Updates
March 06, 2020
FDA Releases Report to Congress Regarding CBD

The federal Food and Drug Administration (FDA) just released a report to Congress regarding the agency's progress toward comprehensive regulation of hemp-derived cannabidiol (CBD). The report echoes the hard-line approach to CBD safety that the agency took on November 25, 2019, when it announced that CBD is not "generally recognized as safe" (GRAS) among qualified experts for use in human or animal food," but, importantly for CBD businesses, also confirms agency interest in developing a risk-based enforcement approach in order to keep up with the burgeoning market for CBD products.

When Congress passed the Consolidated Appropriations Act of 2020 (H.R. 1158), it directed $2 million to the FDA for "research, policy evaluation, market surveillance, and issuance of an enforcement discretion policy and appropriate regulatory activity" for hemp-derived CBD. This appropriation further required the FDA to produce a report on its progress toward obtaining and analyzing data to help determine (1) a policy of enforcement discretion and (2) a process in which hemp-derived CBD will be evaluated for use in products. The report was due 60 days after the bill's enactment, but the FDA belatedly issued it this week.

The report confirms the FDA's already-expressed skepticism as to CBD safety, but offers hope that the agency seeks to take expeditious, clarifying regulatory action given market growth and uncertainty. The report reiterates that until the FDA obtains more data resolving its concerns about CBD contaminants, mislabeling, and lack of scientific research regarding side effects or adverse health effects, it cannot consider CBD safe as a food additive (a position the agency has already made clear). But the report also emphasizes the FDA's willingness to develop a "risk-based enforcement policy that would provide greater transparency…while FDA potentially engages in…a rulemaking." Promisingly, the agency recognizes not only the "vast proliferation of CBD consumer products," but also the "significant interest in the development of therapies and other consumer products derived from cannabis and its components, including CBD," and "the potential opportunities that CBD may offer," all of which outstrip "limited FDA [enforcement] resources."

What CBD Businesses Need to Know

The report covers several issues, albeit at a high level. The list below summarizes the primary points of interest from a CBD business perspective. Of particular note, the FDA expressed desire for product-specific information, consistent with the agency's interest, expressed in the report, for a more nuanced, discretionary approach to enforcement. Along those lines, the FDA stated that it is trying to develop ways for companies to share proprietary and trade secrets, in the interests of providing data that the FDA can use in evaluating CBD enforcement.

The report summarizes the FDA's current positions as to the following categories:

- **Enforcement.** The FDA stated that it is obtaining CBD safety data and "evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding FDA's enforcement priorities while FDA potentially engages in the process of a rulemaking."
- **Safety.** According to the FDA, available clinical data suggests links between CBD and various potential health risks, including liver injury, drowsiness, and potentially negative drug interactions. The agency

emphasizes that there is insufficient data on dosage, exposure methods, daily use, and drug interactions, among other areas—all issues raised at the agency's May 2019 hearings on CBD.
- **Human and Animal Food.** The FDA repeats its already-stated position that CBD is not generally regarded as safe (GRAS) for use as a food additive, and requests more data on this topic from interested parties.
- **Human and Animal Drugs.** The FDA states that there are clear regulatory pathways for CBD drug development and review of new drug or new animal drug applications, given past approval of anti-seizure drug Epidiolex.
- **Dietary Supplements.** The FDA proposes taking a fairly conservative approach: using notice-and-comment rulemaking to create an exemption under current law for certain CBD products to be marketed as dietary supplements. The agency is evaluating what data is sufficient to support a conclusion that CBD can safely be allowed in dietary supplements.
- **Cosmetics.** The FDA notes that while cosmetic ingredients do not generally require pre-market approval, cosmetics marketers are responsible for ensuring the safety of their products, and warns that there is limited data on CBD's safety as a topical.

In all, the report offers little new insight to CBD industry watchers, but it does offer some hope that the FDA will move quickly on a risk-based enforcement policy that will clarify agency expectations and ways manufacturers and marketers can mitigate the risk of commercializing CBD products. Unfortunately, the report is insufficiently detailed to inform short-term strategies for avoiding FDA warning letters or more serious enforcement action. Otherwise, however, the report does not offer meaningful new insights or clues about the agency's timeline or anticipated policy changes. Additionally, the report's reference to notice and comment rulemaking is frustrating because this process—which the FDA has not even initiated here—typically takes approximately two years to complete.

Until the FDA issues new guidance or rules, manufacturers, distributors, and retailers should approach CBD responsibly. Marketing and labeling should be scrupulously accurate, and we continue to recommend strongly against making extreme or unsupported health claims (the FDA's history of warning letters provides a useful practical delineation of what is unacceptable).

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