Food and Drug Law Alert

Akin Gump
STRAUSS HAUER & FELD LLP

FDA Submits Report on CBD Sampling Study to Congress

July 9, 2020

Yesterday, the Food and Drug Administration (FDA) submitted a report to Congress detailing the agency's progress on a sampling study of the current cannabidiol (CBD) marketplace and its efforts to determine the extent to which products are mislabeled or adulterated. The joint explanatory statement accompanying the Further Consolidated Appropriations Act, 2020 directed the agency to conduct a sampling study and submit this report.

The report describes CBD product testing FDA conducted both before and after the passage of the 2018 Farm Bill, which removed hemp and its compounds from the federal controlled substances list. The document also outlines the preliminary results of ongoing testing. FDA's testing has revealed widespread discrepancies between labeled and actual CBD content. Furthermore, FDA has found that many CBD products also contain delta-9 tetrahydrocannabinol (THC).

In its ongoing testing, which was paused due to the COVID-19 pandemic, the agency selected 200 hemp products sold online across various product categories, including tinctures, gummies and beverages. Of the products tested thus far that indicated a specific amount of CBD, almost 55 percent contained a CBD level that differed from the labeling by more than 20 percent. Just under half of the products tested contained THC or a related compound. Hemp products must contain no more than 0.3 percent THC to avoid potentially facing scrutiny for containing marijuana, which remains an illegal substance under federal law.

FDA plans to begin a larger sampling study of products sold online and in stores before the end of this year. This long-term study will assess a broader range of products, including conventional food products, leave-on cosmetics, such as lotion, and vape cartridges. FDA explains that it will sample products across brands, product categories and distribution channels, while prioritizing products with a higher market share. The report states that FDA will provide the results from both its ongoing study and its planned, long-term study when complete data sets are available.

FDA's report explains that the agency "believes that understanding the characteristics of marketed CBD products is critical to making informed decisions about how to best protect public health in the current marketplace." FDA's plans for another, more

Contact Information

If you have any questions about this alert, please contact:

G. Hunter Bates
Partner
hbates@akingump.com
Washington, D.C.
+1 202.887.4147

Arshi Siddiqui
Partner
asiddiqui@akingump.com
Washington, D.C.
+1 202.887.4075

Josh Teitelbaum
Senior Counsel
jteitelbaum@akingump.com
Washington, D.C.
+1 202.887.4081

Mallory A. Jones
Associate
jonesm@akingump.com
Washington, D.C.
+1 202.887.4259

Taylor M. Daley
Public Policy Specialist
tdaley@akingump.com
Washington, D.C.
+1 202.416.5541

comprehensive sampling study suggest that the agency needs further information before issuing proposed regulations regarding CBD products. FDA has repeatedly indicated that it needs additional scientific data to develop sound policy regarding safe levels of CBD.

The release of FDA's report on CBD product testing comes days after the House Appropriations Committee released a draft report that would designate $5 million of FDA funding for CBD enforcement and the development of a "regulatory pathway for cannabis and cannabis derived products." The Committee is still considering the accompanying draft FDA appropriations bill.

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