Beveridge & Diamond

News Alert

Following Hearing, FDA Will Accept Comments on Cannabis Until July 2

June 25, 2019

AUTHORS

Alan Sachs
Principal
+1.202.789.6049
asachs@bdlaw.com

Mackenzie Schoonmaker
Principal
+1.212.702.5415
mschoonmaker@bdlaw.com

On May 31, 2019, the U.S. Food and Drug Administration (FDA) held a full-day public hearing to obtain scientific information about issues associated with food and other products that contain cannabis and cannabis-derived compounds (like cannabidiol, or CBD). Comments were presented by over 100 speakers, representing a wide range of stakeholders from academic, agriculture, consumer and other groups, followed by formal presentations by interested companies and organizations. Those with a stake in the industry should pay close attention to these comments, and submit their own by July 2, as these comments are expected to shape FDA 's regulatory actions moving forward. Comments may be submitted here.

As expected, Acting FDA Administrator Dr. Norman Sharpless began the hearing with no new announcements, and instead reiterated that CBD and THC cannot lawfully be added to a food, dietary supplement, or cosmetic product. Nevertheless, Dr. Sharpless emphasized that although FDA's role in this arena is not new, the increasing number of state laws allowing for medical or recreational cannabis use and the recent removal of hemp as a controlled substance under Federal law has now made FDA's authority over these products "more relevant."

Creating an exception for CBD and tetrahydrocannabinol (THC) to be added to food, dietary supplements, or cosmetics by regulation would, Dr. Sharpless explained, "be new terrain for the FDA." He added in his remarks that there are "real risks" and "critical questions" associated with the use of CBD and THC in food, dietary supplements, and cosmetics, which require careful evaluation.

ABOUT B&D

Beveridge & Diamond's over 100 lawyers in eight U.S. offices focus on environmental and natural resources law, litigation and alternative dispute resolution. We help clients around the world resolve critical environmental and sustainability issues relating to their products, facilities, and operations.

Learn more at bdlaw.com

These questions are what led FDA to form an internal working group to address existing data gaps.

Dr. Sharpless' comments specifically highlighted FDA's prior approvals of several drug products containing cannabis compounds, including CBD products for pediatric seizure patients and THC products for the treatment of anorexia. Several other cannabis-derived ingredients (like hemp seeds) have been "generally recognized as safe" (or GRAS) for use as food additives by FDA. In closing his remarks, however, Dr. Sharpless emphasized that FDA is concerned about companies that are currently selling unapproved CBD products, especially those claiming to prevent, diagnose, mitigate, treat, or cure serious diseases, such as cancer. He warned that selling unapproved drug products with unsubstantiated therapeutic claims is a violation of the law and puts patients at risk and that FDA does not have a policy of enforcement discretion with respect to these products.

The FDA is accepting comments on this issue until July 2, 2019.

During the rest of the hearing, FDA made clear that it is looking for as much data as possible to gain a better understanding of the safety and efficacy of CBD and THC products. FDA is particularly interested in information pertaining to dosing and its impacts, how different routes of administration affect the safety of these substances, and how these substances function in the body based on the various routes of administration. In addition, FDA is interested in the cumulative exposure from these compounds across a wide range of pathways, long-term impacts, and the effects of these compounds on special populations (e.g., children, the elderly, pregnant and lactating women), and animals.

Many individual speakers asked FDA to establish a clear regulatory pathway for the lawful use of CBD in food and dietary supplements through the development of a science-based approach that does not overburden the industry with unnecessary regulation. The hearing made clear that a key issue that FDA is grappling with is whether deregulating CBD and THC could affect the incentive for research on these products as drugs. In their comments at the hearing, industry and academic representatives alike denied that having cannabis and cannabis-derived products available for sale would negatively affect research.

Several commenters expressed general concern about potential harms associated with cannabis-derived products. Specific concerns were also expressed regarding marketing these products to children; in particular, FDA is concerned about the sale of items that are attractive to minors. Many states already have requirements that packaging of cannabis products cannot be geared towards children for these reasons.

FDA has stated that it is targeting as early as August to start providing findings from its internal working group.

Beveridge & Diamond's Industrial Hemp & Cannabis industry group assists cannabis-based businesses with state-level environmental compliance, product liability, project planning, environmental risk avoidance, and, where appropriate, litigation services and defense against state-level environmental enforcement actions. For more information, please contact the authors.

Possession, use, distribution, and sale of cannabis may be a federal crime. This alert is not intended to provide any guidance or assistance in violating federal law, or in providing guidance or assistance in complying with federal law.