Food and Drug Law Alert

FDA Submits Progress Report on Policy Development Related to CBD Products

March 6, 2020

Yesterday, the Food and Drug Administration (FDA) submitted a report to Congress providing an update on FDA action to develop an enforcement discretion policy and evaluate potential regulatory pathways for consumer products containing hempderived cannabidiol (CBD). The joint explanatory statement accompanying the Further Consolidated Appropriations Act, 2020, which enacted FDA's appropriations, directed FDA to submit this report.

In the report, FDA indicates that it is considering the issuance of a risk-based enforcement discretion policy that would include the factors FDA takes into account in prioritizing enforcement action against companies marketing CBD products. Additionally, the agency explains that it is evaluating potential lawful pathways by which CBD products could enter the market "on the fastest possible timeframe."

FDA's report reiterates the agency's concerns regarding the safety of CBD in foods and dietary supplements, particularly for vulnerable populations such as children and the elderly. The report emphasizes that FDA is continuing to gather scientific data regarding the effects of CBD and that more research is needed to determine safe conditions of use. Nevertheless, FDA signals that it is exploring potential rulemaking to allow CBD in dietary supplements. Notably, the agency does not make similar statements regarding food products.

In the report, FDA explains that it is reopening the public docket associated with its May 2019 public meeting on products containing cannabis or cannabis compounds to provide a clear way for stakeholders to submit new information to the agency. In particular, FDA notes that it is actively seeking information regarding "full spectrum" and "broad spectrum" hemp extracts to help the agency understand how those products differ from products containing CBD isolate. Many in the industry have been pressing FDA to differentiate between CBD isolate and other hemp-derived products that contain CBD. FDA will likely receive input arguing that the safety issues are different for various forms of hemp-based products.

FDA Commissioner Stephen Hahn issued a statement endorsing the report. Dr. Hahn has, in the past, signaled his support for clarifying CBD's legal status. For example, in

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lagnello@akingump.com Washington, D.C. +1 202.887.4212 February, he remarked, "People are using these products. We're not going to be able to say you can't use these products. It's a fools game to try to even approach that."

The legal and policy status of CBD has been evolving since the 2018 Farm Bill removed hemp and its compounds, including hemp-derived CBD, from the list of controlled substances. Some stakeholders have pressed for more rapid policymaking from FDA, as have some members of Congress. We expect that stakeholders will continue to press both FDA and Congress to move quickly to establish a clear regulatory framework for CBD products.

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