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FDA Issues CBD Consumer Update and Warning Letters

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Food, Beverage, and Dietary Supplements

Yesterday, the Food and Drug Administration (FDA) published a consumer update on its ongoing analysis of the safety of products containing cannabis or cannabis-derived compounds, including cannabidiol (CBD). FDA also issued warning letters to 15 companies for selling CBD-containing products in violation of the Food, Drug, and Cosmetic Act (FD&C Act). These appear to be the most in-depth safety-related statements that FDA has made so far in its ongoing evaluation of CBD. Below is more detail about FDA's announcement and the warning letters, and some considerations for their significance in the broader context of the federal and state landscapes surrounding CBD products.

FDA Consumer Update

In its consumer update, FDA identified several specific health risks potentially posed by CBD. The agency stated that CBD is associated with the potential for liver injury, and the risk of liver injury may be more difficult to manage without medical supervision. CBD may also impact the efficacy of other medications, while other medications might impact the potency of CBD products. Additionally, CBD is associated with male reproductive toxicity in animals, and FDA is working to understand whether that risk would also translate to humans. FDA emphasized that consumers might be harmed by these risks without noticing. FDA also identified health risks that consumers might more readily detect, including changes in alertness, gastrointestinal distress, and changes in mood, which FDA noted should improve once CBD is stopped or reduced.

FDA also advised consumers of more general risks, like that CBD products might be marketed with unproven medical claims, which may delay the consumer in seeking medical care. The agency also asserted that many CBD products do not contain the levels of CBD that the products claim, and that it is investigating reports of certain CBD products that might also contain THC or unsafe contaminants like pesticides or heavy metals. FDA explained that it is raising these potential risks because it wants consumers to know what the agency knows. It encourages consumers to "think carefully before exposing themselves, their family, or their pets, to any product, especially products like CBD, which may have potential risks, be of unknown quality, and have unproven benefits."

Looking forward, FDA stated that it continues to evaluate the potential regulatory pathway associated with CBD products intended for non-drug use. The agency reiterated its position that it is currently illegal under federal law to add CBD to a food or market it as a dietary supplement. FDA highlighted the need for more high-quality scientific information about the safety of CBD as the agency continues its work in setting science-based policy.

FDA Warning Letters

FDA issued warning letters to 15 companies across several different states for illegally selling CBD-containing products. Each of the warned companies made fairly egregious claims that its products could be used to treat serious diseases, consistent with the targets of FDA's prior warning letters for CBD products, though the agency also alleged a wide variety of FD&C Act violations. Certain of the letters also included CBD products that, in addition to being marketed with serious disease claims, target particularly vulnerable populations like infants and children, as well as CBD products that are intended for food-producing animals, which might affect human food products derived from those animals. Notably, FDA also expressly stated in a number of the letters that it is aware of no basis for general recognition of safety for the use of CBD in food.

Implications for the Federal and State Landscapes Surrounding CBD Products

These documents reflect FDA's most in-depth public statements to consumers to date about the agency's ongoing safety review of CBD and the potential risks of CBD products that FDA is evaluating, and the warning letters include some charges beyond those seen in earlier CBD warning letters. But FDA also emphasized that the agency continues to explore potential pathways for various types of CBD-containing products to be lawfully marketed. This exploration has been strongly encouraged by Congress, which continues to urge FDA to find an avenue for the lawful marketing of these products in the wake of the 2018 Farm Bill provisions legalizing hemp and CBD from hemp.[1] These announcements may thus reflect an effort by FDA to slow the growth of the CBD industry while the agency completes its safety evaluation and considers next steps. The warning letters are consistent with the agency's recent CBD enforcement approach of going after companies marketing CBD-containing products with serious disease claims, and don't necessarily suggest a shift in that approach, though certain of the letters include more detail than we have previously seen about the grounds for its position that CBD is unlawful separate from the marketing claims.

So it seems that at the federal level, these announcements and actions do not reveal a significant change in FDA's enforcement or policy stance, except perhaps a hardening of the agency's view that it has not yet received data sufficient to establish safety of CBD in food and supplements at any particular level. FDA said it plans to provide an update on its progress in this space in the coming weeks, and reiterated its call for further study and request for all available high quality scientific information about the safety and potential uses of CBD.

The implications of FDA's update for enforcement and policy developments at the state and even local government levels, however, remain to be seen. While some states have expressly legalized CBD, including for use in food and supplements, others have announced that such products remain unlawful because FDA says they are. FDA's statements likely will not persuade those states to change course absent a significant change in federal CBD law and policy. The

[1] See our client alert on the 2018 Farm Bill here.

patchwork of state law and enforcement will thus continue to create confusion for consumers and potential marketers of CBD-containing products.

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Covington continues to monitor federal and state law developments regarding CBD, and will keep our clients and contacts updated. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplement practice:

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