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FDA Issues Warnings to 15 Companies for Illegally Selling Products Containing CBD

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On November 25, 2019, the U.S. Food & Drug Administration ('FDA') published a press release, published a revised Consumer Update, and announced the issuance of new warning letters to 15 companies for illegally selling and marketing various products containing hemp-derived cannabidiol ('CBD').

To quote the FDA:

> *"Today's actions come as the FDA continues to explore potential pathways for various types of CBD products to be lawfully marketed. This includes ongoing work to obtain and evaluate information to address outstanding questions related to the safety of CBD products, while maintaining the agency's rigorous public health standards. The FDA plans to provide an update on its progress regarding the agency's approach to these products in the coming weeks."*

In the meantime, however, these steps appear to be an effort to stem the tide of proliferation of CBD products on the market – and the growing consumer demand for those products. It is great that the FDA intends to provide an update on its efforts to develop a regulatory pathway for CBD products under the Federal Food Drug & Cosmetic Act ("FD&C Act"). But, it is frustrating that the FDA still refuses to identify a set date for that update – or, to publicly commit to a meaningful resolution of the regulatory uncertainty that persists for CBD products today.

A Reminder: Don't Make Unsubstantiated Claims

As made clear in prior FDA warning letters – and the 15 letters released on November 25th – there continues to be significant regulatory risk in the labeling and marketing of CBD products for sale in interstate commerce. However, the FDA's enforcement efforts still appear to be focused on companies and products that engage in the most egregious violations of the FD&C Act – including those making disease claims and those marketed to (or for use by) children and other vulnerable populations.

Among other things, this round of warning letters address the following major issues:

- Marketing products for use by children and other vulnerable populations.
- Including a supplements facts panel on product labels, which indicated the company's intention to market the product as a dietary supplement.
- Marketing products that are intended for use in the cure, mitigation, treatment, or prevention of diseases and/or intended to affect the structure or any function of the body.
- Posting materials on the companies' social media websites that link to a third party's content indicating that CBD can be used in the cure, mitigation, treatment, or prevention of diseases and/or intended to affect the structure or any function of the body.
- Misbranding products intended to be marketed as drugs.
- Marketing human and animal food containing CBD in interstate commerce.
- Marketing unapproved new animal drugs by selling pet products containing CBD that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals and/or intended to affect the structure or any function of the body of animals.

Many of these issues have been referenced in prior actions and warning letters released by the FDA. By now, it should be clear to all market participants that it is illegal (and irresponsible) to market your CBD products as a cure for cancer, Alzheimer's, diabetes, or other medical diseases, ailments, or conditions. CBD companies should heed this clear warning and stop the practice. Just don't do it.

The New Concerns

This round of enforcement action seems to signal that the FDA is taking a more aggressive stance on its view of CBD health and safety issues. The press release and the consumer update both indicate that the FDA has broad safety concerns about CBD products, that there exist many unanswered questions and data gaps about CBD toxicity, and that some of the data available to the FDA raises serious concerns about potential harm from CBD.

The consumer update contains troubling statements like "*CBD has the potential to harm you, and harm can happen even before you become aware of it,*" and "*CBD can cause liver injury*." But, no direct evidence or substantiation for these claims is linked to the consumer update or press release. Instead, the consumer update attempts to draw a corollary line between the data obtained from trials performed in connection with one FDA-approved CBD drug and the non-pharmaceutical products available on the market today. Equating that data against the products available to consumers today does not produce an apples-to-apples comparison. There are likely different scientific outcomes from, and different levels of toxicity caused by, the delivery of high dosages of concentrated CBD to mice in a clinical laboratory setting versus the relatively low dosages of CBD found in many food and supplement products available to consumers today.

More scientific research is absolutely needed on the efficacy and safety of CBD used in products intended for human consumption. And that research will come in time. But, the information released by the FDA this week appears to be an overstatement of the potential health risks associated with CBD products – at least, as they are known today. There are health risks associated with bad products – and there are bad products on the market today – but that merely highlights the need for clear regulatory guidance from the FDA.

The Future of CBD

The FDA recognizes that there is a significant public interest in CBD. It also recognizes that there are reports of CBD products containing potentially harmful contaminants, such as pesticides and heavy metals. Yet, despite that strong interest

and recognition of a need for regulation in the industry, the FDA has delayed its development and implementation of meaningful regulatory guidance for CBD companies. That continuing delay does a disservice to the industry and to the general public.

Companies that cut corners and sell CBD products containing potentially harmful substances need to be regulated out of existence. Consumers deserve to know that the CBD brands they purchase and use have been responsibly grown, responsibly and safely manufactured, and are free from potentially harmful substances, like heavy metals and pesticides. And well-intentioned, responsibly operating CBD companies need and deserve clear regulatory guardrails within which they can safely – and legally – operate their business.

Unfortunately, it appears that regulatory uncertainty will continue to persist until there is more scientific data to support the safety and efficacy of CBD in consumer products. Obtaining that additional research and data will take time, so the industry may face a long slog until the FDA identifies a clear, detailed regulatory "pathway forward" for CBD. Until then, it is important for CBD companies to carefully consider the FDA's position on CBD and the warnings sent this week, and to incorporate those factors into their internal compliance practices as they develop, produce, advertise, and sell their products in interstate commerce.

Ward and Smith's Hemp Law attorneys are actively helping individuals and businesses navigate the complex and rapidly changing state and federal regulations governing the hemp industry.

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 For further information regarding the issues described above, please contact Tyler J. Russell o Allen N. Trask, III.