Updates
July 15, 2020
FDA Releases Report to Congress on CBD Labeling

The U.S. Food and Drug Administration (FDA) submitted a report to Congress on July 8, 2020, providing an analysis of the cannabidiol (CBD) marketplace. The submission was in response to the Further Consolidated Appropriations Act of 2020, which, among other things, required the FDA to produce reports on mislabeling and adulteration in the CBD market. The report is a guidepost in the agency's continuing path towards producing regulations for this growing industry.

In the report, the agency recognizes "significant public interest in CBD products," and continues to express its concerns about the limited data available about such products, particularly whether labelling matches actual composition. The report builds on three sets of tests conducted between 2014 and 2018, during 2019, and earlier this year in 2020, that involved a small sample size that do not necessarily reflect the industry. Nevertheless, the agency's results to date are a reminder of the importance of substantiating labeling claims, particularly those concerning CBD concentration.

Test Results

According to the report, knowing "the characteristics of marketed CBD products is critical to making informed decisions about how best to protect public health in the current marketplace." Under that standard, the labelling of the products tested apparently fell short.

For example, one CBD product tested this year contained levels of lead warranting additional review. Testing from prior years identified two products with high levels of controlled substances (tetrahydrocannabinol (THC) and the synthetic cannabinoid MMB-FUBINACA), and the FDA referred these products to the U.S. Drug Enforcement Agency for further investigation. The agency concedes that the testing covered in the report is drawn from a limited sample and "cannot be used to draw definitive conclusions" regarding the CBD marketplace, but the industry can still learn from key findings in the 2020 report:

- Two products labeled as containing CBD contained no identifiable amount of the cannabinoid
- Eighteen products contained less than 80% of the CBD amount indicated on the labelling
- Thirty-eight products contained more than 120% of the CBD amount indicated
- Levels of THC varied up to 3.1 mg/serving

In its report, the agency indicates that it is developing a long-term sampling plan to be conducted by a third party that will include a broader sample size. The agency is also purchasing data on brands, product categories, and distribution channels for CBD products and developing its own "comprehensive list of brands operating in the CBD market space by assembling data from targeted internet searches and analytics." Unfortunately, the report does not offer specific timing for these efforts, i.e., a timeline that CBD companies have long sought in the quest for commonsense regulatory standards.

Takeaways

Courts across the country are seeing a significant increase in CBD-related litigation, particularly cases related to mislabeling. Numerous already-filed cases allege that the amount of CBD specified on product labels is inaccurate. To mitigate potential litigation risk, companies should ensure that claims made on product labeling,

including those related to CBD and THC content, are substantiated.

More generally, the report responds to a congressional directive meant to push the FDA towards establishing regulations for CBD. This suggests legislative recognition that the market is outpacing FDA efforts to regulate the industry. Importantly, Congress has not pushed for an outright ban of CBD products. Instead, this reporting requirement seems to signal legislative appreciation for CBD products, and is intended to help prompt the FDA into providing guardrails for responsible growth of the industry.

The CBD marketplaces continues to develop. This growth is occurring amid regulatory uncertainty, with states largely leading the way and developing a patchwork of complex regulatory requirements. The FDA's recent report may be a step forward in developing federal standards for CBD products.

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