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FDA Holds First-Ever Public Hearing on CBD

By Madison Lisotto Whalen

The Food and Drug Administration ("FDA") held its first-ever public hearing on cannabidiol ("CBD") on Friday, May 31, 2019 with over one hundred (100) speakers and ten (10) hours of testimony. The purpose of the hearing was to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. This was a necessary first step to determine how the FDA will handle the regulation of CBD moving forward. Following the passage of the US Farm Bill in December 2018, which legalized hemp production given certain conditions and concentration levels, the confusion around the legality of hemp-derived CBD intensified. Nonetheless, the CBD industry continues to expand, with a constant stream of new food, beverage, dietary supplements, and medical products containing CBD becoming available.

FDA Commissioner Ned Sharpless's opening remarks indicated concern over safety issues stating, "There are real risks associated with [THC and CBD] and critical questions remain about the safety of their widespread use in foods and dietary supplements." Throughout the ten (10) hours of testimony, CBD proponents and opponents, some of which included researchers, biotech companies, health professionals and manufactures, provided an extremely wide array of differing opinions, demonstrating the chaotic state of this industry. A common theme expressed in testimony centered on the need for quality safety standards and testing, as well as proper and accurate labeling.

Three top biotech companies – Corbus Pharmaceuticals, Zynerba Pharmaceuticals, and GW Pharmaceuticals – all testified, which may be a sign that cannabis-based biotech will be protected in the future. GW Pharmaceuticals is the maker of Epidiolex, which is a drug used to treat childhood epilepsy, and the only cannabis-based drug with FDA approval. While most cannabis stocks decreased on Monday following the hearing, GW Pharmaceutical stock gained 1.1%.

Testimony from Consumer Reports indicated that about sixty-five (65) million Americans have tried CBD with sixty-three percent (63%) finding CBD to be effective, so future regulation of the industry is becoming increasingly important. Dr. Amy Abernethy, the Principal Deputy Commissioner for the FDA and leader of a working group to explore how CBD can be sold legally, shared a general summary of the hearing on her Twitter as follows:

1. "First, there is a need to further clarify the regulatory framework to reduce confusion in in the market. The product questions apply to people and animals."

2. "Given the rapid expansion of the market, timely clarification of the path forward is critical, but it's [the FDA's] responsibility to ensure that the regulatory path is scientifically sound and in the interest of public health."

3. "Key questions about product safety need to be addressed. Data are needed to determine safety thresholds for CBD; datasets/information should be objective, of adequate quality and available for transparent review. Lab testing and data analyses need to be replicable."

4. “There are both positive supporters of cannabis-cannabis derived products including CBD and also concerned citizens worried that widely available products can be harmful.”

5. “Consumers need consistent information and labeling. State/government entities need support in knowing what to do. And we really need to understand the implications for children when they take CBD-containing products at different dosage ranges.”

The FDA will allow public comments on this topic through July 2, 2019.

Roetzel will continue to keep you informed of the latest cannabis developments. If you have questions, contact any of the listed attorneys for further information.

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