View on our website.

GIBSON DUNN

FDA & Health Care Update April 29, 2026

DEA Downschedules State Medical Marijuana to Schedule III; Expedited Hearing Set to Consider Broader Rescheduling

A Drug Enforcement Administration final order moves (1) marijuana contained in a Food and Drug Administration-approved drug product and (2) marijuana subject to a state medical marijuana license from Schedule I to Schedule III of the Controlled Substances Act, effective April 28, 2026.

Background

On April 23, 2026, Acting Attorney General Todd Blanche announced the issuance of an order on behalf of the DEA downscheduling from Schedule I to Schedule III two categories of marijuana under the Controlled Substances Act: (1) marijuana contained in an FDA-approved drug product; and (2) marijuana subject to a state medical marijuana license.[1] Blanche also provided notice of an expedited DEA hearing that will be held this summer to consider whether marijuana more broadly (including recreational marijuana) should be downscheduled through a formal rulemaking process.[2] Although the order loosens restrictions under federal law on the manufacture, distribution, and sale of marijuana subject to a qualifying state medical marijuana license, as well as on clinical research, it leaves unresolved questions about the legal status of marijuana sold as foods, dietary supplements, or unapproved drugs.

The DEA order follows on a December 2025 Executive Order directing the Attorney General to expedite the process of rescheduling marijuana to Schedule III.[3] The scope of the order is limited to marijuana in an FDA-approved drug product or subject to a state medical marijuana license; any other form of marijuana — i.e., unlicensed marijuana crops, bulk marijuana, and any extract from, or other derivative of, marijuana that is not incorporated into an FDA-approved drug product — will remain in Schedule I.[4] The order cites as authority in part the Attorney General's obligation to align DEA scheduling decisions with U.S. treaty obligations under the 1961 U.N. Single Convention on Narcotic Drugs, a mechanism that allows the order to go into immediate effect without notice-and-comment rulemaking.[5]

Upcoming Administrative Hearing

According to the DEA hearing notice, the expedited administrative hearing will begin June 29, 2026, and will consider whether all forms of marijuana should be downscheduled from Schedule I to Schedule III through the formal rulemaking process. The notice states that an administrative law judge (ALJ) to be designated by Blanche will preside over the hearing. This hearing process builds on a proposed rule issued in May 2024 and will replace a previous hearing process, which was initiated in August 2024, and stayed in January 2025.[6] DEA's sole ALJ then retired in July 2025.[7]

What Changes under the DEA Order

The effects of downscheduling from Schedule I to Schedule III are significant. Schedule I substances cannot lawfully be manufactured, distributed, or sold under federal law in any form, with stringent restrictions on scientific research. In contrast, Schedule III substances can be manufactured, distributed, and dispensed by entities that hold a valid DEA registration and meet all applicable requirements under the Controlled Substances Act, including related to registration, fees, disposal, prescribing, security, labeling and packaging, inventory, reporting, and recordkeeping.

The DEA order provides for new DEA registration requirements for manufacturers, distributors, and dispensers of marijuana subject to state medical marijuana licenses. These requirements, as set forth in new DEA regulations, provide for an expedited process that requires DEA to grant registration to applicants holding state medical marijuana licenses, unless doing so would conflict with the public interest[8] or with the requirements of the Single Convention.

The downscheduling action also allows for expanded opportunities for marijuana research. The DEA order specifies that practitioners can engage in research on marijuana if they are registered with DEA to conduct such research and obtain marijuana from a state licensee with a valid federal registration at the time of transfer.

Unresolved Issues

Of significant note, the order leaves unresolved the legal status of marijuana sold as foods, dietary supplements, or unapproved drugs under the Federal Food, Drug, or Cosmetic Act (FDCA). The FDCA prohibits the sale of unapproved drug products, and FDA also has taken the position that products containing THC cannot be lawfully sold as foods or dietary supplements.[9] FDA has not issued any guidance or other statement on the impact of the rescheduling.

The White House's directive to loosen restrictions on marijuana suggests that FDA is likely to continue exercising enforcement discretion after rescheduling. In recent years, both DEA and FDA have declined to take enforcement action against marijuana manufacturers or distributors despite widespread violation of federal law. This approach is consistent with annual appropriations bills that prohibit DOJ (which includes DEA) from spending appropriated funds to prevent states from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.[10] Further, FDA lacks independent litigating authority so must refer any proposed civil or criminal enforcement action to DOJ. However, FDA likely will receive pressure to regulate the space more assertively from companies interested in developing and submitting applications for approved drugs containing THC or other substances found in marijuana as an active ingredient.

Looking Ahead

DEA's rescheduling order represents a substantial shift in federal marijuana policy. Gibson Dunn attorneys are closely monitoring these developments, including DEA's approach to the hearing process and any legal challenges to the order, and are available to discuss these issues as applied to your business.

[1] U.S. Department of Justice, Justice Department Places FDA-Approved Marijuana Products and Products Containing Marijuana Subject to a Qualifying State-issued License in Schedule III, Strengthening Medical Research While Maintaining Strict Federal Controls (Apr. 23, 2026), https://www.justice.gov/opa/pr/justice-department-places-fda-approved-marijuana-products-and-products-containing-marijuana; Drug Enforcement Administration, Department of Justice, Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana From Schedule I to Schedule III; Corresponding Change to Permit Requirements, Final rule, 91 Fed. Reg. 22714 (Apr. 28, 2026).

[2] Drug Enforcement Administration, Department of Justice, Notice of hearing on proposed rulemaking, 91 Fed. Reg. 22777 (Apr. 28, 2026).

[3] Increasing Medical Marijuana and Cannabidiol Research, Executive Order 14370 (Dec. 18, 2025).

[4] Note that, following the passage of the continuing resolution bill in November 2025, H.R. 5371, the definition of marijuana is set to broaden in November 2026 to include certain cannabinoids containing THC (including certain CBD products) that were previously considered "hemp" under the 2018 Farm Bill. Once in effect, the definition of hemp will be limited to products to those with not more than 0.3% THC. See Pub. L. No. 119-37 (Nov. 12, 2025), Div. B, § 781.

[5] See 21 U.S.C. 811(d).

[6] Drug Enforcement Administration, Department of Justice, Notice of hearing on proposed rulemaking; withdrawal, 91 Fed. Reg. 22778 (Apr. 28, 2026).

[7] Drug Enforcement Administration, Department of Justice, Notice to the Parties, in the Matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, available at:

https://www.dea.gov/sites/default/files/2025-07/Marijuana%20Rescheduling_Notice%20to%20the%20Parties.pdf.

[8] Taking into account the factors set forth in 21 U.S.C. 823(e)-(g), as applicable.

[9] See, e.g., 21 U.S.C. §§ 331(a), (c), (d), (g), 352(f)(1), 355(a) (provisions related to adulterated and misbranded drugs, as well as unapproved new drugs); §§ 321(ff), 331(ll) (provisions related to food and dietary supplements); FDA, "FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)."

[10] See, e.g., Section 531, H.R. 6938, as enacted January 23, 2026.

The following Gibson Dunn lawyers prepared this update: Katlin McKelvie, Carlo Felizardo, and Wynne Leahy.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding these developments. Please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any leader or member of the firm's FDA & Health Care practice group.

Katlin McKelvie – Washington, D.C. (+1 202.955.8526, kmckelvie@gibsondunn.com)

Gustav W. Eyler – Washington, D.C. (+1 202.955.8610, geyler@gibsondunn.com)

Carlo Felizardo – Washington, D.C. (+1 202.955.8278, cfelizardo@gibsondunn.com)