AIMEDALLIANCE

ESSENTIAL ELEMENTS OF A REGULATORY FRAMEWORK

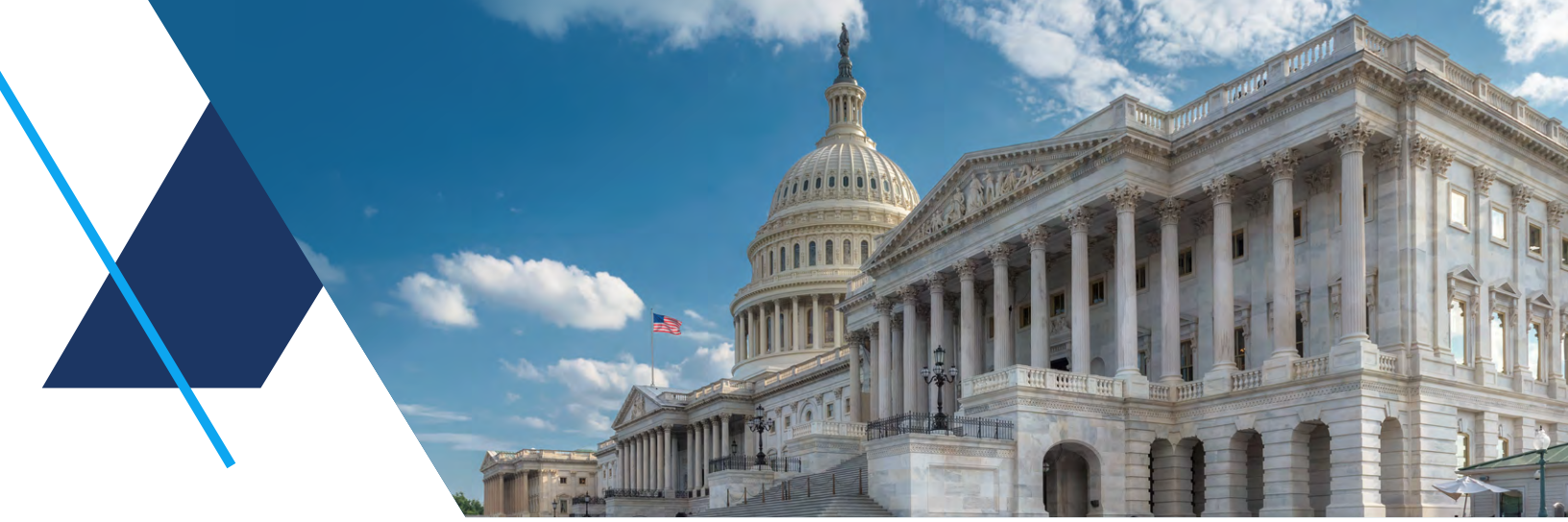
for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion

The Food and Drug Administration (FDA) has concluded that consumer products containing cannabidiol (CBD) that are intended for human ingestion cannot meet the current safety standards for foods and dietary supplements. Consequently, existing federal laws governing the marketing of food additives and dietary supplements are not suitable for such products.[1] **Therefore, the FDA has requested that Congress establish a regulatory framework specifically for CBD-containing consumer products that are intended for human ingestion.**[2]

Legislation to establish a regulatory structure for consumer products containing CBD and intended for human ingestion should also apply to consumer products that contain other cannabinoids, such as delta-9 tetrahydrocannabinol (THC) and delta-8 THC. Congress should adopt a hybrid approach to such regulation by incorporating elements from the regulations currently imposed on foods, dietary supplements, tobacco products, and over-the-counter (OTC) drugs.

CBD legislation should establish cannabinoid content limits on a per serving and per package basis to protect consumer safety, ensure transparent marketing practices, and maintain product quality standards. It should prioritize providing consumers with sufficient and accurate information about the products, enabling consumers to make well-informed decisions.

Ultimately, the legislation authorizing the regulation of consumer products containing cannabis-derived ingredients and intended for human ingestion should adequately protect the public's health and safety.



PRE-MARKET SAFETY NOTIFICATION & EVIDENCE OF SAFETY

The Federal Food, Drug and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, requires that all new tobacco products undergo premarket review and receive a marketing-granted order from the FDA before such products may be sold to consumers.[3] In contrast, the FD&C's dietary supplement regulations do not require manufacturers to provide the FDA with evidence substantiating a supplement's safety, and notification requirements solely focus on reporting new ingredients.[4] This approach places the burden on the FDA to rely heavily on post-marketing surveillance efforts, yet does not require manufacturers to report non-serious adverse events.[5] Further, current law does not enable the FDA to efficiently remove unsafe products from the market.[6]

At minimum, the manufacturers or distributors of consumer products containing cannabis-derived ingredients and intended for human ingestion should be required to submit a premarket notification to the FDA at least 75 days before introducing the product into interstate commerce. Congress should require that the premarket notification include adequate, credible evidence that the new product is safe under the conditions of its intended use.

CURRENT GOOD MANUFACTURING PRACTICES

The FDA requires food manufacturers to comply with Good Manufacturing Practices (CGMPs) to prevent contamination and ensure product integrity throughout the food manufacturing process.[7] CGMPs impose standards for personal hygienic practices, design and construction of food plants and maintenance of plant grounds, plant equipment, facility sanitation, and process controls for the production of food.[8] Congress should require the producers of consumer products containing cannabis-derived ingredients and intended for human ingestion to follow CGMPs like those applicable to foods.

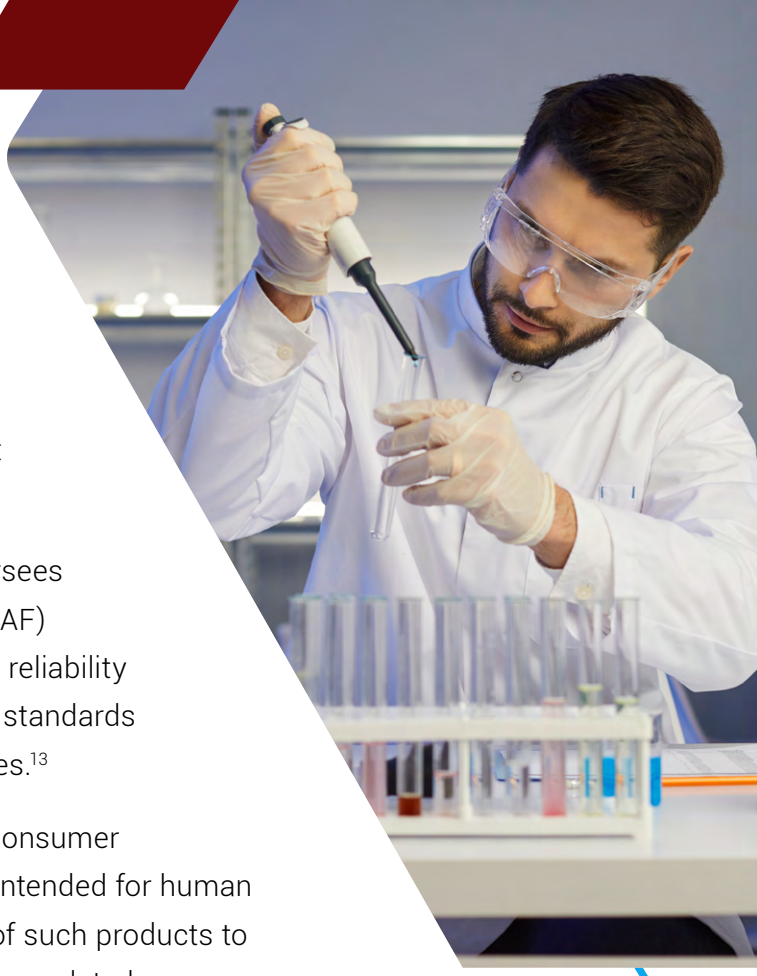
PER-SERVING & PER-PACKAGE LIMITS

Congress should require the FDA to set per-serving limits on the amount of CBD, THC, and other psychoactive cannabinoids in consumer products containing cannabis-derived ingredients and intended for human ingestion. There are no current laws or regulations that allow the FDA to impose limits on the serving size of a dietary supplement or the amount of a dietary ingredient that can be in a serving of a dietary supplement.[9] In contrast, the FDA has proposed a similar approach for cigarettes and other tobacco products in an effort to reduce nicotine use, addiction, and death.[10]

Additionally, to prevent exposure to unsafe amounts of CBD, THC, or other psychoactive cannabinoids by ingesting multiple servings, Congress should require the FDA to limit the total amount of each cannabinoid per package.

PRODUCT PURITY & CONSISTENCY STANDARDS

Congress should require the FDA to implement product purity standards for consumer products derived from cannabis and intended for human ingestion, including limits on fertilizer, lead, mold, chemical processing residues, and other impurities. This requirement would be an extension of the FDA's current role, as it is already responsible for implementing food product purity standards and limiting the levels of contaminants, including mold, insect filth, and heavy metals, in foods.[11] The FDA also monitors the levels of pesticide chemical residues in domestic and imported foods to ensure that they do not exceed Environmental Protection Agency limits.[12] The FDA should do the same for consumer products containing cannabis-derived ingredients that are intended for human ingestion.



ACCURACY & PRODUCT TESTING

New regulatory standards for consumer products containing cannabis-derived ingredients and intended for human ingestion should ensure labeling accuracy by limiting variances between labeled content and actual product content.

Under the Food Safety Modernization Act, the FDA oversees the Laboratory Accreditation for Analyses of Foods (LAAF) program. The LAAF program ensures the accuracy and reliability of certain food testing through laboratory uniformity of standards and enhanced FDA oversight of participating laboratories.[13]

To ensure the accuracy and reliability of the testing of consumer products containing cannabis-derived ingredients and intended for human ingestion, Congress should require the manufacturers of such products to use laboratories approved under LAAF or a similar FDA-regulated program.

REGULATORY & ENFORCEMENT RESOURCES

The FDA must have adequate resources and capacity to establish and enforce compliance with new regulations before such regulations take effect. Without sufficient resources and capacity to regulate the safety of consumer products containing cannabis-derived ingredients and intended for human ingestion, the FDA will be unable to satisfy the requirements of a new law, thereby maintaining the current state of inadequate regulation and enforcement.

CONSUMER LABELING

Congress should ensure that consumers have access to adequate, accurate product information to make informed decisions about consumer products containing cannabis-derived ingredients and intended for human ingestion.

For more information on how Congress should address labeling of consumer products containing cannabis-derived ingredients and intended for human ingestion, read Aimed Alliance's "Essential Labeling Requirements for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion," available **here**.

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