The cannabis world is abuzz with news about the latest federal Food & Drug Administration (FDA) report regarding cannabidiol (CBD). We break down what it is, and what it means for the industry and the regulatory landscape for CBD looking forward.

On March 5, 2020, the FDA released a report updating the public on its progress in establishing a regulatory framework for CBD that meets the definition of hemp. The report was prepared in response to a directive set forth in a statement accompanying the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), which, in providing the FDA with funds to evaluate the path forward for CBD regulation, requested a report on the FDA’s progress in this regard within 60 days of enactment. While industry participants may be disappointed in the report’s failure to offer a clear path forward for the legal marketing of CBD products, the report, nonetheless, is an important guidance document for industry because it provides meaningful insight into the agency’s plans to establish a regulatory framework and the enforcement path ahead.

The 18-page report provides an update on what the FDA has learned to date about CBD in a variety of categories. Specifically, the report provides an update on the agency’s views on CBD in: (i) human drugs; (ii) animal drugs; (iii) dietary supplements; (iv) foods for humans, pets and other animals; (v) cosmetics; (vi) vape products; and (vii) products outside FDA’s jurisdiction. The report then addresses FDA’s thoughts on enforcement in view of what it has learned and next steps for the FDA.

While at its outset the report notes that it will not repeat the FDA’s past guidance on CBD, it does significantly restate the FDA’s prior-stated views on various categories of CBD products from animal and human drugs to dietary supplements. This background is helpful context to the FDA’s discussion of the open questions regarding the safety of CBD and its plans for further evaluation of CBD and CBD products. The structure of the report also signals that the FDA’s approach to CBD will likely vary based on the type of product in which it is contained and method of delivery, as the FDA has suggested in prior guidance.

One consistent theme throughout the report is that there are still numerous unanswered questions about CBD and its impact on human and animal health.
While this proposition is not new, the report provides a greater level of precision as to what these unanswered questions are than the agency has provided in the past. Specifically, the report notes that while clinical data demonstrate that CBD is associated with potential risks, including liver injury, drowsiness, and the potential for drug interactions, the agency is still working to further understand the safety profile of CBD, especially for sustained and/or cumulative exposure, co-administration with other medicines and herbal supplements, the impact on the developing brain, and on vulnerable populations like children, pregnant and lactating women, the elderly, and unborn children.

While repeating and expounding on its views regarding these open questions, the report does address several important new issues.

First, and most importantly, the report provides a preview of the FDA’s thinking about using the dietary supplement route as a regulatory pathway for CBD. Specifically, the report notes that the FDA is proactively examining the possibility of permitting CBD use as a dietary supplement while setting forth the obstacles to doing so, including the agency’s lack of authority to require dietary supplement manufacturers to report the products they are making to the agency. The report further notes that regulatory changes to require such reporting would create significant workload and prioritization issues for the agency. The report references the FDA’s authority under Section 201(ff)(3)(B) of the FD&C Act to create an exemption through notice and comment rulemaking. If such a rulemaking process were to proceed, the FDA will seek to establish a factual basis to support a rule where the underlying rationale and factual assertions can be deemed reasonable.

Second, the report addresses with specificity an important public health topic. While the FDA has issued past guidance on vaping generally, the report specifically addressed the vaping of CBD. The report acknowledges that there may be certain dangers associated with vaping CBD, specifically that these products may be dangerously attractive to children and adolescents, and that vape products meeting the definition of tobacco products will be regulated by FDA as such – meaning, among other things, that they cannot be marketed without FDA pre-market authorization.

Finally, the report set forth the agency’s forward-looking agenda as it moves toward creating a regulatory pathway for CBD. We can expect to see movement
in several areas in 2020:

**Issuance of Risk-Based Enforcement Policy.** The report indicates that the FDA is still some time away from putting forth rulemaking for a CBD regulatory framework. Accordingly, the immediate next step, based on the report, is most likely the FDA’s issuance of a risk-based enforcement policy. Such a policy would provide some clarity in the existing regulatory framework by setting forth factors the FDA would consider in enforcing the current prohibition on CBD in food and drink. For example, such a policy might clearly state that the FDA would actively enforce the existing prohibition against any company who claims its products can treat any medical condition. This policy will likely serve as an ad hoc regulatory mechanism while more permanent and robust legislation is being drafted. The report may also be signaling increased enforcement efforts by the FDA against what it deems to be illegally marketed CBD products.

**Additional Information Gathering and Research.** The report addresses several avenues for additional research and information-gathering, while suggesting that universe of clinical knowledge regarding CBD is in its infancy. In fact, the report pointedly acknowledges that it was difficult to study CBD before the passage of the 2018 Farm Bill because cannabis-derived CBD was considered a Schedule I controlled substance. Accordingly, the report laments the limited systematic data available and repeatedly notes that further clinical study will aid the agency in understanding the potential therapeutic benefits of CBD—it even identifies efforts to encourage such research. Not only has the FDA issued grants for additional research to answer some of the vital open questions about CBD’s health effects, Congress has directed the FDA to perform a sampling study of the current CBD marketplace to determine the extent to which products are mislabeled or adulterated, and to provide a report on this sampling study in 180 days. The FDA is also reopening its docket, established after last May’s hearing, indefinitely to continue to collect data and information in this vein. We can expect some interim reports from the FDA as they collect, review and synthesize the submitted information and the findings of ongoing research studies. These reports will help the public understand the factors driving regulatory policy and provide additional clarity to CBD manufacturers.

**Full v. Broad Spectrum CBD.** In the report, the FDA expressed its interest in the processes by which “full spectrum” and “broad spectrum” hemp extracts are derived, their content, and the manner in which they differ from CBD isolate, inviting stakeholders to submit further information on these issues. This development is not entirely surprising given the FDA’s expressed interest in these issues at last year’s hearing. But the request suggests that the
The report notes its collaboration with other federal agencies, such as the Department of Health and Human Services, and other authorities in evaluating viable regulatory pathways. This nod to collaboration suggests that the states and countries with more developed regulatory frameworks (e.g. Canada, Oregon, Colorado, California) are likely to inform the FDA’s approach to regulating CBD.

In short, the report provides a meaningful and robust overview of the FDA’s efforts to date and gives the public some information about when and in what form we can expect additional FDA guidance. Of course, the report stops short of providing what industry continues to long for—a clear and consistent nationwide regulatory framework—but it does telegraph to industry participants where further information is needed to guide FDA’s efforts. The report, which is entirely consistent with FDA’s prior statements on CBD, suggests that despite mounting pressure from industry, as a science-based, public health agency, the FDA will not promulgate any meaningful regulatory framework without gathering and analyzing additional robust data on CBD, its interactions with other drugs, and the impacts of its long term use. So, although we anticipate the FDA will issue some sort of risk-based enforcement policy in 2020, those waiting for a comprehensive CBD regulatory framework should get comfortable with the continued uncertainty—it may be a while yet.

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