April 1, 2026

Mr. Kyle Diamantas, J.D.
Deputy Commissioner for Human Foods
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dr. Tracy Beth Hoeg, MD, PhD
Acting Director, Center for Drug Evaluation and Research
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Diamantas and Dr. Hoeg:

Subject: Hemp-Derived Cannabidiol Products in Medical Research Models

Legislative Background:

The Agriculture Improvement Act of 2018 (Public Law 115-334), referred to herein as "the 2018 Farm Bill," changed how cannabis is treated under the Controlled Substances Act (CSA). The 2018 Farm Bill created a definition of *hemp*, which includes cannabis and derivatives or extracts of cannabis with a delta-9 tetrahydrocannabinol (delta-9 THC) concentration of not more than 0.3 percent on a dry weight basis.[1] Significantly, the 2018 Farm Bill removed *hemp* from the definition of *marihuana*[2] provided in section 102 of the CSA,[3] which means that substances meeting the definition of *hemp* are no longer controlled substances under Federal law. The definition of *hemp* was again amended in November 2025 through the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Continuing Appropriations Act). The Continuing Appropriations Act narrowed the definition of *hemp* to exclude, among other things, any products with cannabinoids not capable of being naturally produced in the *Cannabis sativa L.* plant, any cannabinoids that are capable of being naturally produced in the plant but were synthesized or manufactured outside the plant, and any final products with more than 0.4 milligrams (mg) per container of combined tetrahydrocannabinols and cannabinoids that produce, or are marketed to produce, similar effects as tetrahydrocannabinols.

The 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section

[1] 7 U.S.C. 1639o(1). For a detailed discussion of the calculation of delta-9 THC content, including the procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp and proper treatment of measurement uncertainty, see the Department of Agriculture's interim final rule "Establishment of a Domestic Hemp Production Program" (84 FR 58522; Oct. 31, 2019) and any succeeding regulations.
[2] The CSA uses the spelling *marihuana*; *marijuana* is a common alternative.
[3] 21 U.S.C. 802(16).

351 of the Public Health Service Act. This preservation of FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act was unaffected by the modification of the definition of *hemp* in the Continuing Appropriations Act. Thus, FDA-regulated products containing cannabidiol (CBD) are subject to the same legal and regulatory requirements as other FDA-regulated products.

The applicable regulatory framework, and the relevant legal requirements, that apply to a given FDA-regulated CBD product will depend on the type of product at issue. FDA has jurisdiction over a variety of product types, and an FDA-regulated product that contains CBD is subject to the framework and requirements that apply to that product type (food, drug, cosmetic, etc.).

Recent Executive Action:

Executive Order 14370[4] of December 18, 2025, "Increasing Medical Marijuana and Cannabidiol Research," directs the Secretary of Health and Human Services, the Commissioner of Food and Drugs (FDA), the Administrator of the Centers for Medicare and Medicaid Services (CMS), and the Director of the National Institutes of Health to develop research methods and models utilizing real-world evidence to improve access to hemp-derived cannabinoid products in accordance with Federal law and to inform standards of care.

FDA Enforcement Posture:

The CMS has signaled an intention to expand various coverage flexibilities to potentially include hemp-derived CBD products.[5,6]

The FDA does not intend to enforce sections 502(f)(1) or 505 of the Federal Food, Drug, and Cosmetic Act with respect to an orally administered, hemp-derived CBD product solely on the basis that it contains CBD, provided that the product (1) is manufactured, marketed, and labeled in a manner that would be consistent with the dietary supplement framework, including bearing a supplement facts panel and structure/function claims, (2) is not contaminated, (3) is not packaged or labeled in a manner that would be attractive to or marketed for children, and (4) is provided to a beneficiary through a program of medical items or services payable under Title XVIII of the Social Security Act, under the direction of the patient's treating physician, in a manner ancillary to the covered items or services furnished under such program.

Sincerely,

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs

[4] https://www.federalregister.gov/executive-order/14370
[5] https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive
[6] https://www.federalregister.gov/documents/2025/11/28/2025-21456/medicare-program-contract-year-2027-policy-and-technical-changes-to-the-medicare-advantage-program

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