AIMEDALLIANCE

ESSENTIAL LABELING REQUIREMENTS

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

The Food and Drug Administration (FDA) has determined that consumer products containing cannabidiol (CBD) and intended for human ingestion cannot meet the current safety standards for foods and dietary supplements. As such, existing federal laws governing the marketing of food additives and dietary supplements are inappropriate for products containing CBD that are intended for human ingestion.[1] **Therefore, the FDA has asked Congress to authorize a regulatory framework for consumer products containing CBD that are intended for human ingestion.**[2]

Legislation to create a regulatory framework for consumer products intended for human ingestion that contain CBD should also cover consumer products intended for human ingestion that contain other cannabis-derived ingredients, such as delta-9 tetrahydrocannabinol (THC) and delta-8 THC. Congress should use a hybrid approach to such regulation, drawing from the current requirements for foods, dietary supplements, tobacco products, and over-the-counter (OTC) drugs. Furthermore, Congress should ensure that the FDA has adequate resources and capacity to establish and enforce compliance with new labeling requirements before the new regulatory framework takes effect.

CBD legislation should foster research, promote transparency, and ensure product and labeling consistency. Such legislation should ensure that consumers have access to adequate, accurate product information to make informed decisions.

Specifically, legislation to authorize the regulation of consumer products containing cannabis-derived ingredients and intended for human ingestion should ensure that consumers have access to the following product information:

FAMILIARITY

The FDA currently regulates the labeling of most foods and dietary supplements.[3] Consumers are familiar with these products' labels and know where to look for information of interest to them. Consumer products containing cannabis-derived ingredients and intended for human ingestion should be subject to the labeling requirements applicable to foods and dietary supplements. The labeling requirements for this new category of consumer products should be in addition to, not in place of, the labels with which consumers are familiar.

PER-SERVING & PER-PACKAGE LIMITS

To help ensure the safe use of cannabinoid-containing consumer products intended for human ingestion, Congress should require the FDA to establish per-serving limits on the amounts of CBD, THC, and other psychoactive ingredients in such products. Currently, there are no laws or regulations that allow 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.[4] Similarly, Congress should require the FDA to establish per-package limits on the amounts of psychoactive ingredients in cannabinoid-containing consumer products intended for human ingestion. Congress should also require that these per-serving and per-package limits be clearly stated on product labels.

PROMINENT PER-SERVING INTAKE VALUES

The FDA requires that calorie counts be displayed in a large and bold font on foods' Nutrition Facts labels and that calorie declarations be clear and prominently placed on food items sold in vending machines.[5] Similarly, Congress should require that labels of consumer products containing cannabis-derived ingredients and intended for human ingestion prominently display the per-serving intake values of CBD, THC, and other psychoactive ingredients.

SAFETY WARNINGS

The FDA requires health warnings on cigarette packages to improve public understanding of the negative health consequences of cigarette smoking.[6] Labeling of consumer products containing cannabis-derived ingredients and intended for human ingestion should include warnings that alert consumers of evidence-based health and safety risks. For example:

- Pregnancy – FDA strongly advises against the use of CBD and THC (and marijuana) in any form during pregnancy or while breastfeeding due to potential serious health consequences.[7]
- Drug interactions – CBD and THC, like prescription drugs, are broken down by enzymes in the liver, and may interfere with the concentrations, toxicity levels, and efficacy of other drugs.[8]
- Machinery and driving – While CBD is generally considered non-impairing, THC use can impair important skills required for safe driving and operating machinery.
- Child Ingestion – The FDA has warned that children's ingestion of foods containing THC may cause serious adverse events.[9]

The 2022 Medical Marijuana and Cannabidiol Research Expansion Act requires the federal government to report on the impacts of marijuana on adolescent brains and the ability to operate motor vehicles. Congress should expand that research to include additional cannabinoids. Known harms or risks associated with cannabinoids in consumer products intended for human ingestion should be described on the labels of such products.

ADDITIONAL HEALTH & SAFETY PROTECTIONS

For more information on the essential elements of a regulatory framework for consumer products containing cannabis-derived ingredients and intended for human consumption, read Aimed Alliance's "Essential Elements of a Regulatory Framework for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion," available here.

REFERENCES

1. Andrew Jacobs, *F.D.A. Seeks More Authority to Oversee CBD Products*, N.Y. Times (Jan. 26, 2023), https://www.nytimes.com/2023/01/26/health/fda-cbd-oversight.html.
2. *Id.*
3. *Food Ingredients & Packaging*, U.S. Food & Drug Admin., https://www.fda.gov/food/food-ingredients-packaging (Mar. 8, 2023); *Dietary Supplement Labeling Guide*, U.S. Food & Drug Admin., https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide (Apr. 1, 2005).
4. *Questions and Answers on Dietary Supplements*, U.S. Food & Drug Admin. (Oct. 26, 2022), https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements.
5. U.S. Dep. Agric., Food & Nutrition Serv. Memorandum SP 28 – 2016, CACFP 09 – 2016, SFSP 11 - 2016, *FDA Requirements for Vending Machines* (Mar. 2, 2016), https://www.fns.usda.gov/cn/fda-requirements-vending-machines; *Calories on the New Nutrition Facts Label*, U.S. Food & Drug Admin., https://www.fda.gov/food/new-nutrition-facts-label/calories-new-nutrition-facts-label (Feb. 25, 2022).
6. *Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide (Revised)*, U.S. Food & Drug Admin. (July 2021), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/required-warnings-cigarette-packages-and-advertisements-small-entity-compliance-guide-revised.
7. *What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding*, U.S. Food & Drug Admin., https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding (Oct. 16, 2019).
8. *CBD might not mix with your meds*, Portland Clinic (Nov. 8, 2021), https://www.theportlandclinic.com/cbd-might-not-mix-with-your-meds/.
9. *FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC*, U.S. Food & Drug Admin. (June 16, 2022), https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc.

AIMED ALLIANCE

1455 Pennsylvania Ave, NW, Suite 400
Washington, DC 20004

(202) 349-4089

AimedAlliance.org