Updates
November 26, 2019

FDA Declines to Conclude CBD is Safe and Sends Flurry of Warning Letters

On November 25, 2019, the U.S. Food and Drug Administration (FDA) took several significant actions regarding sellers of products containing cannabidiol (CBD). The FDA announced that it cannot conclude that CBD is "generally recognized as safe" (GRAS) among qualified experts for use in human or animal food. In support of this announcement, the agency pointed to numerous "unanswered questions and data gaps about CBD toxicity," especially those related to the cumulative use of CBD and its consumption by animals or particular populations, such as children or the elderly. The FDA also revised its *Consumer Update* concerning its open questions regarding CBD safety.

In its CBD-related *Consumer Update*, the agency noted that it has only approved one drug that contains CBD, a prescription product for treating two rare epilepsy conditions. The FDA emphasized that it has "limited data about CBD's safety." Further, the agency declared its position that marketing CBD "by adding it to a food or labeling it as a dietary supplement" is illegal.

The FDA's conclusion that CBD has not yet achieved GRAS status coupled with the revised *Consumer Update* suggest that the agency may take a more forceful approach to CBD enforcement. Just yesterday, the agency announced that it had issued 15 warning letters to CBD manufacturers who are alleged to have marketed their products in violation of the Food, Drug, and Cosmetic Act. This is nearly as many warning letters regarding CBD as the FDA sent companies in 2015 through 2018 combined (a total of 19 warning letters). As noted in these letters, the FDA concluded that certain CBD products had entered the market as unapproved or misbranded drugs. The agency also alleged that products containing CBD do not meet the definition of a dietary supplement and cannot be legally marketed as such. The warning letters demanded a report of corrective actions taken within 15 working days to avoid further legal actions, such as seizure or injunction. The FDA has not actually launched enforcement or legal actions, beyond issuing letters, relating to CBD in food or dietary supplements.

A senior FDA official issued a statement that the agency recognized the "significant public interest in CBD and [that the FDA] must work together with stakeholders and industry to fill in the knowledge gaps about the science, safety and quality of many of these products." Consistent with prior recommendations from Perkins Coie, companies in the CBD industry can limit the risk of unwanted attention from the FDA by marketing products as follows:

- Ensure express and implied health claims are supported by competent and reliable scientific evidence
- Avoid claims that are difficult or impossible to verify, such as "CBD gummies can help treat cancer"
- Avoid marketing that suggests your product has "drug-like" qualities, although claims regarding general health and wellness are fine

Following these guidelines cannot completely eliminate the possibility of attracting unwanted attention from the FDA, but given the types of claims targeted by the agency's warning letters to date, the guidelines will help reduce the risk of enforcement.

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