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Stigler and DiGiamcomo Co-Author Regulatory uncertainty continues in the expanding cannabinoid market

Natural Products Insider

While the market for products containing cannabis or cannabis-derived compounds continues to expand, producers seek a clear regulatory path forward from FDA.

As the market for industrial hemp products rapidly expands, companies continue to seek regulatory clarification and guidance regarding the treatment of cannabis and cannabis-derived compounds—including cannabidiol (CBD)—that have been incorporated into dietary supplements, topical products and foods. Since the passage of the Agriculture Improvement Act of 2018 (the 2018 Farm Bill), the market for CBD and other cannabinoids has seen exponential growth and consumer demand for hemp-derived products has formed a new and exciting market for hemp producers.

Unfortunately, regulatory guidance for products containing cannabis or cannabis-derived compounds has not been keeping pace with the rapidly expanding market, leaving producers wanting for guidelines. With the recent release of the U.S. Domestic Hemp Production Program by USDA, companies and hemp producers seemed to get a bit of relief. Specifically, USDA's interim final rule has been helpful in providing guidance regarding hemp production, manufacturing, testing and transportation, but the outpouring of comments on these rules caused USDA to extend the notice and comment period through Jan. 29, 2020. Finalizing these rules will be an important step toward establishing regulatory guidance regarding industrial hemp.

USDA's interim final rule noted, however, "the 2018 Farm Bill explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) ..."

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Based on this statement, it is clear USDA will not provide guidance regarding the treatment of finished hemp products, including CBD and other cannabinoids, and the agency intends to leave those issues to FDA under FD&C. This explicit reference to FDA's authority to regulate hemp products under FD&C has left many wondering when the agency will provide more clear guidance for supplement, topical and food producers.

As of today, we do not know when FDA will reach a final decision regarding the rules for regulating hemp products containing CBD and other cannabinoids, but the agency has given some indications of what future regulation will entail.

The first indication came in 2019 when FDA sent 22 warning letters to companies producing and selling CBD products. The warnings targeted companies making disease claims about the hemp products they were selling. On Nov. 25, 2019, FDA issued its most recent round of warning letters to 15 more companies regarding statements they made about CBD. Included in these letters were violations such as marketing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to human and animal foods. "It is important to note that these products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease," FDA states on its website, in reference to the warning letters. These warning letters are highly indicative of the ways in which FDA plans to regulate the sale of hemp products containing CBD and other cannabinoids.

In addition to the warning letters, FDA recently provided a revised consumer update regarding what consumers need to know about products containing cannabis or cannabis compounds, including CBD. The update clearly states FDA has only approved the sale of one CBD product, for the treatment of severe forms of epilepsy. It also notes FDA has only limited data regarding CBD safety, and this limited data "point to real risks that need to be considered before taking CBD for any reason." These are all indications that treatment of hemp products under FD&C will be taken seriously.

In a press release issued on Nov. 25, 2019, FDA stated, "Based on the lack of scientific information supporting the safety of CBD in food, the FDA is also indicating today that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food." If FDA does not recognize a substance as GRAS, in accordance with sections 201(s) and 409 of FD&C, then FDA will require some level of premarket approval of the product before it can be authorized for sale. Further, FDA can take an enforcement action and stop the distribution of a food containing the product subject to premarket approval on the grounds that such foods contain an unlawful food additive.

Ultimately, this leaves a lot of uncertainty for manufacturers and producers who wish to incorporate CBD and other cannabinoids into dietary supplements, topical products and foods. For those looking for immediate answers, FDA has stated it intends to look for a clear scientific basis for its decisions related to these products. As the science related to production and extraction of CBD and other cannabinoids continues to develop, it is likely to lead to additional regulatory considerations. That means it will almost certainly be some time before FDA reaches any final decisions.

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