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FDA Issues Warning Letters to 15 Companies, Consumer Update on CBD Safety

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On November 25, 2019, FDA issued Warning Letters to 15 companies illegally marketing cannabidiol (CBD) products. On the same day, U.S. Food & Drug Administration (FDA) published a revised consumer update, "What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD," describing the "very limited" scientific information available about CBD and its health effects. The points made in the Warning Letters and update are nothing new to those closely following the FDA working group on cannabis and CBD, but the actions signal the FDA's continued enforcement against companies marketing CBD foods, supplements, and cosmetics with unsupported health claims.

The Warning Letters cite companies for selling CBD tinctures, oils, gummies, lotions, and other human (and pet) products with health claims such as "relieves pain and inflammation," a "treatment for opioid addiction," "reduces anxiety," and "prevents arthritis." Some companies also cross the line by making therapeutic claims for diseases such as Alzheimer's, PTSD, Schizophrenia, and others.

In the consumer update, FDA states that although it recognizes the significant public interest in CBD, there are "many unanswered questions" about the science, safety, and quality of products containing CBD. FDA has been seeking information on these questions since its public hearing on May 31, 2019, and has an open public docket to collect information and data. FDA specifically is looking for information regarding:

- The cumulative exposure of CBD across a broad range of consumer products (e.g., if a consumer eats food containing CBD in the afternoon, then applies a CBD-infused skin cream at night);
- Effects of CBD in special populations (e.g., the elderly, children, adolescents, pregnant women); and
- The safety of CBD for pets and other animals.

FDA also alerts consumers to the potential risks associated with consuming CBD, including risks evaluated during the Agency's review of Epidiolex, an approved prescription CBD. Those safety concerns include: (1) liver injury; (2) drug interactions (e.g., whether taking CBD with other medications increases or decreases the effects of other medications); and (3) male reproductive toxicity (based on studies in laboratory animals).

FDA has genuine safety concerns from its work on Epidiolex, and every practitioner in this area should realize that any "health" claim associated with these products has a good chance of drawing unwelcome scrutiny from FDA. However, FDA does not address the material differences between Epidiolex and CBD products available now in the marketplace.

For example, Epidiolex is a highly concentrated form of CBD isolate, which means it is derived from cannabis or hemp extract, but in its purest form, with all terpenes, flavonoids, and cannabinoids (other than CBD) removed. Commonly available products, variously named "hemp extract" or "full-spectrum" or "broad-spectrum" CBD oil, contain significantly lower levels of CBD, and in a complex matrix of other substances that may individually or together function in the body in different ways than a highly concentrated, purified CBD isolate.

As the industry and the science regarding CBD products in their various forms progress, policymakers and advisers should exercise caution before associating the safety and other scientific data on CBD isolate to these other, different forms of CBD on the market.

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