Michael Best

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FDA Issues Overdue CBD Enforcement Update to Congress

The Food and Drug Administration (FDA) issued its first report to Congress on March 5, 2020 on the status of rulemaking for cannabidiol (CBD). The report provides some relief to the hemp industry that FDA is still considering options to allow hemp and CBD to be marketed as dietary supplements, but provides no timeline for when the industry can anticipate such a change.

After the 2018 Farm Bill, federally legalized hemp and its derivatives, Congress mandated FDA under separate appropriations legislation passed late last year to provide an update on its regulatory approach to CBD within 60 days. That deadline came and went, but, on March 5, FDA released the report and a public update regarding its progress in evaluating lawful pathways for the marketing of CBD products and considering a risk-based enforcement policy.

We have already written about FDA's enforcement policy around hemp products, and the March 5 report continues the risk-based enforcement we have observed. FDA's main concern continues to be companies marketing CBD products using drug and health claims that could "deter consumers from seeing proven, safe medical therapies for serious illnesses – potentially endangering their health or life." FDA is also concerned about potential contamination risk and consumer exposure to things like residual solvents and heavy metals, and false claims in labelling.

In its report the Agency also confirmed that it will continued to closely monitor the market and take enforcement action against unapproved CBD products that lack safety, and that are labeled with claims that are false and misleading. For companies selling in the U.S. today, extra attention should be given to ensuring that their products are supported by high-quality data and properly labeled Products that are not may find themselves the subject of Agency enforcement action.

FDA will be reopening a public docket for "Products Containing Cannabis or Cannabis-Derived Compounds," to

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solicit additional scientific information about the risk and benefits of the cannabis compound.

To fill in current knowledge gaps, FDA has specifically requested the submission of high-quality data discussing the sedative effects of CBD; the impacts of long-term sustained or cumulative exposure to CBD; transdermal penetration and pharmacokinetics of CBD; the effect of different routes of CBD administration (e.g., oral, topical, inhaled) on its safety profile; the safety of CBD for use in pets and food-producing animals; and the processes by which “full spectrum” and “broad spectrum” hemp extracts are derived, what the content of such extracts is, and how these products may compare to CBD isolate products.

The rulemaking process will ultimately lead to FDA’s establishment of regulations governing how these products may be marketed and sold in the U.S. Therefore, it is important for companies with a vested interest in the CBD sector to get involved now to influence how these products will be regulated in the future. For this reasons, companies should strongly consider the submission of comments and high-quality data to FDA relevant to their own CBD-products and their intended uses to ensure favorable regulatory treatment.

Michael Best attorneys can assist you and your company with the drafting and filing of public comments and will continue to provide updates as FDA’s rulemaking continues.

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