LEGAL UPDATES

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Clarity at Last? FDA Announces Plans for Meeting on Cannabis-Derived Compounds

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The public hearing, which is scheduled to be held on May 31, 2019, is intended to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling and sale of products containing cannabis and cannabis-derived compounds.

Safety, Manufacturing and Marketing

Along with the scheduling of the public meeting, FDA also announced the opening of a docket for public comments. FDA has requested that responses submitted to the docket address questions on three general topics:

- Health and safety risks
- Manufacturing and product quality
- Marketing, labeling and sales.

One of the long-standing questions to be addressed by the FDA is how to handle products containing CBD. FDA approved the prescription drug Epidiolex in June of 2018, which contains a purified form of CBD as its active ingredient. As noted by FDA, the Federal Food, Drug, and Cosmetic Act prohibits the introduction in interstate commerce of any food, animal feed or dietary supplement that contains an active ingredient of an approved drug product (subject to certain conditions and exemptions). While FDA notes in its announcement that CBD is subject to this prohibition, enforcement has historically been limited to products that make unapproved medical claims. In the announcement, FDA states that it is "consider[ing] whether it is appropriate to exercise [its] authority to allow the use of CBD in dietary supplements and other foods."

The question of whether FDA might allow the marketing of food and dietary supplement products containing CBD appears to be largely driven by questions over the health and safety of the compound. On this point, FDA has requested specific information and data related to safety, and is particularly interested about methods by which the maximal acceptable daily intake of cannabis and cannabis-derived compounds may be determined. FDA appears to be focused on fairly granular details in its review, having requested information on health effects among different populations (e.g., children, adolescents, pregnant and lactating women, specific species and breeds of animals) and the influence that the mode of delivery (e.g., ingestion, absorption, inhalation) affects safety and exposure.

The ability to positively affect FDA's decision-making on these issues will require a comprehensive and informed analysis. For example, beyond questions related to the direct effects that cannabis and cannabis-derived compounds would have, FDA also contemplates the drug development implications of marketing food and dietary supplements containing these ingredients.

What This Means to You

Effective responses to FDA's questions will need to be highly sophisticated. This will require drawing on epidemiological, toxicological, clinical and sociological studies and information to form a complex argument on the benefits of a proposed regulatory outcome. Given the existing authority of the agency and its past pronouncements on CBD, industry will need to begin developing an effective strategy now in order to secure the market long-term.

Contact Us

Husch Blackwell has experience working with trade groups on these types of regulatory matters, and has members with the required scientific backgrounds to help strategize and organize responses. Our Cannabis and FDA regulatory lawyers are available to discuss the announcement and upcoming meeting and how industry can appropriately prepare. Contact Seth Mailhot, Steve Levine or your Husch Blackwell attorney.