieb covering new steps to advance the agency's continued evaluation of potential regulatory pathways for CBD products. The five-page statement outlined what the FDA has in store for the industry over the next several months. Among other things, the FDA has:

- Scheduled a public hearing for May 31 to allow stakeholders to share experiences and challenges with CBD products, including opinions on public safety concerns.
- Announced formation of an internal agency working group to "explore potential pathways for dietary supplements and/or conventional foods containing CBD to be lawfully marketed."
- Overhauled its FAQ webpage, providing answers and new guidance for CBD products, including cosmetics.
- Issued three warning letters to companies marketing CBD products using "egregious and unfounded claims aimed at vulnerable populations."

In the press release, Gottlieb reinforced the FDA's position that it is unlawful to introduce food with added CBD or THC into interstate commerce, or to market CBD and THC dietary supplements. While the availability of CBD products has dramatically increased over the past several years, many unanswered questions and potential health risks remain, according to the FDA. Chief among these are the potential for liver injury and cumulative exposure to CBD if accessed by consumers across a range of products.

The FDA is concerned that permitting widespread commercial availability of CBD products negatively impacts research that may otherwise be performed to support regulatory approval through the FDA's drug review process. Similarly, the FDA does not want to incentivize patients to forgo appropriate medical treatment by substituting unapproved products for FDA-approved medicines.

Several large national retailers recently announced they will begin selling CBD-infused products. Shortly after the press release, Commissioner Gottlieb addressed his concerns, tweeting "I was also concerned to hear recently that several national pharmacy chains and other major retailers have

begun to sell or will soon begin to sell CBD products in several states. We'll be contacting them to remind them of FDA obligations and our commitment to protect consumers against products that can put them at risk."

Warning Letters – Updated Guidance for the Industry

Consistent with the FDA's public health concerns, Gottlieb announced that the agency, in collaboration with the Federal Trade Commission (FTC), has issued a new round of warning letters to three companies that have made "egregious claims about their products' ability to limit, treat or cure cancer, neurodegenerative conditions, autoimmune disease, opioid disorder, and other serious diseases, without sufficient evidence and the legally required FDA approval." Gottlieb made clear that these "egregious, over-the-line claims won't be tolerated." Because the three companies claim that their CBD products were intended to diagnose, cure, mitigate, treat or prevent disease, the FDA considered them a drug that may not be introduced into interstate commerce without prior approval.

For the first time, the FDA also has scrutinized the nutrition fact panels on CBD products, warning that, to the extent the product label suggests it is food, it is unlawful to introduce any food into interstate commerce to which CBD has been added.

The most recent round of warning letters also includes another first; a warning from the FTC that it is unlawful under the FTC Act to advertise that a CBD product can prevent, treat or cure disease unless the company has competent and reliable scientific evidence backing up its claims.

The FDA Breaks Its Silence on CBD-Infused Cosmetics in Overhauled FAQ

Since cosmetics are less heavily regulated by the FDA than food and drugs, the agency has remained largely silent on the use of CBD in cosmetics products ? until now. In its FAQ, the FDA provided much-needed insight, stating that "cannabis or cannabis-derived ingredients" are not necessarily prohibited ingredients in cosmetics products and affirmed that these ingredients are not specifically addressed by regulation. However, the FDA warned that no ingredient ? including cannabis-derived ingredients – can be used in a cosmetic if "it causes the product to be adultered or misbranded."

The FAQ also is replete with examples of the Agency's concern over deceptive marketing tactics for unproven health claims. The FDA explained that these practices raise significant public health concerns because "patients and other consumers may be influenced not to use approved therapies to treat serious diseases."

The FDA also briefly touches on THC products and state-sanctioned medical marijuana programs. In response to what is the FDA's reaction to states that allow cannabis to be sold for medical uses without the FDA's approval, the FDA stressed the importance of medical research and welcomed the opportunity to talk with states that are considering support for medical research of cannabis-derived medicine.

The FDA's Notice for Public Hearing

The FDA announced that it is holding a public hearing on May 31, 2019, given the substantial interest in CBD-infused products and congressional interest in fostering development of appropriate hemp

products under the 2018 Farm Bill, while preserving the FDA's ability to protect public health. The anticipated goal of the hearing is to "obtain additional scientific data and other information related to cannabis and cannabis-derived compounds, from both botanical and synthetic sources, to inform FDA's regulatory oversight of these products."

The hearing will cover a range of CBD-related topics, including (1) Health and Safety, (2) Manufacturing and Product Quality and (3) Marketing/Labeling/Sales. The FDA is encouraging public comments and participation at the hearing.

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