After the FDA's Public Hearing on CBD, Industry Efforts Turn Towards Congress

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The Food and Drug Administration's ("FDA" or "agency") public hearing at the end of May presented the cannabis industry with an opportunity to encourage the agency to take a serious look at cannabis-derived products, particularly those that contain cannabidiol ("CBD"). While industry may not have fully agreed on how FDA should regulate CBD products, almost everyone asked FDA to take action and implement a regulatory framework for the legal marketing of these products (i.e., as foods, dietary supplements, or other consumer products).

While it is still unknown what FDA will do in response to the issues raised at the public hearing, the cannabis industry has turned to Congress to pass legislation that would provide the funding that FDA needs to regulate CBD. Last week, the Natural Products Association ("NPA") announced that its work with Congress had resulted in the filing of an amendment to the House Agriculture appropriations bill "to include critical funds that would enable FDA to undertake the appropriate processes and set a safe level of CBD for consumers to use each day." The amendment was filed by Representative Jerry McNerney of California's 9th Congressional district and was passed by the House of Representatives on June 20, 2019. In a news release from NPA, Dr. Daniel Fabricant, President and CEO of the NPA, stated: "We are proud to work with Congressman McNerney to pass this critical amendment that will provide consumers with the clarity and assurance that CBD products are safe . . . . We look forward to working with members of both the House and the Senate to ensure to pass this important legislation for American Consumers."

On the same day, FDA issued a Federal Register Notice extending the comment period for the submission of written comments following the public hearing, until July 16, 2019. The docket was initially set to close on July 2, 2019. At the hearing, FDA was asked for a 30-day extension of the comment period; however, the agency noted that "another 14-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential further action on these important issues."

FDA also recently issued two new communications addressing its current views on CBD and products containing cannabis or cannabis-derived compounds, including CBD, and re-emphasizing its commitment to a "sound, science-based policy on CBD." While FDA did not share any new information about its position on CBD, in "FDA Voices – FDA is Committed to Sound, Science-based Policy on CBD," a FDA online publication written by FDA leadership and experts, Amy Abernethy, M.D., Ph.D., Principal Deputy Commissioner, and Lowell Schiller, J.D., Principal Associate Commissioner for Policy, did highlight some of the "unanswered questions about CBD outside the approved drug context" that warrant further consideration if there is interest in exploring a regulatory framework for CBD:

- How much CBD is safe to consume in a day? How does it vary depending on what form it's taken?
- Are there drug interactions that need to be monitored?
- What are the impacts to special populations, like children, the elderly, and pregnant or lactating women?
- What are the risks of long term exposure?

The second communication, a consumer update entitled, What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD, provides an overview of the current regulatory status of CBD products, while reminding the public that "it is currently illegal" to "add CBD to a food or to label CBD as a dietary supplement." However, FDA is aware that there are a number of products currently marketed as a food or dietary supplement that contain CBD. As such, FDA noted that it is currently evaluating a regulatory framework that would apply to products containing cannabis and cannabis-derived compounds that are intended for non-drug uses, including "whether and/or how [it] might consider updating its regulations, as well as whether potential legislation might be appropriate." FDA also noted that the "information [it has] underscores the need for further study and high quality, scientific information about the safety and potential uses of CBD."

It is the agency's hope that industry stakeholders will provide any data that they have to the public docket by July 16, 2019.

For more information about FDA's regulation of cannabis and cannabis related products, click here.