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Consumer Products, Retail & Franchise Industry Group
July 24, 2019

FDA Warning Letter Confirms Ban on Drug Claims for CBD Containing Products

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The CBD industry has been looking for a resolution to the uncertainty surrounding the legal and regulatory status of CBD containing products. Yesterday (July 23, 2019), the Food and Drug Administration ("FDA" or "the agency") gave a partial answer.

In its first action since the May 31 public meeting, the agency sent a warning letter to a public company, Curaleaf Inc. FDA informed the company that some of its products are unapproved new drugs and misbranded. FDA targeted four items sold by Curaleaf: CBD Lotion, CBD Pain-Relief Patch, CBD Tincture and CBD Disposable Vape Pen. According to the Warning Letter, these products are unapproved new drugs, and also are misbranded. In addition, the agency cited Curaleaf's Bido CBD for Pets products as unapproved and unsafe new animal drugs.

The agency informed the company that materials on the company's website and in social media outlets indicate that Curaleaf plans to market the products as dietary supplements, despite the fact that the items do not fall under the definition of a dietary supplement. FDA demanded corrective action within 15 days, and indicated that the consequences of failure to respond may result in enforcement action.

While this is a critical development, in that Curaleaf is so far the largest CBD producer to receive a Warning Letter, the letter sent to Curaleaf is circumscribed. It indicates that FDA has decided it will take action against companies making what it considers drug claims. This is not a new stance for FDA, but rather a reinforcement of what FDA representatives articulated in the May 31 public meeting. From our perspective, this is a clear indication that companies making what FDA considers drug claims are in jeopardy of similar Warning Letters. FDA is actively monitoring the web and social media in search of violators, and we should expect more such correspondence.

The patchwork of federal and state regulations has muddied the waters for the industry, its consumers, regulators and some in Congress. There are already several bills in the two houses of Congress addressing the legal status of cannabis, and many states have already legalized CBD. It is important to note the distinction between the sources of CBD. Hemp contains CBD and 0.3% or less THC, whereas marijuana contains CBD and from 5 to 20% THC. Hemp (and thus hemp-derived CBD) was legalized under the 2018 Farm Bill. Marijuana (and thus marijuana-derived CBD) continues to be an illegal, Schedule I drug under federal law.

The dichotomy between the approaches to CBD and marijuana by the states on the one hand, and FDA and DEA on the other could not be greater. It is this reality that is spurring congressional action. Complicating matters further are the strong signals from the Department of Justice that it is bowing out of the debate and wants Congress to take action to address both CBD and THC.

In the meantime, our advice to those in the industry is to refrain from making any drug claims for their products. These include any claims that suggest that CBD can be helpful in managing diseases such as cancer, epilepsy and Parkinson's disease, among others.

It remains unclear where the agency is heading in the wake of this letter, but it is certain that any drug claim for CBD will garner attention going forward. More broadly however, the comments made by the FDA at its May 31 public hearing suggest that it is as anxious as all of the other stakeholders for a Congressional response.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors.

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