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There's a New Sheriff in Town: The Food and Drug Administration's Move to Regulate CBD

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Hemp has wide commercial application and appeal with a viable market for nearly every part of the plant, from the seeds, to the roots, to the flower.

And with the passage of the Agriculture Improvement Act of 2018 (the "AIA"), the American hemp industry is poised for exponential growth. Cannabidiol or "CBD" represents one of the fastest growing – and, perhaps, the most controversial and commercially profitable – segments of the hemp industry today.

There is no shortage of claims about CBD's helpful properties, with commonplace industry acceptance that the cannabinoid can be used to, among other things, alleviate inflammation and anxiety. CBD has been, and it continues to be, incorporated into a wide variety of consumer products, including lozenges, honey, and even an FDA-approved prescription medicine. But, as the legal and regulatory landscape surrounding hemp and CBD continues to develop, there remains uncertainty – at least for now – about the legality of using hemp-derived CBD to produce food, cosmetic, and dietary supplement products.

For nearly 50 years, the Drug Enforcement Agency ("DEA") was primarily responsible for law enforcement efforts relating to hemp and its derivatives, including CBD. The

DEA's enforcement authority was derived from hemp's classification as "marihuana" and CBD's classification as a Schedule I substance under the Controlled Substances Act of 1972 ("CSA"). That changed on December 20, 2018, when President Trump signed the AIA into law. Among other things, the AIA broadened the definition of "hemp" on the Federal level, and it stripped both hemp and hemp-derived CBD from the CSA itself. As a result, the DEA is no longer the primary enforcement agency with respect to hemp and hemp-derived CBD.

On the same day that President Trump signed the AIA into law, the Food and Drug Administration ("FDA") released a press release on the matter. The FDA statement is not binding or controlling, but it does forecast the FDA's clear intention to take an active role in regulation and enforcement for hemp and CBD products going forward.

By issuing that press release, the FDA has publicly stated that:

- It will continue to enforce the law (including the Federal Food, Drug, and Cosmetic Act, or "FD&C Act") in an effort to protect patients, the public, and to promote the agency's overall public health role.
- Products containing cannabis or cannabis-derived compounds (like CBD) will be subject to the same authorities and requirements as other non-cannabis FDA regulated products.
- Hemp or hemp-derived CBD products that are **"marketed with a claim of therapeutic benefit, or with any other disease claim"** must be approved by the FDA before being introduced to interstate commerce.
- Hemp or hemp-derived CBD products **marketed "for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases"** are considered drugs and must be approved by the FDA before they are marketed for sale in the U.S.
- It is "**unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.**"

The FDA has the authority to introduce regulation that would allow the use of CBD in foods and dietary supplements, but that has not happened yet, and it remains to be seen whether (or when) that will happen.

For now, questions remain. Will CBD ultimately be regulated entirely as a drug? Will it be treated as an additive not subject to FDA approval? Or perhaps the specific application of CBD to a product will drive how it is treated? We do not yet know the answers to these questions. But we do know, for now, that the FDA sits in the regulatory driver's seat for the CBD industry moving forward.

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