

The interest in hemp-derived products, including CBD has skyrocketed in the past few years. This public interest has not escaped the attention of the US Food and Drug Administration who have repeatedly acknowledged the trend.

The FDA is evaluating the regulatory frameworks that apply to hemp and cannabis-derived products intended for non-drug uses, but this process takes time. The FDA is in the process of gathering comprehensive information on the science, safety, and quality of these CBD products and determining the impact of long-term use and effects in special populations including the elderly, children, and pregnant or lactating women. The priority in regards to these products is protecting public health.

Advancing the science of hemp and cannabis-derived products through good manufacturing practices, regulatory compliance, and therapeutic applications is critical for the cannabis industry. Determining the effects of cannabis-derived compounds, including hemp extracts, is a long-term process. The FDA conducted a hearing in May 2019 and solicited comments through July 2019 on several issues related to the science behind the products. These facets included health and safety information, manufacturing and product quality, and marketing, labeling, and sales.

At the time of writing, the FDA's enforcement actions on CBD consumer programs have focused on those that claim to prevent, diagnose, treat, mitigate, or cure serious diseases. These claims are permitted only for FDA-approved drug products. Currently, under FDA regulations, no hemp products or other cannabis-derived products may make disease claims unless the product is an FDA-approved drug (there is only one approved CBD drug at this time). The FDA is also monitoring for hemp and other cannabis-derived products, including CBD products that may contain dangerous contaminants.

The commercialization of a pharmaceutical-grade CBD product must be developed by science to ensure quality and consistency for consumers. The process of gaining approval from the FDA is a lengthy one, but we are confident that we are creating CBD products that will live up to the standards expected by the agency.

**Wayne Nasby** is the COO of Ocean Grown Ventures, LLC and is also the founder and CEO of Global Compliance Specialty Group. With over 30 years of experience, he is an industry expert in product commercialization, manufacturing, and compliance for the regulated cannabis and pharmaceutical industries. As a U.S. Agent Representative (FDA) for international pharmaceutical companies, he is an experienced specialist in quality management systems to ensure compliance with the Bureau of Cannabis Control and California Department of Public Health regulations.