



July 22, 2021

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Uniform Federal Regulation of CBD Is Needed to Protect Consumer Health, Reduce Consumer Confusion and Enable Market Access for Trusted Manufacturers

Dear Acting Commissioner Woodcock:

Federal action is needed to address the continued rapid growth of cannabidiol (CBD) products. Since hemp was legalized by the 2018 Farm Bill, CBD products have flooded the market. Many make dubious claims with little regard for testing and disclosure of accurate ingredient levels. This is undermining public health and creating consumer confusion.

The current FDA stance on CBD products is not working. FDA has been steadfast in its position over the past several years that CBD-containing dietary supplements and foods cannot be marketed under the exclusionary clauses and that the use of these products presents potentially serious safety concerns. During this time, we have seen continued growth in the CBD market with a recent Consumer Brands Association (Consumer Brands)/Ipsos [poll](#) finding that 26% of Americans have used CBD. FDA inaction is resulting in a marketplace full of CBD-containing products produced in establishments that escape FDA regulation.

Consumer Brands believes a federal regulatory framework for CBD products, in addition to that which exists for CBD-containing pharmaceuticals, is needed now to protect consumers; ensure product safety and transparency; establish guardrails for legal product innovation and distribution in interstate commerce; and provide the clarity needed for manufacturers of these products.

A federal regulatory framework should be established, applying to all business entities, regardless of size and product sales, that empowers federal regulators to:

- Identify the data that is needed to support the safe marketing of foods and dietary ingredients that contain CBD.
- Establish the infrastructure and processes to review safety data and allow the lawful marketing of CBD-containing ingredients that are safe.
- Ensure products are made in full compliance with existing and applicable manufacturing, processing, distributing and product claim requirements.

Consumer Brands Association
1001 19th Street North, 7th Floor
Arlington, VA 22209

Powering every day.



- Provide guidelines to protect trademark and intellectual property.
- Align on how the current marketplace will transition to meet the requirements established through the new federal regulatory framework, in partnership with stakeholders.

Consumer Brands represents the consumer packaged goods industry. Our members' more than 1,700 brands encompass household, personal care, food and beverage products. Our industry plays a vital role in powering the U.S. economy, contributing \$2 trillion to U.S. GDP and supporting more than 20 million American jobs. Consumer Brands advocates for smart regulatory frameworks that build consumer trust in the products they depend on while providing CPG manufacturers a blueprint to innovate, invest and meet evolving consumer demand. We believe the actions listed above will provide greater protection to consumers and give businesses certainty that will bring trusted manufacturers to the CBD market. These actions should be taken by the agency immediately, given the continued expansion of a "Wild West" CBD market.

Federal action is particularly needed to reduce widespread consumer confusion regarding CBD products — including the misperception that the FDA *already* regulates CBD, including in food and beverage products. Consumer Brands' recent [poll](#) found that 74% of American consumers either incorrectly assume or have no idea if CBD is regulated. The market is growing and Americans are using products without FDA oversight — and without a good understanding of CBD. When asked to rate their knowledge of CBD on a scale of one to ten, consumers rated themselves an average of 3.3. This knowledge gap, in concert with the lack of federal regulation, should create urgency for FDA to engage.

Consumer Brands believes Americans deserve to know the products they purchase are safe and of consistent quality. Without FDA leadership, state legislatures are putting their own policies in place. There are currently 135 proposals in 38 states which threaten to further confuse the disparate CBD regulations already on states' books. Some states, like New York, have promulgated very robust regulatory requirements. Unfortunately, well-intentioned state CBD regulations have created a confusing, conflicting regulatory patchwork that fails to establish uniform requirements for the safe formulation, production, labeling and marketing of these products.

Until the federal government establishes clear, uniform standards for testing, safety and ingredient levels, the CBD market will continue to grow without appropriate federal oversight, potentially placing American consumers at risk. To move federal leadership and regulatory oversight forward, Consumer Brands respectfully requests that the FDA:

1. **Publish a research roadmap.** The FDA should provide an update to stakeholders on the current state of scientific data needed to determine the safety of CBD products. In conjunction with that update, the agency should prepare a research roadmap that highlights current data gaps relative to the safety of CBD and includes commentary on



the types of studies needed to address the identified data gaps. This roadmap should be updated as needed.

2. **Review the safety of CBD.** The FDA should establish a regulatory framework where CPG companies should notify the agency of CBD-containing products and provide safety data for FDA review so consumers can have confidence that the products on the market are safe.
3. **Provide an update on progress.** Stakeholders are unsure as to whether the FDA is making progress establishing a federal regulatory framework for CBD products. Consumer Brands would welcome an update from the FDA on its progress and an opportunity to share its perspective on what is critical for the safe and lawful marketing of CBD-containing foods and dietary supplements.
4. **Provide technical assistance to Congress.** There is growing bipartisan interest in finding workable solutions and ensuring the timely development of a federal regulatory framework for CBD products. The FDA should inform such discussions.
5. **Take necessary enforcement actions.** The FDA, with its federal partners, must continue to take enforcement actions against bad actors to remove unsafe CBD-containing products and those with misleading claims from today's marketplace.
6. **Establish a plan of action for transitioning currently marketed CBD-containing products to the new regulatory framework.** While the new regulatory framework is being developed, we urge FDA to work with stakeholders to develop a plan that can be implemented to make certain those products currently on the market are subject to the new regulatory framework.

The Consumer Brands Association is united with the FDA in the shared belief that American consumers need smart, consistent regulations to assure CBD products in the marketplace are safe. We look forward to working toward this shared goal.

Sincerely,

A handwritten signature in black ink, appearing to read 'Betsy Booren', written in a cursive style.

Betsy Booren
Senior Vice President, Regulatory Affairs