IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NEW DIRECTIONS ADDICTION RECOVERY SERVICES; KENNETH FINN, M.D.; ELIZABETH "LIBBY" B. STUYT, M.D.; CANNABIS INDUSTRY VICTIMS EDUCATING LITIGATORS; MMJ INTERNATIONAL HOLDINGS, INC.; MMJ BIOPHARMA CULTIVATION, INC.; and MMJ BIOPHARMA LABS, INC., *Petitioners*, v. DONALD J. TRUMP, in his official capacity as President of the United States; TODD BLANCHE, in his official capacity as Acting Attorney General of the United States; UNITED STATES DEPARTMENT OF JUSTICE; TERRANCE C. COLE, in his official capacity as Administrator of the Drug Enforcement Administration; and DRUG ENFORCEMENT ADMINISTRATION, *Respondents.*	Case No. 26-1136

PETITION FOR REVIEW OF FINAL AGENCY ACTION

Petitioners New Directions Addiction Recovery Services ("New Directions"); Kenneth Finn, M.D.; Elizabeth "Libby" B. Stuyt, M.D.; Cannabis Industry Victims Educating Litigators ("CIVEL"); and MMJ International Holdings, Inc. ("MMJIH") with its subsidiaries MMJ BioPharma Cultivation, Inc. ("MMJBC") and MMJ BioPharma Labs, Inc. ("MMJBL") (collectively, "MMJ"), by and through their undersigned counsel, respectfully petition this Court pursuant to 21 U.S.C. § 877, 28 U.S.C. § 2344, and 5 U.S.C. §§ 701–706 for review of the final order of the Attorney General of the United States

entitled "Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana and Products Containing Marijuana Subject to a Qualifying State-issued License From Schedule I to Schedule III; Corresponding Change to Permit Requirements," AG Order No. 6754-2026, 91 Fed. Reg. 22,714 (Apr. 28, 2026) (the "Final Order"), which became effective on April 22, 2026. A copy of the Final Order is attached hereto as Exhibit A.

I. Jurisdiction and Venue

This Court has jurisdiction under 21 U.S.C. § 877, which provides that "[a]ll final determinations, findings, and conclusions of the Attorney General" under the Controlled Substances Act ("CSA") "shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals" for the circuit in which the person resides or has a principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit. This Court additionally has jurisdiction under 28 U.S.C. §§ 2112 and 2344 and 5 U.S.C. § 702.

Venue is proper in this Circuit pursuant to 21 U.S.C. § 877, which expressly authorizes any person aggrieved by a final decision of the Attorney General under the CSA to obtain review in the United States Court of Appeals for the District of Columbia Circuit. The D.C. Circuit is the appropriate forum for this challenge because it has longstanding expertise in CSA scheduling matters and is the court of record for the seminal decision construing § 811(d)(1). *See NORML v. DEA*, 559 F.2d 735 (D.C. Cir. 1977). Additionally, Petitioner CIVEL is a named plaintiff in *Smart Approaches to Marijuana, Inc.*

v. Kennedy, No. 1:26-cv-01081-TNM (D.D.C.), and counsel for Petitioners maintain offices in Washington, D.C.

This Petition is timely filed within thirty (30) days of the publication of the Final Order in the Federal Register on April 28, 2026. *See* 21 U.S.C. § 877.

II. Background

On December 18, 2025, President Donald J. Trump issued Executive Order No. 14370, titled "Increasing Medical Marijuana and Cannabidiol Research," 90 Fed. Reg. 60,541 (Dec. 23, 2025) (the "Executive Order"), which directed the Attorney General to "take all necessary steps to complete the rulemaking process related to rescheduling marijuana to Schedule III of the CSA in the most expeditious manner in accordance with Federal law, including 21 U.S.C. 811." At the Oval Office signing ceremony, President Trump stated that rescheduling marijuana is "really something having to do with common sense" and predicted that "[t]his reclassification order will make it far easier to conduct marijuana-related medical research allowing us to study benefits, potential dangers and future treatments. It's going to have a tremendously positive impact." *Remarks on Signing an Executive Order on Increasing Medical Marijuana and Cannabidiol Research and an Exchange With Reporters*, The American Presidency Project (Dec. 18, 2025), https://tinyurl.com/3229zz3p.

President Trump credited Howard Kessler—a Palm Beach billionaire, financial services executive, and longtime personal friend of the President who founded The Commonwealth Project in 2019 to advocate for cannabis's supposed medical benefits—as the driving force behind the Executive Order. Trump told the assembled press that

Kessler "came to see me on more than one occasion" and "said there's been nothing like this and we're going to have to take a good strong look at it." *Id.* Secretary Robert F. Kennedy Jr. stated at the ceremony that "without [Kessler] we wouldn't be here today," noting that Kessler "drove this change in the schedule" based on "his own experience" mitigating the effects of chemotherapy. *Id.*

On April 22, 2026, Acting Attorney General Todd Blanche issued the Final Order placing two categories of marijuana products into Schedule III of the CSA: (1) drug products containing marijuana that have been approved by the Food and Drug Administration ("FDA"), and (2) marijuana products subject to a qualifying state-issued license to manufacture, distribute, and/or dispense marijuana for medical purposes ("state medical marijuana license"). 91 Fed. Reg. at 22,714. The Final Order simultaneously amended DEA regulations at 21 C.F.R. Part 1312 to require import and export permits for the rescheduled products, and established an expedited registration process under 21 C.F.R. Part 1301 for entities holding state medical marijuana licenses. *Id.*

The Acting Attorney General purported to act under the authority of 21 U.S.C. § 811(d)(1), the treaty-implementation provision of the CSA, claiming that this action was "required to satisfy the responsibility of the Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961." *Id.* However, the Final Order is also intended to carry out the Executive Order. *See* 91 Fed. Reg. 22,777–22,778 (Apr. 28, 2026).

The Final Order was issued without prior notice-and-comment rulemaking under 5 U.S.C. § 553, without a formal hearing on the record under 21 U.S.C. § 811(a), without

consultation of the recommendation of the Department of Health and Human Services ("HHS") on rescheduling, without consideration of the administrative process regarding rescheduling that was already in progress, and without compliance with the procedural requirements of 5 U.S.C. §§ 556–557.[1] The Respondents avoided many of these procedural safeguards by issuing their rescheduling decision under Section 811(d).

Simultaneously, the Department of Justice withdrew the prior Notice of Proposed Rulemaking, 89 Fed. Reg. 44,597 (May 21, 2024), terminated the ongoing administrative hearing proceedings before former Chief Administrative Law Judge John J. Mulrooney, II (DEA Docket No. 1362, Hearing Docket No. 24-44) (the "Administrative Hearing"), and issued a new Notice of Hearing for an expedited rescheduling hearing to commence June 29, 2026, and conclude by July 15, 2026.

The Final Order has immediate and sweeping consequences, including:

- The elimination of the deduction disallowance imposed by 26 U.S.C. § 280E for state-licensed marijuana businesses;
- The creation of a novel, bifurcated federal scheduling framework never contemplated by Congress;
- The effective federal endorsement of state medical marijuana programs that have never undergone FDA approval; and
- The reduction of federal controls on marijuana products in a manner that will foreseeably increase marijuana availability and use.

[1] The Acting Attorney General explicitly stated that he was "not required to consider [the] HHS recommendation when issuing an order under section 811(d)(1)." *Id.* at 22,718.

III. Identification of Petitioners and Standing

Each Petitioner is a "person aggrieved" by the Final Order within the meaning of 21 U.S.C. § 877. Petitioners satisfy the requirements of Article III standing because each has suffered or will imminently suffer a concrete and particularized injury in fact that is fairly traceable to the Final Order and redressable by a favorable decision of this Court. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). Each Petitioner's interests fall within the zone of interests protected by the CSA and the APA. *See Americans for Safe Access v. DEA*, 706 F.3d 438, 443–49 (D.C. Cir. 2013).

A. New Directions Addiction Recovery Services

New Directions is a substance abuse recovery clinic and retreat center located in McHenry County, Illinois.

The Final Order directly and concretely injures New Directions and its patients by rescheduling marijuana products to Schedule III without adequate consideration of marijuana's well-documented addiction potential, thereby signaling to the public and to persons in recovery that marijuana is less dangerous than its prior Schedule I classification indicated. According to the Centers for Disease Control and Prevention, approximately three in ten people who use cannabis develop cannabis use disorder. This rescheduling will foreseeably increase the availability and social acceptability of marijuana, undermining New Directions' organizational mission to assist individuals in overcoming substance abuse, including cannabis use disorder, and diverting organizational resources to address increased marijuana-related harm among its patient population. Additionally, the Final Order deprives New Directions of accurate and reliable medical information necessary to counsel patients who are using or considering

the use of marijuana, as there are no FDA-approved dosing guidelines, package inserts, or clinical protocols that would enable New Directions's clinicians to provide evidence-based treatment guidance regarding a substance now classified as a Schedule III drug.

The Final Order also injures New Directions by providing no avenue for comment under the APA and no access to an administrative hearing under the CSA. New Directions would have had an opportunity to present evidence of the Final Order's harms before and after its publication, but because the Final Order was issued under Section 811(d) instead of as a Notice of Proposed Rulemaking under Section 811(a), it was deprived of due process and equal protection of the laws.

B. Kenneth Finn, M.D.

Dr. Finn is a physician who practices comprehensive pain medicine in Prescott, Arizona, and is board-certified in Physical Medicine and Rehabilitation, Pain Medicine, and Pain Management. He is certified in Cannabis Science through the University of Colorado, is former President of the American Board of Pain Medicine, and has served on that Board's Exam Council for over 25 years. Dr. Finn serves on the Board of Directors of the International Academy on the Science and Impacts of Cannabis ("IASIC") and is the editor of *Cannabis in Medicine: An Evidence-Based Approach* (Springer, 2020). Dr. Finn also served on the Governor's Task Force for Amendment 64, which legalized marijuana for recreational use in Colorado, and served four years on the Colorado Marijuana Scientific Advisory Council. His clinical practice, academic work, and policy involvement place him in direct and ongoing contact with the consequences of inadequate regulatory frameworks governing marijuana as a purported medical therapy. He wishes to prescribe

cannabis to patients for pain management using safe and effective products and following proper dosing requirements, but cannot do so.

Dr. Finn was designated as a participant in the Administrative Hearing and was found to have established standing by Chief Administrative Law Judge John J. Mulrooney II. The ALJ found that Dr. Finn "raised issues related to his pain management practice where he claims that he will be adversely affected by the promulgation of the NPRM" and that "this type of allegation clearly sounds within the reach of the APA and CSA's standing requirements under the regulations, and militate in favor of standing." Order Regarding Standing, Scope, and Prehearing Procedures at 19-20 (Nov. 19, 2024). The ALJ concluded that "all four of the [Standing Criteria] favor standing" and that Dr. Finn had established standing to participate in the Administrative Hearing. *Id.* Dr. Finn is also a named plaintiff in *Smart Approaches to Marijuana, Inc. v. Kennedy*, No. 1:26-cv-01081-TNM (D.D.C.), challenging the Centers for Medicare & Medicaid Services' Substance Access Beneficiary Engagement Incentive.

The Final Order directly and concretely injures Dr. Finn by requiring him, as a practitioner seeking to prescribe cannabis products to his patients for pain management, to do so without the benefit of the standardized dosing protocols, package inserts, drug interaction data, and FDA-approved labeling that ordinarily accompany Schedule III controlled substances—but which are absent in the Final Order. Because the Final Order allows state-licensed dispensaries to dispense marijuana using certifications that omit the drug name, strength, dosage form, quantity prescribed, and directions for use required by 21 C.F.R. § 1306.05(a), Dr. Finn cannot determine whether a patient is consuming a

smoked product of 15% THC or a 95% THC concentrate such as wax or shatter—each carrying materially different risk profiles. This absence of standardized prescribing information also prevents Dr. Finn from evaluating potential cannabis-drug interactions, which presents significant patient safety risks. The Final Order thus bypasses the normal FDA drug-approval process, depriving Dr. Finn of the clinical information necessary to provide informed patient care and exposing him to increased professional liability.

Additionally, Dr. Finn is procedurally injured. Issuing the Final Order arbitrarily and capriciously under Section 811(d) and thereby terminating the ongoing Administrative Hearing, in which he had standing and was prepared to present evidence and arguments, prevents him from participating in the regulatory process and violates his Fifth Amendment right to due process and equal protection of the laws. Issuing the Final Order without notice or comment also violates Dr. Finn's right to provide comments on rulemakings with the force and effect of law.

C. Elizabeth "Libby" B. Stuyt, M.D.

Dr. Elizabeth "Libby" B. Stuyt is a board-certified psychiatrist with Added Qualifications in Addiction Psychiatry from the American Board of Psychiatry and Neurology. She holds a Colorado Medical License and has served as Medical Director of the Circle Program at the Colorado Mental Health Institute at Pueblo and as Senior Instructor in the Department of Psychiatry at the University of Colorado Health Sciences Center. Dr. Stuyt is a member of the Board of Directors and Secretary of the International Academy on the Science and Impacts of Cannabis ("IASIC"), serves on the SAMHSA Drug Testing Advisory Board, the Colorado Retail Marijuana Public Health Advisory

Committee, and the Johnny's Ambassadors Scientific Advisory Board. She is a nationally recognized expert on the harms of high-potency THC and its relationship to psychosis, violence, and addiction. Dr. Stuyt is licensed in Colorado, where state-licensed medical marijuana dispensaries operate under the programs that the Final Order purports to federally endorse.

The Final Order directly and concretely injures Dr. Stuyt in the same manner as Dr. Finn: as a practitioner licensed in a state with a medical marijuana program that the Final Order now federally endorses, Dr. Stuyt is required to navigate a clinical landscape in which marijuana products are dispensed as Schedule III controlled substances without the standardized dosing protocols, package inserts, drug interaction data, or FDA-approved labeling that accompany all other Schedule III drugs. The Final Order deprives Dr. Stuyt of the clinical information necessary to provide informed patient care in her addiction psychiatry practice and exposes her to increased professional liability. Because the Final Order was issued without notice-and-comment rulemaking or a formal hearing, Dr. Stuyt's statutory and constitutional rights to participate in the regulatory process were abridged.

D. Cannabis Industry Victims Educating Litigators (CIVEL)

CIVEL is a marijuana industry victims' advocacy organization that educates lawyers on how to hold the marijuana industry accountable to its victims and enables litigation to protect the rights of cannabis industry victims and to obtain justice for cannabis-related injuries such as psychosis or suicide. CIVEL was designated as a participant in the DEA's prior rescheduling hearing proceedings (DEA Docket No. 1362,

Hearing Docket No. 24-44) and was recognized as having associational standing by the Chief Administrative Law Judge, who found that CIVEL "is apparently engaged in the active representation of individuals who claim/have claimed harmful effects from marijuana, and equips trial attorneys and the public with legal citations and tactical approaches for engaging in anti-marijuana litigation." CIVEL was also recognized as having associational standing in *Botteon v. Murphy*, NJ Superior Court MID-L-002293 (2020). CIVEL is also a named plaintiff in *Smart Approaches to Marijuana, Inc. v. Kennedy*, No. 1:26-cv-01081-TNM (D.D.C.).

The Final Order directly and concretely injures CIVEL by impairing its core programmatic activities: the rescheduling will increase the use of marijuana, reduce the public perception of its dangerousness, lower medical standards for determining what constitutes a medicine, and generate additional victims of the marijuana industry whom CIVEL must serve—all requiring CIVEL to divert staff time and resources from its existing victim assistance and legal education programs to monitor, analyze, and respond to the consequences of the Final Order.

Additionally, CIVEL is procedurally injured. Issuing the Final Order arbitrarily and capriciously under Section 811(d) and thereby terminating the ongoing administrative hearing process in which CIVEL has standing and was prepared to present evidence and arguments prevents CIVEL from participating in the regulatory process and violates its Fifth Amendment right to due process and equal protection of the laws. Issuing the Final Order without notice or comment also violates CIVEL's right to provide comments on rulemakings with the force and effect of law.

E. MMJ International Holdings

MMJIH is a private pharmaceutical cannabinoid development company and the parent of MMJBC and MMJBL. MMJBL holds an active DEA Schedule I analytical laboratory registration. MMJBC has pursued the federal pharmaceutical pathway from inception, securing FDA Investigational New Drug applications, obtaining Orphan Drug Designation for Huntington's disease, developing pharmaceutical soft-gel cannabinoid formulations, building DEA-inspected laboratory systems, and pursuing botanical-drug chemistry under FDA guidance. Duane Boise serves as President and CEO.

The Final Order directly and concretely injures MMJ by creating a regulatory double standard that rewards state-market marijuana operators who operated outside the federal Controlled Substances Act while penalizing federally compliant pharmaceutical developers like MMJ that invested millions in the FDA pathway, DEA registration, and pharmaceutical manufacturing controls. The Final Order's expedited registration pathway for state licensees effectively bypasses the rigorous public-interest standards, criminal-history requirements, and diversion-prevention controls that DEA imposed on pharmaceutical applicants like MMJ, constituting a competitive injury cognizable under Article III. Additionally, MMJBC challenged the constitutionality of the DEA's Administrative Law Judge structure in *MMJ BioPharma Cultivation Inc. v. Bondi*, Civil Action No. 1:24-cv-127-WES-PAS (D.R.I.), and the Department of Justice formally conceded that "the multiple layers of removal restrictions for administrative law judges ('ALJs') in 5 U.S.C. § 7521 do not comport with the separation of powers and Article II." The Final Order compounds this injury by proceeding to restructure the scheduling

framework while the constitutional defect in the DEA's adjudicatory system remains unresolved. Because the Final Order was issued without notice-and-comment rulemaking or a formal hearing, MMJ's statutory and constitutional rights were abridged.

IV. Statement of Issues Presented For Review

Petitioners seek review and vacatur of the Final Order on the following grounds, which will be developed fully in Petitioners' opening brief:

1. Whether the Final Order is *ultra vires* and in excess of the Attorney General's statutory authority under 21 U.S.C. § 811(d)(1), which the D.C. Circuit in *NORML v. DEA*, 559 F.2d 735 (D.C. Cir. 1977), construed as having a "limited purpose" that does not authorize placement of marijuana below Schedule II, where the Single Convention on Narcotic Drugs does not require Schedule III placement.
2. Whether the Final Order is unlawful because it creates a hybrid schedule not authorized by Congress or Section 811(d), by placing marijuana in Schedule III while simultaneously imposing Schedule I- and II-style regulatory requirements (quotas, import-export permits, enhanced registration) that are not characteristic of Schedule III, effectively creating a regulatory framework that Congress never enacted.
3. Whether the Final Order is arbitrary and capricious under 5 U.S.C. § 706(2)(A) because the agency failed to adequately consider marijuana's well-documented health risks—including the well-documented harms of cannabis use, such as the onset and exacerbation of serious mental health disorders

(including psychosis, bipolar, PTSD, depression, and anxiety) impaired adolescent neurological development, prenatal exposure risks, respiratory damage, drugged driving fatalities, cannabis use disorder, and cardiovascular harm—which DEA's own scientific review in the Administrative Hearing extensively documented but which the Final Order failed to meaningfully address or reconcile with prior agency findings.

4. Whether the Final Order is arbitrary and capricious because the agency failed to provide FDA-quality indication, dosing, risk-benefit, delivery, and monitoring systems and guidance and other information to physicians that is required to properly prescribe marijuana to patients.

5. Whether the Final Order is arbitrary and capricious because it relies on state medical marijuana licensing programs that do not satisfy the "adequate safeguards" required by the Single Convention on Narcotic Drugs—including the Convention's requirements for medical prescriptions (Article 30), manufacturing quotas (Article 21), and import-export permits (Article 31)—where state programs instead rely on "recommendations" or "certifications" that do not satisfy these treaty obligations.

6. Whether the Final Order is arbitrary and capricious under 5 U.S.C. § 706(2)(A) because it lacks any rational evidentiary basis for its implicit determination that marijuana as dispensed under state medical marijuana programs constitutes an effective medical treatment, where

a. no marijuana product dispensed under a state license has received FDA approval, and the agency's rescheduling to Schedule III—a schedule historically reserved for drugs that have undergone FDA review—represents an unexplained departure from the agency's own longstanding practice and the CSA's statutory framework requiring consideration of "scientific evidence of [the drug's] pharmacological effect," 21 U.S.C. § 811(c)(3), and "the state of current scientific knowledge regarding the drug," id. § 811(c)(4);

b. the state medical marijuana programs on which the Final Order relies are so widely divergent in their qualifying conditions, permitted product types, potency limitations, dosing requirements, and oversight mechanisms that no rational scheduling determination can be applied uniformly across the category the agency has defined—rendering the agency's factual premise that these programs constitute a coherent regulatory category for CSA scheduling purposes arbitrary on its face; and

c. there is no body of adequate and well-controlled scientific studies demonstrating that cannabis as sold in state-licensed dispensaries—as distinguished from isolated, pharmaceutical-grade cannabinoid formulations—can effectively treat any specific medical condition with the degree of scientific rigor historically required for CSA

scheduling determinations. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

7. Whether the Final Order was issued without observance of procedure required by law, in violation of the APA's notice-and-comment requirements, 5 U.S.C. § 553, and the CSA's requirement that scheduling rules be "made on the record after opportunity for a hearing," 21 U.S.C. § 811(a), where the Final Order was issued as an immediately effective order without prior notice-and-comment rulemaking or a formal hearing on the record.
8. Whether the Final Order deprived Petitioners of procedural due process under 21 U.S.C. § 811(a) by circumventing their statutory right to a hearing on the record—including by withdrawing the prior Notice of Hearing and terminating the proceedings before the ALJ in which Petitioners Dr. Finn and CIVEL had established standing, filed prehearing statements, and prepared for a hearing originally scheduled for December 2, 2024—and issuing a final order effective April 22, 2026 without any recourse to a hearing or public comment.
9. Whether the Final Order violates the major questions doctrine under *West Virginia v. EPA*, 597 U.S. 697 (2022), because the Attorney General used the ancillary treaty-implementation provision of § 811(d)(1) to accomplish a decision of vast economic and political significance—including the restructuring of DEA regulations and the immediate elimination of the 26 U.S.C. § 280E tax bar for state-licensed marijuana businesses—without clear

congressional authorization for such economically and politically transformative action.

10. Whether the Final Order violates the equal protection component of the Fifth Amendment's Due Process Clause by creating a novel, condition-based scheduling framework that treats chemically identical marijuana products differently based solely on whether they are covered by a state medical marijuana license or FDA approval, without rational basis in the CSA's statutory structure.
11. Whether the Final Order contravenes the United States' obligations under the Single Convention on Narcotic Drugs, where DOJ's own Office of Legal Counsel conceded that Schedule III alone does not fully satisfy the Convention's requirements and the State Department acknowledged that only "most—but not all" of the Convention's obligations would be met.
12. Whether the Final Order is unlawful under *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024), because the Acting Attorney General's contested interpretation of § 811(d)(1) cannot survive *de novo* judicial review of the statute's best meaning.
13. Whether the Final Order is unlawful because it was issued under the authority of an administrative structure that the Department of Justice itself has conceded violates the separation of powers and Article II of the Constitution, where DOJ formally acknowledged in *MMJ BioPharma Cultivation Inc. v. Bondi*, Civil Action No. 1:24-cv-127-WES-PAS (D.R.I.), that "the multiple layers of

removal restrictions for administrative law judges ('ALJs') in 5 U.S.C. § 7521 do not comport with the separation of powers and Article II," and the same constitutionally defective administrative structure is expected to conduct the expedited rescheduling hearing commencing June 29, 2026. *See Axon Enterprises, Inc. v. FTC*, 598 U.S. 175 (2023).

V. Relief Requested

WHEREFORE, Petitioners respectfully request that this Court:

a. Stay the effectiveness of the Final Order under 5 U.S.C. § 705 pending this Court's review, or, in the alternative, remand to the agency with instructions to stay the order pending completion of the formal rulemaking procedures required by 21 U.S.C. § 811(a);

b. Declare the Final Order, AG Order No. 6754-2026, 91 Fed. Reg. 22,714 (Apr. 28, 2026), to be unlawful, arbitrary and capricious, *ultra vires*, in excess of statutory authority, issued without observance of procedure required by law, and in violation of the Constitution and laws of the United States;

c. Vacate and set aside the Final Order in its entirety;

d. Award Petitioners their costs and reasonable attorneys' fees to the extent permitted by law; and

e. Grant such other and further relief as this Court deems just and proper.

Date: May 28, 2026

Respectfully submitted,

/s/Connor W. Mighell

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Attorney for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that on May 28, 2026, I caused a true and correct copy of this Petition for Review to be delivered to the Attorney General of the United States as required by 21 U.S.C. § 877, and to be served upon the following parties by U.S. first-class and certified mail, return receipt requested.

President Donald J. Trump
1600 Pennsylvania Avenue
Washington, DC 20500

The Hon. Todd Blanche
Acting Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530

In accordance with 21 C.F.R. § 1316.68, I have sent five true and correct copies of this Petition for Review by U.S. first-class and certified mail, return receipt requested, at the following address.

The Hon. Terrance C. Cole
Administrator
Drug Enforcement Administration
8701 Morissette Drive
Springfield, VA 22152

Respondent agencies will be served by the Clerk of Court pursuant to FRAP 15(c).

/s/Connor W. Mighell
Connor W. Mighell

EXHIBIT A

is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Executive Order 12866

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

Signing Authority

In accordance with Treasury Order 100–20, the Secretary of the Treasury has delegated to the Secretary of Homeland Security the authority related to the customs revenue functions vested in the Secretary of the Treasury as set forth in 6 U.S.C. 212 and 215, subject to certain exceptions. This regulation is being issued in accordance with Department of Homeland Security Delegation 07010.3, Revision 03.2, which delegates to the Commissioner of CBP the authority to prescribe and approve regulations related to cultural property import restrictions.

Rodney S. Scott, Commissioner, having reviewed and approved this document, has delegated the authority to electronically sign this document to the Director of the Regulations and Disclosure Law Division of CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, and Reporting and recordkeeping requirements.

Amendment to the CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, amend the table in paragraph (b) by revising the entry for Afghanistan to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

* * * * *

(b) * * *

State party	Cultural property	Decision No.
*	*	*
Afghanistan	Archaeological material of Afghanistan ranging in date from 50,000 B.C. through A.D. 1747, and ethnological material of Afghanistan ranging in date from the 9th century A.D. through A.D. 1920.	CBP Dec. 22–04, extended by CBP Dec. 26–09.
*	*	*

Robert F. Altneu,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2026–08223 Filed 4–27–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1308, and 1312

[AG Order No. 6754–2026]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, which constitutes a final order, the Acting Attorney General of the U.S. Department of Justice places drug products containing marijuana that have been approved by the Food and Drug Administration (FDA) in schedule III of the Controlled Substances Act (''CSA''). This action is required to satisfy the responsibility of the Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961. In general, this final rule applies to marijuana as defined in the CSA, marijuana extracts, and delta-9-tetrahydrocannabinol and other compounds derived from the marijuana plant (other than the mature stalks and seeds) that falls outside the definition of hemp, to the extent that any of these are included in an FDA-approved drug product or are subject to

a state-issued license to manufacture, distribute, and/or dispense marijuana or products containing marijuana for medical purposes (''state medical marijuana license''). Also consistent therewith, this final rule adds such drugs to the list of substances that may only be imported or exported pursuant to a permit. This final rule also establishes an expedited registration process under 21 CFR part 1301 for entities holding state medical marijuana licenses, enabling such entities to engage in the manufacture, distribution, and/or dispensing of marijuana for medical purposes under federal law consistent with the requirements of the Single Convention.

DATES: Effective April 28, 2026.

ADDRESSES: 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Dr. Clara Hellickson, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The United States' Treaty Obligations

The United States is a party to the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 (''Single Convention''), as amended by the 1972 Protocol. The Single Convention entered into force for the United States on June 24, 1967, after the Senate gave its advice and consent to the United States' accession.[1] The enactment and enforcement of the CSA are the primary means by which the United States carries out its obligations under the Single Convention.[2] Various provisions of the CSA directly reference the Single Convention. One such provision is 21 U.S.C. 811(d)(1), which relates to scheduling of controlled substances.

Under 21 U.S.C. 811(d)(1), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970''—which includes the Single Convention—the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [21 U.S.C. 811(a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811(a) and (b)].'' [3] This provision is consistent with the Supremacy Clause of the U.S. Constitution, which provides that all treaties made under the authority of the United States ''shall be the supreme Law of the Land.'' [4] In accordance with this constitutional mandate, under section 811(d)(1), Congress directed the Attorney General to ensure that compliance by the United States with our nation's obligations under the Single Convention is given top consideration when it comes to scheduling determinations.[5] Importantly, the Department of Justice's Office of Legal Counsel (OLC) concluded in a 1972 opinion that 21 U.S.C. 811(d)(1) is not limited to those instances where a substance is newly added to an international schedule.[6]

Parties to the Single Convention are required to impose several control measures regarding drugs listed in Schedule I of the Convention.[7] These include the following:

- Limiting exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of such drugs. Article 4.
- Furnishing to the International Narcotics Control Board (INCB) annual estimates of, among other things, quantities of such drugs to be consumed for medical and scientific purposes, utilized for the manufacture of other drugs, and held in stock. Article 19.
- Furnishing to the INCB statistical returns on the actual production, utilization, consumption, imports and exports, seizures, and stocks of such drugs during the prior year. Article 20.
- Requiring that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Articles 21 & 29.
- Requiring manufacturers and distributors of such drugs to be licensed. Articles 29 & 30.
- Requiring medical prescriptions for the dispensing of such drugs to patients. Article 30.
- Requiring importers and exporters of such drugs to be licensed and requiring each individual importation or exportation to be predicated on the issuance of a permit. Article 31.
- Prohibiting the possession of such drugs except under legal authority. Article 33.
- Requiring those in the legitimate distribution chain (manufacturers, distributors, scientists, and those who lawfully dispense such drugs) to keep records that show the quantities of such drugs manufactured, distributed, dispensed, acquired, or otherwise disposed of during the prior two years. Article 34.

Because the CSA was enacted in large part to satisfy United States obligations under the Single Convention, many of the CSA's provisions directly implement the foregoing treaty requirements.

Under the Single Convention, cannabis, cannabis resin, and extracts and tinctures of cannabis are listed in Schedule I.[8] The CSA, in implementing

[1] *See* Single Convention, 18 U.S.T. 1407.

[2] *See* S. Rep. No. 91–613, at 4 (1969) (''The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility.''); *Office of Legal Counsel, Control of Papaver Bracteatum,* 1 Op. O.L.C. 93, 95 (1977) (''[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention.'').

[3] *See also* 21 CFR 1308.46.

[4] U.S. Const., art. VI, sec. 2.

[5] The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration. 28 CFR 0.100.

[6] *Petition to Decontrol Marijuana; Interpretation of Section 201 of the Controlled Substances Act of 1970,* Op. O.L.C. at 7–8 (Aug. 21, 1972) (recognizing that the House Report ''clearly shows that a much broader application was intended''). Consistent with this understanding of the CSA and the Single Convention, on September 28, 2018, DEA issued a final rule under 21 U.S.C. 811(d)(1) placing FDA-approved drug products that contain cannabidiol (CBD) derived from the cannabis plant and no more than 0.1 percent tetrahydrocannabinols (THC) into schedule V of the CSA. *See Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements,* 83 FR 48950 (Sept. 28, 2018).

[7] The text of the Single Convention capitalizes schedules (*e.g.,* ''Schedule I''). In contrast, the text of the CSA generally refers to schedules in lower case. This document will follow this approach of using capitalization or lower case depending on whether the schedule is under the Single Convention or the CSA. It should also be noted that the schedules of the Single Convention operate somewhat differently than the schedules of the CSA. Unlike the CSA, the Single Convention imposes additional restrictions on drugs listed in Schedule IV that go beyond those applicable to drugs listed in Schedule I. All drugs in Schedule IV of the Single Convention are also in Schedule I of the Convention. Cannabis and cannabis resin are among the drugs were also listed in Schedule IV of the Single Convention, but the U.N. Commission on Narcotic Drugs removed cannabis from Schedule IV in 2020.

[8] Under the Single Convention, '''[c]annabis plant' means any plant of the genus Cannabis.'' Single Convention art. 1(1)(c). The Single Convention defines ''cannabis'' to mean ''the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.'' *Id.* art. 1(1)(b). This definition of ''cannabis'' under the Single Convention is slightly less inclusive in certain respects than the CSA definition of ''marijuana,'' which includes all parts of the cannabis plant except for the mature stalks, sterilized seeds, oil from the seeds, and certain derivatives thereof. *See* 21 U.S.C. 802(16). Cannabis and cannabis resin are included in the list of drugs

Continued

these requirements, generally defines marijuana to mean ''the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.'' [9] In 2018, Congress amended the CSA to remove ''(i) hemp, as defined in section [1639*o* of title 7 of the U.S. Code]'' from the definition of marijuana.[10] Section 1639*o*(1) of title 7, in turn, defines hemp as ''the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.'' [11] Delta-9-tetrahydrocannabinol (Δ9–THC) is the major psychoactive intoxicating cannabinoid in marijuana. This exclusion of hemp from the definition of marijuana had the effect of removing many products containing predominantly cannabidiol (''CBD'') derived from hemp and containing no more than 0.3 percent Δ9–THC on a dry weight basis from control as marijuana. Effective November 12, 2026, the definition of hemp in 7 U.S.C. 1639*o*(1) is being amended, with corresponding impact on the definition of marijuana in 21 U.S.C. 802(16)(A).

In addition to the requirements for drugs in Schedule I discussed above, the Single Convention requires the United States to take the following additional measures specific to the growing of marijuana plants within the United States:

- Register and regulate growers, including by designating the land upon which they may grow marijuana plants;
- Limit growing of the marijuana plant to that required for legitimate domestic scientific, medical, and industrial needs, and for legitimate exports;
- Establish the upper limit of marijuana that each grower may grow in a calendar year, as well as the total amount of marijuana that can be grown in the United States annually for legitimate needs;
- Purchase all harvested crops of marijuana and monopolize the wholesale trade in harvested marijuana.[12]

Moreover, the CSA also recognizes that the United States is also a party to the Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175 (Convention on Psychotropic Substances).[13] As with the Single Convention, parties to the Convention on Psychotropic Substances are obligated to take various control measures related to the drugs that are covered by the treaty.[14] Congress implemented the additional authority necessary to comply with the Convention on Psychotropic Substances through various amendments to the CSA.[15] Δ9–THC is a substance covered by schedule II of the Convention on Psychotropic Substances, in addition to being covered by Schedule I of the Single Convention if it is extracted from the cannabis plant. This final rule places in schedule III (i) those FDA-approved drug products that contain Δ9–THC falling within the CSA's definition of marijuana, specifically FDA-approved drug products containing Δ9–THC derived from the plant Cannabis sativa L., other than the mature stalks and seeds; and (ii) marijuana subject to a state medical marijuana license.

Existing State Regulatory Systems

Over the last three decades, forty U.S. states have legalized the sale and use of marijuana for medical purposes as a matter of state law and have established systems to regulate that activity. States that have authorized medical marijuana have done so through a licensing regime that restricts cultivation, manufacture, and distribution to entities approved by a designated state agency—typically a department of health, department of agriculture, or a dedicated cannabis regulatory authority. These agencies conduct application review, perform inspections, and maintain ongoing oversight of licensees. State licensees are required to maintain detailed records of plant counts, harvested quantities, inventory levels, and sales or transfers, and to report that information to state regulators on a periodic basis. State medical licensing regimes oversee permissible uses of medical marijuana, confining distribution to registered patients or caregivers through approved dispensaries or other authorized channels. Registered and licensed physicians oversee patient qualification for medical marijuana based on state specific criteria and qualifying conditions.

Authority To Place Certain Marijuana Products in Schedule III

The Administrator has the authority under Section 811(d)(1) of the CSA to move FDA-approved drug products containing marijuana and marijuana subject to state-issued licenses to Schedule III.

Based on a 2024 OLC opinion, if marijuana is listed in schedule III, most of the Single Convention's obligations noted above will continue to be met by CSA statutory authorities and associated regulations.[16] Similarly, the controls available under schedule III are also sufficient to comply with the requirements of the Convention on Psychotropic Substances with respect to Δ9–THC. As discussed in more detail below, this final rule ensures that the United States will continue to meet these obligations without delay or disruption.

As indicated above, Article 31 of the Single Convention obligates parties to require a permit for the importation and exportation of drugs listed in Schedule I of the Convention. This permit requirement applies to drug products containing marijuana because, as further indicated above, such a product is a Schedule I drug under the Single Convention. However, under the CSA [17] and DEA regulations, the import/export permit requirement does not apply to all controlled substances. Rather, a permit is required to import or export any controlled substance in schedule I and II as well as certain controlled substances in schedules III, IV, and V.[18] Thus, in order to control FDA-approved drug products containing marijuana and

in Schedule I of the Single Convention, and cannabis is subject to the same controls as Schedule I drugs as well as additional controls. *See* Single Convention art. 2(6); *id.* art. 28.

[9] 21 U.S.C. 802(16)(A).

[10] Agricultural Improvement Act of 2018, Public Law 115–334, sec. 12619; 132 Stat. 4490, 5018.

[11] As of November 12, 2026, this definition is revised to refer to a ''total a total tetrahydrocannabinols concentration (including tetrahydrocannabinolic acid) of not more than 0.3 percent on a dry weight basis,'' rather than the current reference to the concentration of Δ9–THC. Public Law 119–37, sec. 781.

[12] DEA implemented the requirement to purchase harvested crops of marijuana and to monopolize the wholesale trade in marijuana through regulations pursuant to a 2018 OLC opinion. *See Office of Legal Counsel, Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs,* 42 Op. O.L.C. 1 (June 6, 2018), *https://www.justice.gov/olc/file/1272131/dl?inline* (''2018 OLC Opinion'').

[13] *See also* 21 U.S.C. 801a(2).

[14] *Id.*

[15] *Id.* 801a(2)–(3).

[16] *See Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana,* 45 Op. O.L.C., at *33–34 (Apr. 11, 2024).

[17] The provisions of federal law relating to the import and export of controlled substances—those found in 21 U.S.C. 951 through 971—are more precisely referred to as the Controlled Substances Import and Export Act. However, federal courts and DEA often use the term ''CSA'' to refer collectively to all provisions from 21 U.S.C. 801 through 971 and, for ease of exposition, this document will do likewise.

[18] *See* 21 U.S.C. 952 and 953; 21 CFR 1312.11, 1312.12, 1312.21, 1312.22.

marijuana subject to state-issued licenses in schedule III, DEA must simultaneously amend the regulations to require a permit to import or export such products.

It bears emphasis that where, as here, control of a drug is required by the Single Convention, an order under 21 U.S.C. 811(d)(1) must be issued ''*without regard to* the findings required by [21 U.S.C. 811 (a) or 812(b)] and *without regard to* the procedures prescribed by [21 U.S.C. 811 (a) or (b)].'' Thus, in such circumstances, the plain and unambiguous statutory language does not require the Administrator to request a medical and scientific evaluation or scheduling recommendation from the Department of Health and Human Services (HHS), as is normally done pursuant to rulemaking under section 811(b).[19]

Nonetheless, in a letter dated August 29, 2023, HHS provided DEA with a medical and scientific evaluation and scheduling recommendation that marijuana be controlled in schedule III of the CSA.[20] HHS found, *inter alia,* that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II, and that the abuse of marijuana may lead to moderate or low physical dependence or high psychological dependence.[21] These findings would correspond to the criteria for placement of a substance in schedule III.[22] While each of these findings are discussed briefly below, HHS's scientific and medical evaluation entitled, ''Basis for the Recommendation to Reschedule Marijuana Into Schedule III of the Controlled Substances Act,'' is available in its entirety under the ''Supporting and Related Material'' of the public docket for this final rule at *https://www.regulations.gov* under docket number DEA–1362.

First, HHS found that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II. As noted above, marijuana contains Δ9–THC, the substance responsible for the abuse potential of marijuana. Δ9–THC has agonist properties at CB_1 cannabinoid receptors and produces rewarding responses in animals, as evidenced by its ability to produce self-administration and CPP. When marijuana is administered to humans under experimental conditions, it produces a wide range of positive subjective responses in addition to certain negative subjective responses. Common responses to marijuana when it is used by individuals for nonmedical purposes include euphoria and other positive subjective responses, as well as perceptual changes, sedative responses, anxiety responses, psychiatric, social, and cognitive changes, and physiological changes.[23]

HHS noted that epidemiological data from the 2022 National Survey on Drug Use and Health (NSDUH) show that marijuana is the most frequently used federally illicit drug in the United States on a past-year and past-month basis among the illicit comparator drugs considered. Although 50 percent of respondents in NSDUH reported using marijuana nonmedically fewer than 5 days per month, another 30 percent reported using it nonmedically for 20 days or more per month.[24]

Despite the high prevalence of nonmedical use of marijuana, HHS observed that an overall evaluation of epidemiological indicators suggests that it does not produce serious outcomes compared to drugs in schedules I or II. HHS found this especially notable given the availability of marijuana and marijuana-derived products that contain extremely high levels of Δ9–THC. Due to such availability, the epidemiological data described in HHS's evaluation inherently include the outcomes from individuals who use marijuana and marijuana-derived products that have doses of Δ9–THC that range from low to very high, and yet the data demonstrate that these products overall are producing fewer negative outcomes than drugs in schedules I or II.[25]

HHS compared the rank ordering of selected drugs that are abused for various epidemiological measures and observed that marijuana was among the drugs at the very lowest ranking for a number of measures, including poison center (PC) abuse cases, likelihood that any use would lead to a PC call, accidental or unintentional poisoning, utilization-adjusted rates of unintentional exposure, utilization-adjusted and population-adjusted rates for emergency department visits and hospitalizations, likelihood of being diagnosed with a serious substance abuse disorder, deaths reported to PCs, and overdose deaths when used with other drugs or as a single substance (as total numbers and when utilization-adjusted). In contrast, comparators such as heroin (schedule I), oxycodone (schedule II), and cocaine (schedule II) typically were in the highest rank ordering on these measures.[26]

For the various epidemiological measures evaluated above, HHS noted that marijuana was also compared to controlled substances in schedule III (ketamine) and schedule IV (benzodiazepines, zolpidem, and tramadol), as well as to other schedule II substances (fentanyl and hydrocodone). The analyses were conducted in this manner to provide a comprehensive assessment of the relative abuse potential of marijuana. However, the rank order of these substances regarding harms does not consistently align with the relative scheduling placement of these drugs in the CSA due to the pharmacological differences between various classes of drugs.[27]

There are a number of confounding factors that likely influence the adverse outcomes measured in various epidemiological databases and account for the rank ordering of the drugs evaluated on these measures. For example, a different population abuses each substance, and each substance has

[19] In the House Report to the bill that would become the CSA, this issue is explained as follows:

Under subsection [811(d)], where control of a drug or other substance by the United States is required by reason of its obligations under [the Single Convention], the bill does not require that the Attorney General seek an evaluation and recommendation by the Secretary of Health, Education, and Welfare, or pursue the procedures for control prescribed by the bill but he may include the drug or other substance under any of the five schedules of the bill which he considers most appropriate to carry out the obligations of the United States under the international instrument, and he may do so without making the specific findings otherwise required for inclusion of a drug or other substance in that schedule.

H. Rep. No. 91–1444, at 36 (1970). *See also Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements,* 83 FR 48950, 48952 & n.8 (Sept. 28, 2018). Of note, a 1977 D.C. Circuit decision considered not the plain text of the statute, but rather certain aspects of the legislative history, to conclude that 21 U.S.C. 811(d)(1) still requires DEA to request a scientific and medical evaluation and scheduling recommendation from HHS in certain circumstances, such as when a substance can be placed in more than one schedule under the CSA and still satisfy obligations under the Single Convention. *Nat'l Org. for Reform of Marijuana Laws (NORML)* v. *Drug Enforcement Admin.,* 559 F.2d 735, 746–47 (D.C. Cir. 1977) (stating that the ''language of Section 201(d) is consistent with the clear import of the Act's legislative history,'' including certain floor debates and comments by various congressmen, and ''must be read against this backdrop of intense concern with establishing and preserving [HHS's] avenue of input into scheduling decisions''). Because HHS has provided DEA with a medical and scientific evaluation and scheduling recommendation for marijuana, DEA has met this additional procedural requirement.

[20] *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023) (''August 2023 Letter''); *see also* Memorandum for DEA, from HHS, *Re:* Basis for the Recommendation to Reschedule Marijuana to Schedule III of the Controlled Substances Act (''HHS Basis for Rec.'').

[21] HHS Basis for Rec. at 62–65.

[22] *See* 21 U.S.C. 812(b)(3).

[23] HHS Basis for Rec. at 62.

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.* at 63.

a different prevalence of abuse and a different profile of severe adverse outcomes in a setting of nonmedical use and abuse. Thus, it is challenging to reconcile the ranking of relative harms associated with the comparators used in this evaluation when the rankings differ across various epidemiological databases and when these rankings often do not align with the scheduling placement of these comparators under the CSA.[28]

To address these challenges, HHS evaluated the totality of the available data and concluded that it supports the placement of marijuana in schedule III. Overall, these data demonstrate that, according to HHS, although marijuana is associated with a high prevalence of abuse, the profile of and propensity for serious outcomes related to that abuse lead to a conclusion that marijuana is most appropriately controlled in schedule III under the CSA.[29]

Second, HHS found that abuse of marijuana may lead to moderate or low physical dependence or high psychological dependence.[30] Regarding physical dependence, as evidenced by its associated withdrawal symptomology upon abrupt discontinuation of use, the most commonly reported marijuana withdrawal symptoms in clinical investigations are sleep difficulties, decreased appetite and weight loss, craving, irritability, anger, anxiety or nervousness, and restlessness. Marijuana withdrawal symptoms typically peak within two to six days and decline over one to two weeks as Δ9–THC is eliminated. Similarly, the drug labels for the FDA-approved drug products Marinol and Syndros state that, following chronic administration of dronabinol, drug discontinuation leads to irritability, insomnia, and restlessness at 12 hours, and by 24 hours the withdrawal symptoms can include hot flashes, sweating, rhinorrhea, diarrhea, and anorexia.[31]

HHS observed that marijuana withdrawal syndrome has been reported in individuals with heavy, chronic marijuana use, but its occurrence in occasional users of marijuana has not been established. Marijuana withdrawal syndrome appears to be relatively mild compared to the withdrawal syndrome associated with alcohol, which can include more serious symptoms such as agitation, paranoia, seizures and even death. Multiple studies comparing the withdrawal symptoms associated with marijuana and tobacco demonstrate that the magnitude and time course of the two withdrawal syndromes are similar.[32]

Based on the evidence, HHS determined that the abuse of marijuana may lead to moderate or low physical dependence, depending on frequency and degree of marijuana exposure. HHS further concluded that marijuana can produce psychic dependence in some individuals, but that the likelihood of serious outcomes is low, suggesting that high psychological dependence does not occur in most individuals who use marijuana.[33]

Although I am not required to consider this HHS recommendation when issuing an order under section 811(d)(1), because I believe there are several legally viable scheduling options that would satisfy the United States' obligations under the Single Convention based on OLC's 2024 opinion discussed above, I exercise my discretion in determining the most appropriate schedule by choosing the option that most closely aligns to HHS's findings and best positions the United States to carry out its obligations under the Single Convention with regard to marijuana crops and other marijuana that has not yet been manufactured into an FDA-approved product or subject to a state medical marijuana license. Namely, I am hereby ordering that FDA-approved drug products containing marijuana, as well marijuana in any form covered by a state medical marijuana license, be placed in schedule III of the CSA.[34]

Additionally, maintaining unlicensed bulk marijuana in schedule I allows the United States to continue to meet two of its obligations under the Single Convention without disruption. First, as indicated above, for drugs listed in Schedule I of the Single Convention, parties are obligated to require that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture. The purpose of this treaty requirement is to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Under this scheduling order, the United States will continue to meet this obligation without disruption or delay because unlicensed bulk marijuana, marijuana extract, and Δ9–THC material used to make FDA-approved drug products will remain in schedule I of the CSA and thus be subject to all applicable quota provisions under 21 U.S.C. 826; and because state-licensed marijuana will be required to meet the quota requirements of the Single Convention.

Second, as also discussed above, pursuant to a 2018 OLC opinion, DEA must buy marijuana crops from registered manufacturers, be the seller of that marijuana to any eligible registered purchaser, and establish prices for such purchase and sale.[35] Marijuana growers must pay DEA an administrative fee for such transactions.[36] These actions are necessary for the United States to meet its obligations under articles 23 and 28 of the Single Convention.[37] By maintaining in schedule I all unlicensed marijuana crops, bulk marijuana, and any marijuana or marijuana extract that has not yet been incorporated into a FDA-approved drug product, and by requiring that state-licensed marijuana satisfy the requirements relating to the purchase and sale of marijuana by DEA, the United States will continue to meet these obligations without disruption or delay.

Placing only FDA-approved products containing marijuana and state-licensed marijuana in schedule III also is consistent with articles 23 and 28 of the Single Convention and 21 CFR 1318.04(b), which specify that the requirement to monopolize the wholesale trade in marijuana does not extend to ''medicinal cannabis.'' Medicinal cannabis is defined in 21 CFR 1318.02(b) to mean ''a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act [(FD&C Act)].'' The final rule exempts marijuana subject to state medical marijuana licenses from the requirement to monopolize the wholesale trade in marijuana.

This final rule rescheduling marijuana contained in FDA-approved products or subject to a state medical marijuana license applies to marijuana as listed in 21 CFR 1308.11(d)(23), as well as marijuana extracts as defined in 21 CFR 1308.11(d)(58) because they meet the statutory definition of marijuana and, prior to 2017, were included in 21 CFR 1308.11(d)(23).[38] In addition, this final

[28] *Id.*

[29] *Id.*

[30] *Id.* at 65.

[31] *Id.* at 64.

[32] *Id.*

[33] *Id.* at 65.

[34] Article 5 of the Single Convention requires parties to take legislative and administrative measures ''to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of'' the substances covered by the treaty. In this order, DEA is carrying out this obligation by limiting the rescheduling to FDA-approved drug products and marijuana covered by licenses issued under state-medical-marijuana regulatory regimes.

[35] *See 2018 OLC Opinion, supra n.12. See also* 21 CFR 1318.06(b).

[36] 21 CFR 1318.06.

[37] *2018 OLC Opinion, supra n.12. See also* Single Convention arts. 23, 28.

[38] *See Establishment of a New Drug Code for Marijuana Extract,* 81 FR 90194 (Dec. 14, 2016).

rule applies to Δ9–THC derived from the marijuana plant (other than the mature stalks and seeds) that falls outside the definition of hemp, because it meets the statutory definition of marijuana.

This final rule does not apply to synthetically derived THC, which is outside the CSA's definition of marijuana. Tetrahydrocannabinols that can be derived only through a process of artificial synthesis (*e.g.,* delta-10-tetrahydrocannabinol) are excluded. HHS provided a scientific and medical evaluation only relating to ''marijuana'' as defined in the CSA. That definition is limited to the plant (other than the mature stalks and seeds) and derivatives of the plant. Therefore, synthetic THC remains in schedule I.

This final rule also does not affect the status of hemp (as defined in 7 U.S.C. 1639*o*), because hemp is excluded from the definition of marijuana. This final rule is not rescheduling any drug product containing marijuana or THC that previously has been rescheduled out of schedule I (*e.g.,* Marinol and Syndros). Nor does it impact the status of any previously scheduled synthetic cannabinoids.

As noted, this order placing FDA-approved drug products containing marijuana and state-licensed medical marijuana in schedule III will only comport with 21 U.S.C. 811(d)(1) if all importations and exportations of products containing marijuana remain subject to the permit requirement. Until now, since all marijuana has been a schedule I controlled substance, any importation has been subject to the permit requirement. To ensure this requirement remains in place (and thus to prevent any lapse in compliance with the requirements of the Single Convention), this order amends the DEA regulations (21 CFR 1312.30) to add FDA-approved drug products containing marijuana and state-licensed medical marijuana to the list of nonnarcotic schedule III through V controlled substances that are subject to the import and export permit requirement.[39]

Tax Implications

The Acting Attorney General further notes that, as a consequence of this rule, state licensees will no longer be subject to the deduction disallowance imposed by Section 280E of the Internal Revenue Code, which applies only to businesses engaged in ''trafficking in controlled substances . . . in a schedule I or II,'' 26 U.S.C. 280E. Nothing in this rule constitutes a determination regarding federal tax liability, and qualifying state licensees should consult with tax counsel regarding the applicability of Section 280E to their specific circumstances.

Requirements for Handling FDA-Approved Drug Products Containing Marijuana

Preliminarily, it should be noted that any form of marijuana other than in an FDA-approved drug product or marijuana subject to a state medical marijuana license remains a schedule I controlled substance, and those who handle such material remain subject to the regulatory controls, and administrative, civil, and criminal sanctions, applicable to schedule I controlled substances set forth in the CSA and DEA regulations.

However, for those who handle marijuana exclusively in the form of an FDA-approved drug product, the following is a summary of the schedule III regulatory requirements that will apply upon the effective date of this final rule:

1. *Registration.* Any person who handles (*e.g.,* manufactures, distributes, dispenses, imports, exports, engages in research, reverse distributes, or conducts instructional activities or chemical analysis with) FDA-approved drug products containing marijuana must be registered with DEA to conduct such activities.[40] That is, persons and entities wishing to distribute or dispense (including prescribe) marijuana in an FDA-approved product must first obtain a DEA registration applicable to schedule III controlled substances. Entities that transfer marijuana to patients, including dispensaries, must register with DEA as ''practitioners'' under 21 U.S.C. 823(g). Registration under that provision does not allow the practitioner to possess or dispense (including prescribe) schedule I controlled substances, including marijuana and marijuana extracts that are in a form other than an FDA-approved drug product or marijuana subject to a state medical marijuana license.

2. *Disposal of stocks.* Schedule III FDA-approved drug products containing marijuana must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Fees.* Each applicant for registration, other than those employed by state or Federal governments, must pay a registration fee. Current fees are: (1) Manufacturers: $3,699 annually; (2) Distributors: $1,850 annually; and (3) Dispensers, including pharmacies: $888 for a registration valid for 3 years.

4. *Prescriptions.* Prescriptions for FDA-approved drug products containing marijuana are required prior to dispensing, except when dispensed directly by a DEA-registered practitioner, such as a physician, dentist, veterinarian, or hospital.[41] Prescriptions must be ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.'' [42] Prescriptions must include ''the drug name, strength, dosage form, quantity prescribed, directions for use,'' among other items.[43] Under DEA's regulations, both the prescribing practitioner and the pharmacist who fills the prescription have responsibility for the proper prescribing and/or dispensing of controlled substances.[44]

5. *Records and Reports.* All DEA registrants must maintain records and submit reports with respect to FDA-approved drug products containing marijuana.[45]

6. *Security.* All DEA registrants must comply with regulatory security requirements.[46]

7. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of FDA-approved drug products containing marijuana must meet all applicable schedule III labeling and packaging requirements.[47]

8. *Inventory.* Any person registered with DEA to handle FDA-approved drug products containing marijuana must make an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances. After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including

[39] It is DEA's intention that the provisions of this final rule shall operate independently of each other. If this final rule, or any portion of this final rule, is ultimately declared invalid or stayed as to a particular provision, it is DEA's intent that the final rule nonetheless be severable and remain valid with respect to those provisions not affected by a declaration of invalidity or stayed. DEA concludes it would separately adopt all of the provisions contained in this final rule.

[40] 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301, 1312, and 1318.

[41] 21 U.S.C. 829(a), (b); 21 CFR 290.1. *See also* Single Convention, art. 30. Dispensing generally refers to the lawful delivery of marijuana by a DEA registrant to an ultimate user. *See* 21 U.S.C. 802(10).

[42] 21 CFR 1306.04(a).

[43] 21 CFR 1306.05(a).

[44] *Id.* 1306.04(a).

[45] 21 U.S.C. 827 and 832(a); 21 CFR 1301.74(b) and (c), and parts 1304, 1312, and 1317.

[46] 21 U.S.C. 821, 823; 21 CFR 1301.71–1301.76; 1301.90–1301.93.

[47] 21 U.S.C. 825 and 958(e); 21 CFR part 1302.

FDA-approved drug products containing marijuana) on hand every two years.[48]

9. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule III controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of FDA-approved products containing marijuana may only be for the legitimate purposes authorized by the FD&C Act and the CSA.

10. *Liability.* Any activity involving FDA-approved drug products containing marijuana not authorized by, or in violation of the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions

Registration of State Licensees

State medical marijuana regulatory systems have matured significantly since California first authorized medical use in 1996, and today the vast majority of States maintain comprehensive licensing frameworks governing cultivation, processing, distribution, and dispensing of marijuana for medical purposes. These state regimes have developed robust infrastructure for preventing diversion, ensuring product safety, maintaining records, and conducting facility inspections—functions that fulfill the objectives of federal registration and recordkeeping requirements. The Attorney General has reviewed the operation of these state systems and finds that, taken as a whole, they demonstrate a sustained capacity to achieve the public-interest objectives that underlie the CSA's registration framework, including protecting public health and safety and preventing the diversion of controlled substances into illicit channels.

In light of that record, the Attorney General has determined that incorporating state licensing systems into the federal registration framework represents the most effective and efficient means of achieving the CSA's objectives with respect to medical marijuana while promoting the medical benefits of marijuana and causing the least disruption for patients and existing state systems. The rule accordingly leverages existing regulatory infrastructure while preserving the Administrator's authority to deny or revoke registration where specific public-interest concerns arise and to ensure compliance with the Single Convention. This approach reflects the Attorney General's considered judgment that cooperative federalism best serves the statutory purposes of the CSA in the context of a well-regulated medical marijuana market.

The proposed amendments to part 1301 establish a new registration pathway for state-licensed medical marijuana entities seeking federal DEA registration as manufacturers, distributors, and/or dispensers. The regulation creates an expedited review process under which applicants holding state medical marijuana licenses may submit their existing state credentials as conclusive evidence of state-law authorization. The Administrator must grant registration unless doing so would be inconsistent with the public interest under the 21 U.S.C. 823 factors or with the requirements of the Single Convention. A DEA registration automatically suspends upon suspension, revocation, or expiration of the underlying state-issued license, ensuring that federal authorization tracks state authorization. To facilitate a prompt transition, the Administrator is directed to process applications submitted within 60 days of publication within six months, and early applicants may lawfully operate under their state-issued licenses during the pendency of review.

The rule contains several provisions designed to reduce regulatory burden on compliant state-licensed entities. Reporting, recordkeeping, and order-form requirements are limited to what is strictly necessary to satisfy federal statutory and treaty obligations, with state-required records accepted to the maximum extent permissible. State-authorized medical marijuana certifications or similar documents are sufficient to permit the dispensing of medical marijuana to users, provided they include the user's name and address, are dated and signed on the day of issuance, and identify the issuing practitioner. Similarly, registrants may rely on state-law labeling, packaging, disposal, and physical-security requirements in lieu of the otherwise-applicable federal requirements, subject to inclusion of the statutory warning label required by 21 U.S.C. 825(c).

To address Single Convention compliance under Article 23, the rule establishes a nominal-price purchase-and-resale mechanism through which the Administration acquires and resells registered manufacturers' marijuana crops, thereby satisfying the Convention's requirement that a government agency serve as the exclusive purchaser of cannabis production. Registered manufacturers must store crops in a facility to which DEA maintains access until that transaction is complete, and each manufacturer registration must specify the areas in which cultivation is permitted. The Administrator is also authorized to require record-keeping and reporting necessary to comply with the Single Convention, and the Administrator must take into account the requirements of the Single Convention, including any quota requirements, in evaluating applications.

Out of an abundance of caution, the Administrator clarifies that researchers who obtain marijuana or marijuana-derived products from a state licensee for use in scientific research shall incur no civil or criminal liability under the Controlled Substances Act solely by reason of having obtained such products from a state-licensed source rather than a separately DEA-registered bulk manufacturer, provided that the researcher is registered with the Administration to conduct research with marijuana under 21 CFR. 1301.13 and the state licensee from whom the researcher obtained the marijuana held a valid federal registration at the time of the transfer. The Administrator shall not treat the use of state-licensed marijuana products in federally registered research as a basis for adverse action against a researcher's registration.

The Administrator further notes that, as a consequence of this rule, holders of state medical marijuana licenses will no longer be subject to the deduction disallowance imposed by Section 280E of the Internal Revenue Code, which applies only to businesses engaged in ''trafficking in controlled substances . . . in a schedule I or II,'' 26 U.S.C. 280E. The Administrator encourages the Secretary of the Treasury to consider providing retrospective relief from Section 280E liability for taxable years in which a state licensee operated under a state medical marijuana license. Nothing in this rule constitutes a determination regarding federal tax liability, and state licensees should consult with tax counsel regarding the applicability of Section 280E to their specific circumstances.

Regulatory Analyses

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols.[49] If control is required pursuant to such international

[48] 21 U.S.C. 827 and 958(e); 21 CFR 1304.03, 1304.04, and 1304.11.

[49] 21 U.S.C. 811(d)(1).

treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, and ''without regard to'' the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b).[50]

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order, as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a). Therefore, DEA believes that the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.

Executive Orders 12866, 13563, 14192, and 14294

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866, Regulatory Planning and Review, and the principles reaffirmed in E.O. 13563, Improving Regulation and Regulatory Review. DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

While this scheduling action is exempt from review under E.O. 12866, DEA recognizes this action may have unique economic impacts. Marijuana is subject to a number of State laws that have allowed a multibillion-dollar industry to develop. DEA acknowledges that there may be large impacts related to Federal taxes and research and development investment for the pharmaceutical industry, among other things.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[51] applies to rules that are subject to notice and comment under the APA or any other law. As explained above, this final rule is not subject to the notice-and-comment procedures of the APA. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new or revised ''collection[s] of information'' as defined by the Paperwork Reduction Act of 1995.[52]

Unfunded Mandates Reform Act of 1995

DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995[53] that this final rule would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review Act (CRA).[54] However, DEA is submitting reports under the CRA to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Registration requirements.

21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting requirement.

For the reasons set out above, DEA amends 21 CFR parts 1300, 1301, 1308, and 1312 as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

■ 2. Amend § 1300.01 by adding the definitions of ''Marijuana''and ''State medical marijuana license'' in alphabetical order to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

Marijuana shall have the meaning set forth at 21 U.S.C. 802(16)(A).

* * * * *

State medical marijuana license means a license issued by a state entity (or by a District of Columbia entity or a federal territorial entity) authorizing the licensee to manufacture, distribute, and/or dispense marijuana or products that contain marijuana for medical purposes.

* * * * *

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965.

■ 4. Amend § 1301.13 by adding paragraph (k) to read as follows.

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(k) *Medical marijuana registrations.* The Administration shall establish an expedited review process for entities holding state medical marijuana licenses who seek registration as a marijuana manufacturer, distributor, or dispenser. Such applicants shall submit, along with the applicable DEA form or forms, proof of a state medical

[50] *Id.*

[51] 5 U.S.C. 601 *et seq.*

[52] 44 U.S.C. 3502(3).

[53] 2 U.S.C. 1501 *et seq.*

[54] 5 U.S.C. 804.

marijuana license in the form specified by the Administrator. The Administrator shall register an applicant under this subsection unless the Administrator determines that the issuance of such registration is inconsistent with the public interest, taking into account the factors set forth at 21 U.S.C. 823(e) through (g), as applicable, and the requirements of the Single Convention on Narcotic Drugs, including any quota requirement. In general, registration of an applicant that complies with a state-law regime that contains robust protections against diversion, requirements for record-keeping and reporting, and safety and inspection measures will not be inconsistent with the public interest so long as registration is consistent with the Single Convention.

(1) *Types of registrations.* (i) A registered marijuana manufacturer may cultivate, produce, process, package, label, and transfer marijuana and products containing marijuana to registered distributors or other registered manufacturers, subject to the limitations of its state license.

(ii) A registered distributor may receive marijuana and products containing marijuana from registered manufacturers and transfer marijuana and products containing marijuana to registered dispensers or other registered distributors, subject to the limitations of its state license.

(iii) A registered dispenser may dispense marijuana and products containing marijuana to individuals authorized by state law to possess marijuana and products containing marijuana for medical purposes, subject to the limitations of its state license.

(iv) Registrations under this subpart do not authorize the manufacture, distribution, dispensing, or use of marijuana or products containing marijuana for non-medical purposes.

(v) A single entity may be granted multiple types of registrations.

(2) *State licenses as evidence of State authorization.* For purposes of 21 U.S.C. 823(e) through (g), and for any other purpose, a state license shall constitute conclusive evidence that the applicant is authorized under state law to engage in the activity for which registration is sought.

(3) *Suspension, revocation, or expiration of State license.* A registration issued under this section shall not exceed the scope of the holder's state medical marijuana license. If the state medical marijuana license is suspended, revoked, or expires, the DEA registration is automatically suspended.

(4) *Reports, records, and order forms.* Notwithstanding any other provision of this part, the Administrator shall require registrants under this subsection to submit only such reports and records, and to use only such order forms, as the Administrator concludes are necessary to comply with federal statutory and treaty obligations. The Administrator shall accept state-required reports, records, and forms to the maximum extent permissible.

(5) *Prescriptions.* Notwithstanding part 1306 of this chapter or any other provision of these rules, a certification or other document (including an electronic document) that state law deems sufficient for a user to obtain marijuana or products containing marijuana for medical purposes shall be sufficient to permit dispensing of marijuana or products containing marijuana to a user so long as the certification or other document is dated as of, and signed on, the day when issued; bears the full name and address of the user; and contains the name, address, and state license number of the practitioner who signed the certification or other document and is authorized to do so under state law.

(6) *Compliance with Article 23 of the Single Convention on Narcotic Drugs.* Part 1318 of this chapter shall not apply to entities holding valid licenses under this paragraph (k)(6).

(i) All manufacturers registered under this subsection shall establish a nominal price for the purchase of their marijuana crops. The Administration shall then purchase the entity's crops at that price and sell the crops back to the entity, or a related or subsidiary entity, at the same price with the addition of the administrative fee as calculated under § 1318.06(a) of this chapter.

(ii) All registered manufacturers shall store marijuana crops in a facility to which the Administration maintains access until the transaction set forth in paragraph (k)(6)(i) of this section is complete. The Administration shall have the right to inspect such facilities on demand.

(iii) A registration for a manufacturer under this subsection shall specify the areas in which marijuana cultivation is permitted.

(7) *Expedition.* The Administrator shall make every effort to process all applications submitted within 60 days of the publication of this regulation in the **Federal Register** within six months. Notwithstanding paragraph (a) of this section, any applicant that submits an application within 60 days of the publication of this rule in the **Federal Register** may engage in the manufacture, distribution, and/or dispensing of marijuana or products containing marijuana for medical purposes in conformity with a state-issued license during the pendency of the application.

(8) *Labeling, packaging, and sealing.* A registrant under this subsection is exempt from the labeling, packaging, and sealing requirements under part 1302 of this chapter, and other provisions of these rules so long as they label, package, and seal marijuana and products containing marijuana in conformity with state law and so long as the label includes the warning required by 21 U.S.C. 825(c), where applicable.

(9) *Disposal.* Notwithstanding part 1317 of this chapter. or any other provision of these rules, a registrant under this paragraph may dispose of marijuana and products containing marijuana in conformity with state law.

(10) *Security Requirements.* Notwithstanding any other provision of these rules, a registrant under this paragraph has sufficient physical-security requirements if the registrant meets the requirements of state law.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 5. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 6. Amend § 1308.13 by adding new paragraphs (g)(2) through (5) to read as follows.

§ 1308.13 Schedule III.

* * * * *

(g) * * *

* * * * * * *

(2) Marijuana, as defined in 21 U.S.C. 802(16), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license	XXXX
(3) Marijuana extract, as defined in 21 CFR 1308.11(d)(58), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license	XXXX
(4) Naturally derived delta-9-tetrahydrocannabinols in a U.S. Food and Drug Administration approved product or in marijuana subject to a state medical marijuana license	XXXX

(i) Naturally derived delta-9-tetrahydrocannabinols means those delta-9-tetrahydrocannabinols, except as in paragraphs (g)(2) and (3) of this section, that are naturally contained in a plant of the genus Cannabis (cannabis plant)..
(ii) Naturally derived delta-9-tetrahydrocannabinols do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*..
(iii) Naturally derived delta-9-tetrahydrocannabinols do not include any delta-9-tetrahydrocannabinols contained in substances excluded from the definition of marijuana as set forth in 21 U.S.C. 802(16)(B)(ii)..
(5) [Reserved] XXXX

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PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

■ 7. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

■ 8. Amend § 1312.30 by:

■ a. Redesignating paragraph (b) as paragraph (e); and

■ b. Adding new paragraphs (b), (c), and (d).

The additions to read as follows:

§ 1312.30 Schedule III, IV, and V non-narcotic controlled substances requiring an import and export permit.

* * * * *

(b) Marijuana, as defined in 21 U.S.C. 802(16), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license.

(c) Marijuana extract, as defined in 21 CFR 1308.11(d)(58), in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license.

(d) Naturally derived delta-9-tetrahydrocannabinols in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license.

(1) Naturally derived delta-9-tetrahydrocannabinols means those delta-9-tetrahydrocannabinols, except as in paragraphs (g)(2) and (3) of this section, that are naturally contained in a plant of the genus Cannabis (cannabis plant).

(2) Naturally derived delta-9-tetrahydrocannabinols do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*.

(3) Naturally derived delta-9-tetrahydrocannabinols do not include any delta-9-tetrahydrocannabinols contained in substances excluded from the definition of marijuana as set forth in 21 U.S.C. 802(16)(B)(ii).

* * * * *

Dated: April 22, 2026.

Todd Blanche,

Acting Attorney General.

[FR Doc. 2026–08176 Filed 4–27–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1917

[Docket No. OSHA–2025–0007]

RIN 1218–AD51

Open Fires in Marine Terminals

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: OSHA is finalizing the revocation of the agency's Open Fires in Marine Terminals Standard.

DATES: The final rule is effective April 28, 2026.

ADDRESSES: *Docket:* The docket for this rulemaking (Docket No. OSHA–2025–0007) is available at *https://www.regulations.gov,* the Federal eRulemaking Portal. Most exhibits are available at *https://www.regulations.gov;* some exhibits (*e.g.,* copyrighted material) are not available to download from that web page. However, all materials in the dockets are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2500 (TDY number 877–889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Contact Frank Meilinger, Director, OSHA Office of Communications, Occupational Safety and Health Administration; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

This final rule revokes the Open Fires in Marine Terminals Standard, 29 CFR 1917.21 (''Open Fires Standard''). OSHA has determined that this standard is no longer necessary to protect employees working in marine terminals from occupational safety and health hazards. This is a deregulatory action per Executive Order 14192, ''Unleashing Prosperity Through Deregulation'' (90 FR 9065 (Feb. 6, 2025)).

II. Legal Authority

The purpose of the Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) (''the Act'' or ''the OSH Act'') is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal Congress authorized the Secretary of Labor (''the Secretary'') to promulgate standards to protect workers, including the authority ''to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce'' (29 U.S.C. 651(b)(3); see also 29 U.S.C. 654(a)(2) (requiring employers to comply with OSHA standards), 29 U.S.C. 655(a) (authorizing summary adoption of existing consensus and established federal standards within two years of the Act's enactment), and 29 U.S.C. 655(b) (authorizing promulgation, modification or revocation of standards pursuant to notice and comment)). An occupational safety and health standard is ''. . . a standard which requires conditions, or