FDA Report: CBD Is Not a Risk-Free Substance, But Risk-Based Enforcement Continues

March 6, 2020 Suzie Trigg, Kayla Cristales

PRACTICES FDA Regulatory and Compliance, Food, Beverage and Restaurant, Retail

This week, FDA issued its much-anticipated report outlining the agency's progress in gathering and analyzing data to help with its development of a policy of enforcement discretion and a regulatory process under which (hemp-derived) CBD will be evaluated for use in FDA-regulated products (the "Report"). The Report reiterates FDA's unresolved questions about the safety of CBD and its increasingly unpopular position that ingestible CBD products are currently prohibited. FDA also signaled its intention to continue exercising a risk-based enforcement policy that prioritizes CBD products that make serious medical claims (*e.g.*, that the product can treat Alzheimer's, cancer, opioid use disorder) or that contain contaminants, such as THC, pesticides, and heavy metals. Overall, the Report confirms much of what the agency has previously communicated regarding its position on the legality of the various categories of FDA-regulated CBD products and provides additional clarity on its intentions with regard to enforcement in the future.

In the Report, FDA clarified its position with respect to the different types of regulated products that may contain CBD. With respect to enforcement, the agency's focus remains fixed on protecting the public, as it intends to continue pursuing more knowledge about the safety of CBD while taking enforcement action against those products which are most likely to endanger public health.[1]

Thus far, "FDA has been actively monitoring the CBD market for violative products that pose the greatest risk to consumers."[2] Such products include:

- unapproved new drug products that make claims that they can treat serious diseases or conditions (*e.g.*, Alzheimer's, cancer, opioid use disorder);
- products that are contaminated with heavy metals, high levels of THC, or other harmful substances;
- products marketed with false claims or statements (*e.g.*, omitted ingredients or incorrect statements about the amount of CBD in the product);
- products marketed for use by vulnerable populations (*e.g.*, children or infants); and
- products that otherwise put the public health at risk.

The Report also highlighted the following key takeaways regarding the legal status of specific types of FDA-regulated products under the federal Food, Drug, & Cosmetic Act:

Dietary Supplements:

Under current law, "CBD products cannot lawfully be sold as dietary supplements." However, FDA "has the authority to remove this exclusion through rulemaking"[3] and is "actively considering potential pathways for certain CBD products to be marketed as dietary supplements."[4] FDA is aware of the significant public interest in the potential for CBD dietary supplements, as well as the vast extent to which such products are already available on the market. Accordingly, the agency is taking a proactive approach to "identify and review all available data to understand the risk profile of

CBD and the potential for CBD to be safely included in dietary supplements, under certain conditions of use."[5]

However, FDA also notes that "there are certain challenges in overseeing CBD in the dietary-supplement marketplace." For example, unlike other products regulated by the agency, FDA "lack[s] clear authority to require individual participants in the dietary supplement industry to tell FDA what products they are making and selling to consumers." Thus, while expanding the agency's dietary supplement program to include new CBD products would address consumer demand for such products, it would also have implications for the agency's ability to prioritize workload, exercise oversight, and identify and address violative products that put the public at risk. Accordingly, FDA clarified that any action it takes will "need to ensure that consumers have an accurate awareness of the degree to which FDA is (and is not) able to provide regulatory oversight, so that they are able to make well-informed decisions."[6] FDA intends to continue working to investigate and establish a clear process by which it can gain additional knowledge regarding CBD in dietary supplements and potential paths toward allowing such products on the market.

Food:

It is not currently lawful to add CBD to human or animal food, and FDA has clarified that available data "raise[s] safety concerns about the use of CBD in food."[7] The agency reiterated in the Report that "[t]here are established pathways for introducing new substances into the . . . food supply, which apply to hemp-derived substances in the same way as they do to any other substances."[8] Accordingly, FDA does not currently permit the addition of hemp-derived CBD to human or animal food, and only authorizes the lawful addition of "certain hemp-derived ingredients containing only de minimus [sic] amounts of CBD (i.e., dehulled hemp seeds, hemp seed protein, and hemp seed oil)"[9] to human food. Although FDA encourages interested parties to continue to share information regarding conditions under which CBD could safely be added to food, its broad prohibition on the use of CBD in human and animal foods remains in place, and such products cannot be lawfully sold in interstate commerce.

Cosmetics:

Though FDA stopped short of alleging that topical, cosmetic products with hemp-derived CBD are unlawful, the agency noted that data regarding the use of CBD in cosmetic products is lacking, and FDA is currently seeking to fill data gaps to broaden its understanding of topical uses for CBD. Although "cosmetic ingredients do not generally require premarket approval," FDA clarified in the report that "[n]o ingredient — including CBD — can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way."[10]Accordingly, cosmetics containing CBD are still generally permitted by the agency if they are not adulterated or misbranded, but FDA is working to gather data regarding the use of CBD in topical applications. As the agency explained, "[s]ome animal studies, not necessarily done for cosmetic products, have provided information on the skin permeability of CBD cream or gel. However, clinical evidence of safety with respect to the dermal penetration and sensitization of topically applied CBD products is lacking."[11] This is an area where the agency is seeking to generate more data, and it initiated a research study "in partnership with the University of Mississippi to evaluate CBD and THC levels in a sample of cosmetic products (about 100 products, including some positive controls), to asses[s] sensitization of THC and CBD topically, and dermal penetration."[12]

OTC Drugs:

FDA clarified that although potential new therapeutic uses for CBD may be discovered through further clinical study, "[t]here are currently no approved OTC drugs containing CBD or any OTC drug monographs that include CBD as an active ingredient." "Generally speaking, a drug must be approved by FDA as safe and effective for its intended use or meet the requirements of an OTC drug monograph before it may be introduced into interstate commerce."[13] Thus, CBD is still not permitted in OTC medications, and only one prescription drug containing CBD - Epidiolex - has been approved by FDA.

Vaping Products:

FDA is still very concerned about the safety of CBD in vaping products and whether "CBD vapes pose public health risks in that vaping CBD raises toxicity concerns — both inherent to the substance and due to potential contaminants—and could attract children and adolescents, which are vulnerable populations." Accordingly, FDA acknowledges that "[m]ore safety data and research are needed on this route of administration and potential implications for local and systemic effects."[14]

"Full Spectrum" and "Broad Spectrum" Hemp Extracts:

The agency acknowledged that many products marketed as containing "full spectrum" or "broad spectrum" hemp extracts "can vary widely in their characteristics, but [FDA's] understanding is that such terms generally are intended to convey that the product is not a CBD isolate, and that the products contain other substances extracted from the [hemp] plant." However, FDA also noted that "many products currently marketed as 'full spectrum' or 'broad spectrum' hemp extracts may contain very high concentrations of CBD, and may be derived from varieties of the hemp plant that have been selected specifically for their high CBD content."[15] Because the regulatory status of such products is unclear, FDA is currently seeking more information regarding the process for producing "full spectrum" and "broad spectrum" hemp extracts and how such products may compare to CBD isolates, in order to inform its evaluation of the regulatory status of these types of products.

Although the Report largely reiterated policies that have been consistently maintained by FDA for more than a year (i.e., since the enactment of the 2018 Farm Bill in December 2018), it dispels many of the rumors that have been running rampant among consumers and industry and provides greater certainty as to FDA's enforcement policies and the regulatory status of CBD products going forward. Manufacturers, retailers, and other businesses seeking to produce or sell CBD products should review the Report in full to maintain compliance and minimize the risk of enforcement action.

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[1] *See* FDA Report in Response to Further Consolidated Appropriations Act, 2020, dated March 5, 2020, at 13.
[2] *Id*. at 12.
[3] *Id*. at 9.
[4] *Id*. at 2.
[5] *Id*. at 10.
[6] *Id*.
[7] *Id*. at 11.

[8] *Id*. at 3.
[9] *Id*. at 11.
[10] *Id*.
[11] *Id*.
[12] *Id*. at 14.
[13] *Id*. at 7.
[14] *Id*. at 12.
[15] *Id*. at 14.