READING THE TEA (OR HEMP) LEAVES

POST FDA HEARING

AIMEDALLIANCE

The May 31, 2019 Food and Drug Administration (FDA) hearing on "Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds" (e.g., Cannabidiol or CBD) highlighted the unregulated "wild-west" CBD market and the need for the agency to take action to keep consumers safe. During the hearing, marketers of cannabis and cannabis-derived products, concerned consumers and public health experts shared widely varying perspectives.

FDA U.S. FOOD & DRUG ADMINISTRATION

Norman Sharpless MD, Acting Commissioner of Food and Drugs, May 31, 2019

> ***The 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds. In doing so, Congress recognized FDA's important public health role with respect to all the products it regulates – including when those products are or contain cannabis ingredients…Our biggest concerns are the marketing of products that put the health and safety of consumers at risk, such as those claiming to prevent, diagnose, mitigate, treat, or cure serious diseases. There are lots of questions we will need to answer to ensure that FDA is taking an appropriate, well-informed, and science-based approach to the regulation of cannabis and cannabis derivatives, including CBD.***

GMA

Betsy Booren, Grocery Manufacturers Association's Senior Vice President of Science and Technology:

"As consumer interest for food, beverage, personal care and household products containing cannabis and cannabis derivatives continues to grow, the necessity for national uniform regulatory frameworks that protect public health is of critical importance."

Bridge the Gap SYNGAP Education & Research Foundation

Monica Weldon, SYNGAP Education & Research Foundation:

"While CBD products continue to be produced, without necessary safeguards in place, we continue putting our most vulnerable and loved population, our children, at risk."

Like many prescription drugs and supplements, CBD has side effects, including potential liver injury and interactions with other medications. Consumers are advised to consult with a healthcare professional (HCP) when considering the use of CBD.

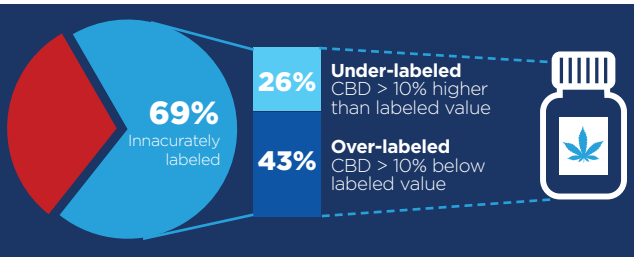
IMPORTANT REASONS EXIST TO GENERALLY PROHIBIT PUTTING DRUGS IN THE FOOD SUPPLY, THC AND CBD ARE NO EXCEPTION[1].

IN APPROVING PRESCRIPTION DRUGS, THE FDA HAS STRINGENT SAFETY AND EFFICACY REQUIREMENTS, INCLUDING:

- Requires clinical trials to determine efficacy and safety.
- Carefully evaluates risks and benefits of a specific formulation, dosage form, and strength for a particular population.
- Inspects manufacturing to ensure batch consistency and stable shelf life.
- Tests to ensure consistent concentration of cannabinoids and other ingredients listed on the label.

IN CONTRAST, CBD SUPPLEMENTS AND FOOD DO NOT NEED TO MEET THESE REQUIREMENTS.

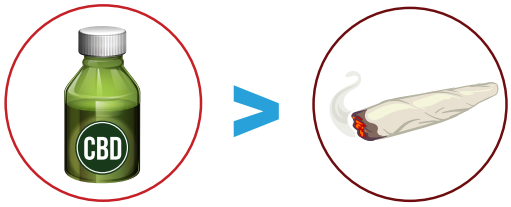
NEARLY 70% OF CBD EXTRACTS SOLD ONLINE ARE MISLABELED[2]



THC was detected in over 20% of retail CBD products

UNDISCLOSED LEVELS OF THC IN CBD CONSUMER PRODUCTS POSE PUBLIC HEALTH AND SAFETY CONCERNS

Up to 82 mg of THC delivered in 30 ml CBD bottle



Up to 17 mg THC delivered in common rolled cannabis cigarette

WHAT'S NEXT

FDA is taking an agency-wide, integrated, and collaborative approach to identify some potential regulatory pathways that may safely allow CBD into the food supply and dietary supplements. An internal working group is currently evaluating potential pathways for CBD products as well as data gaps. Considerable time is expected for FDA to review the thousands of comments received from interested stakeholders.

Comments are expected to expand the agency's understanding, add new information, and reinforce observations from the hearing.

At the conclusion of the hearing, Mr. Schiller, Principal Associate Commissioner for Policy, FDA highlighted several key takeaways and a desire for a regulatory pathway to enable lawful marketing of cannabis-derived products (especially CBD) in food and dietary supplements, with appropriate regulatory oversight that includes:

- Clear safety standards and strong enforcement;
- Need to support research evaluating the therapeutic effects of CBD;
- Need for consistent terminology related to these products; and
- Need for industry standards to address the potentially dangerous manufacturing quality issues with some cannabis-derived products on the market today.

@DrAbernethyFDA

*As we continue to evaluate policy options for CBD, it's important that **we continue to encourage (and don't undermine)** promising clinical research into CBD's therapeutic benefits. [June 28, 2019]*

*At FDA, we're excited about potential clinical and therapeutic uses of CBD. They should be studied and **supported by the same level of evidence** that we expect for therapeutic claims about any other substance. [June 28, 2019]*

***Need clear differentiation** between FDA-approved medicines and consumer-focused foods and supplements. [May 31, 2019]*

[1] https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-sharpless-fda-public-hearing-scientific-data-and-information-about-products-containing
[2] https://www.pennmedicine.org/news/news-releases/2017/november/penn-study-shows-nearly-70-percent-of-cannabidiol-extracts-sold-online-are-mislabeled