

(OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.4880 to subpart E to read as follows:

§ 878.4880 Phototherapy device for reducing the appearance of acute post-surgical incisions.

(a) *Identification.* This device consists of a light-emitting device and a photoconverter gel and is intended to employ light energy for reducing the appearance of acute post-surgical incisions. This classification does not include products which contain drugs or biologics.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include the following:

- (i) Verification and validation testing of the spectrum and power intensity of the light source;
- (ii) Heat dissipation from the area following device application; and
- (iii) Biophotonic properties of the photoconverter gel, including radiant fluence (transmitted light and

fluorescence) delivered through the photoconverter gel by the device.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must evaluate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the photoconverter gel by demonstrating continued sterility and functional performance over the identified shelf life.

(5) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device in the intended use environment.

(6) Software verification, validation, and hazard analysis must be performed for any software components.

(7) Labeling must include the following:

(i) A summary of the device technical specifications, including light wavelength, irradiance, and application area;

(ii) Warnings for ensuring eye safety, including use of protective eyeglasses used for both the operator and the patient; and

(iii) A shelf life for the photoconverter gel.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1604]

Schedules of Controlled Substances: Placement of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA), *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide (other name: ADB-4en-PINACA), ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names:

5F-EDMB-PICA; 5F-EDMB-2201), and methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate (other name: MMB-FUBICA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. This action imposes regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA.

DATES: *Effective date:* May 1, 2026.

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

SUPPLEMENTARY INFORMATION: In this final rule, the Drug Enforcement Administration (DEA) permanently places the following four substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA),
- *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide (other name: ADB-4en-PINACA),
- ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 5F-EDMB-PICA; 5F-EDMB-2201), and,
- methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate (other name: MMB-FUBICA).

Legal Authority

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) may, by rule, and upon the recommendation of the Secretary of Health and Human Services, add to such a schedule or transfer between such schedules any drug or other substance, if she finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C.

812(b) for the schedule in which such drug or other substance is to be placed.

Background

The neurochemical effects of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA occur primarily through cannabinoid receptor systems in the brain. 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA bind to cannabinoid subtype 1 (CB1) receptors, function as full agonists, and have a binding affinity and functional activity profile that is similar to that of other schedule I cannabinoids, including Δ9-THC, JWH-018, XLR11, and AKB-48.

DEA published an order in the **Federal Register** on December 12, 2023, temporarily placing 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety under 21 U.S.C. 811(h)(1).¹ That temporary order was effective upon the date of publication. On December 10, 2025, the DEA Administrator signed a temporary scheduling order to extend the temporary schedule I status of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA for one year, or until the permanent scheduling action for these substances are completed, whichever occurs first.²

DEA and HHS Eight-Factor Analyses

In a letter dated December 3, 2025, in accordance with 21 U.S.C. 811(b), and in response to DEA's April 15, 2025 request, the Department of Health and Human Services (HHS) provided to DEA a scientific and medical evaluation and scheduling recommendation for 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA warrant control in schedule I. Both DEA and HHS's Eight-Factor Analyses are

¹ *Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (Dec. 12, 2023).

² *Schedules of Controlled Substances: Extension of Temporary Placement of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA in Schedule I of the Controlled Substances Act*, 90 FR 58149 (Dec. 16, 2025).

available in their entirety under the tab Supporting Documents of the public docket for this action at <https://www.regulations.gov> under docket number DEA-1604.

Notice of Proposed Rulemaking To Schedule 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA

On December 10, 2025, the DEA Administrator signed a notice of proposed rulemaking (NPRM) to permanently control 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA in schedule I.³ Specifically, DEA proposed to add 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA to the list of hallucinogenic substances under 21 CFR 1308.11(d). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before January 15, 2026. DEA did not receive any requests for a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before January 15, 2026.

Comments Received

DEA received one comment in response to the NPRM that was not related to the rulemaking for the placement of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA into schedule I of the CSA.

Comment that was not related to this rulemaking: DEA received one comment that was neither explicitly for nor against the proposed rule. This comment discussed marijuana and was not related to the current scheduling action.

DEA Response: This comment was outside the scope of the current scheduling action; therefore, it was not considered.

Scheduling Conclusion

After consideration of the public comment, scientific and medical evaluation and accompanying scheduling recommendation from HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA. As such, DEA is permanently scheduling 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA as

³ *Schedules of Controlled Substances: Placement of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA in Schedule I*, 90 FR 58174 (Dec. 16, 2025).

controlled substances under schedule I of the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also specifies the findings required to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the then Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA have a high potential for abuse that is comparable to other scheduled synthetic cannabinoids, such as JWH-018, XLR11, and AKB-48. In vitro studies demonstrate that 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA bind to CB1 receptors and function as full agonists. In drug discrimination studies conducted in animals to evaluate its discriminative stimulus effects, 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA were shown to fully substitute for the discriminative stimulus effects produced by delta 9-THC. The ingestion of 4F-MDMB-BUTICA, ADB-4en-PINACA, or 5F-EDMB-PICA has been documented to result in serious adverse effects, including poisonings and deaths. Based upon results from in vitro and in vivo studies, and its similarity to other schedule I synthetic cannabinoids, MMB-FUBICA in particular would be expected to cause similar serious adverse effects following its ingestion.

(2) 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA have no currently accepted medical use in treatment in the United States. In HHS's 2025 recommendation to control 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA, it was noted there are no approved New Drug Applications and no known therapeutic applications for these substances in the United States. DEA is not aware of any other evidence suggesting that 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA have a currently accepted medical use in treatment in the United States.⁴

⁴ To place a drug or other substance in schedule I under the CSA, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B). First, DEA looks to whether the drug or substance has FDA approval. When no FDA approval exists, DEA has traditionally applied a five-part test to a drug or substance that has not

(3) There is a lack of accepted safety for use of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA under medical supervision. Because 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA have no approved medical use and have not been investigated as new drugs, their safety for use under medical supervision has not been determined.

Based on these findings, the DEA Administrator concludes that 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA, as well as their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA.

Requirements for Handling 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA

4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA are subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct instructional activities or chemical analysis with, and possession

been approved by the FDA: (1) The drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10499 (Mar. 26, 1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter and concluded the test was not satisfied. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this final rule, there is no evidence that health care providers have widespread experience with medical use of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA, or that the use of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied.

of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA must register with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Any person who currently handles 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA and is not registered with DEA to conduct research with a schedule I controlled substance must submit an application for registration and may not continue to handle 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA as of May 1, 2026, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Notwithstanding the foregoing, pursuant to 21 U.S.C. 822(h), if, on May 1, 2026, a person is conducting research on 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA and is already registered to conduct research with another controlled substance in schedule I, the person may continue to conduct research on 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA if they submit a completed application for registration or modification of existing registration, as applicable, to conduct research with 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA not later than 90 calendar days after May 1, 2026. The person may continue to conduct such research until the person withdraws the application or the Administrator serves on the person an order to show cause proposing denial of the application pursuant to 21 U.S.C. 824(c) and in accordance with 21 CFR 1301.37. If the Administrator serves an order to show cause proposing denial of the application or modification, the person may not continue to conduct research with 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA and may not receive or otherwise obtain additional 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA. If an order to show cause is served and the person requests a hearing in accordance with 21 CFR 1301.37(d), the hearing shall be held in accordance with 21 CFR 1301.41–1301.46 on an expedited basis

and not later than 45 calendar days after the request is made, except that the hearing may be held at a later time if so requested by the person. If the person sends a copy of the application to a manufacturer or distributor of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA, receipt of the copy by the manufacturer or distributor constitutes sufficient evidence that the person is authorized to receive 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA pursuant to 21 U.S.C. 822(h)(4). Continuation of research under 21 U.S.C. 822(h) does not authorize any other handling (e.g., distribution) of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA.

Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA to a person registered with DEA before the effective date of the final scheduling action in accordance with all applicable Federal, State, local, and Tribal laws. 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and Tribal laws.

3. *Security.* 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA must comply with the employee screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

5. *Quota.* Generally, only registered manufacturers are permitted to manufacture 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA must take an inventory of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA on hand, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA) on hand every two years, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA, or products containing 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR parts 1304 and 1312.

10. *Liability.* Any activity involving 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA 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.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Overcriminalization in Federal Regulations.

Executive Order 12988, Civil Justice Reform

This regulation 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule 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 rule 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.

Paperwork Reduction Act of 1995

This action does not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.⁵ Also, this rule does not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or

organizations. However, this rule would require compliance with the following existing OMB collections: 1117-0003, 1117-0004, 1117-0006, 1117-0008, 1117-0009, 1117-0010, 1117-0012, 1117-0014, 1117-0021, 1117-0023, 1117-0029, and 1117-0056. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601-612, has reviewed this final rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA), *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide (other name: ADB-4en-PINACA), ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 5F-EDMB-PICA; 5F-EDMB-2201), and methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate (other name: MMB-FUBICA), including their salts, isomers, and salts of isomers, in schedule I of the CSA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA.

Based on the review of HHS's scientific and medical evaluation and all other relevant data, DEA determined that 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. There appear to be no legitimate sources for 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA as marketed drugs in the United States, but DEA notes that this substance is available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, or MMB-FUBICA from legitimate suppliers. Therefore, this final rule will

⁵ 44 U.S.C. 3501-3521.

not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action 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 rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

Determination To Make Rule Effective Immediately

The Administrative Procedure Act (APA) generally requires that rules enacted in accordance with the procedures of 5 U.S.C. 553 to be effective not less than 30 days after publication of the proposed rule.⁶ However, the APA provides three exceptions for when an agency may make a rule effective sooner than 30 days after publication, including if the agency finds for good cause why the rule should be effective sooner and publishes those reasons with the rule.⁷

DEA finds that there is good cause for this scheduling action to be immediately effective upon publication because a delay in the effective date is unnecessary and contrary to the public interest. First, it is unnecessary because 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA are currently listed in schedule I of the CSA under 21 U.S.C. 811(h).⁸ Second, as discussed in the temporary scheduling order and NPRM, 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA pose imminent hazards to public safety. Therefore, DEA

believes it is unnecessary and contrary to the public interest to delay the effectiveness of this final rule by 30 days.⁹

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and record keeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. 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.

■ 2. In § 1308.11:

■ a. Add paragraphs (d)(111) through (114).

■ b. Remove and reserve paragraphs (h)(63), (64), (66), and (67).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *
(d) * * *

*	*	*	*	*	*	*	*
(111)	Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA) ...						7091
(112)	N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide (other name: ADB-4en-PINACA)						7092
(113)	Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 5F-EDMB-PICA; 5F-EDMB-2201)						7094
(114)	Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate (other name: MMB-FUBICA)						7095

* * * * *
Signing Authority

This document of the Drug Enforcement Administration was signed on March 23, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters

the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,
Federal Register Liaison Officer, Drug Enforcement Administration.
[FR Doc. 2026-08517 Filed 4-30-26; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 48

[TD 10047]

RIN 1545-BS04

Section 6435 Payments; Refunds for Previously Taxed Dyed Fuel

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations regarding the statutory provision providing for payments to taxpayers with respect to certain previously taxed dyed fuel. Specifically, these temporary

⁶ 5 U.S.C. 553(d).

⁷ 5 U.S.C. 553(d)(3).

⁸ *Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (Dec. 12, 2023); *Schedules of Controlled Substances: Extension of Temporary*

Placement of 4F-MDMB-BUTICA, ADB-4en-PINACA, 5F-EDMB-PICA, and MMB-FUBICA in Schedule I of the Controlled Substances Act, 90 FR 58149 (Dec. 16, 2025).

⁹ See, e.g., *Schedules of Controlled Substances: Placement of beta-Hydroxythiofentanyl in Schedule I*, 84 FR 20023, 20027 (May 8, 2019); *Schedules of Controlled Substances: Placement of UR-144,*

XLR11, and AKB48 into Schedule I, 81 FR 29142, 29144 (May 11, 2016); *accord Schedules of Controlled Substances: Placement of Seven Specific Fentanyl-Related Substances in Schedule I*, 90 FR 44979 (Sept. 18, 2025); *Schedules of Controlled Substances: Placement of Nine Specific Fentanyl-Related Substances in Schedule I*, 88 FR 85104 (Dec. 7, 2023).