



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-1180]

#### Schedules of Controlled Substances: Placement of 4-Fluoroamphetamine 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 4-fluoroamphetamine (4-FA; 1-(4-fluorophenyl)propan-2-amine; *para*-fluoroamphetamine), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. 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 4-fluoroamphetamine.

**DATES:** Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**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:

##### Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended.

Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)-(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of Health and Human Services (Secretary),<sup>1</sup> after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.<sup>2</sup> In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100) may, by rule, and upon the recommendation of the Secretary, 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**

4-Fluoroamphetamine (also known as 4-FA and *para*-fluoroamphetamine) is a central nervous system stimulant and shares structural and pharmacological similarities with schedule II stimulants, such as amphetamine and methamphetamine, and the schedule I substance 3,4-methylenedioxymethamphetamine. (MDMA). On May 15, 2018, the Secretary-General of the

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<sup>1</sup> As discussed in a memorandum of understanding entered into by the FDA and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (Mar. 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

<sup>2</sup> 21 U.S.C. 811(d)(3).

United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 61<sup>st</sup> session held in March 2018, voted to place 4-FA in Schedule II of the 1971 Convention (CND Dec/61/12).

As a signatory to the 1971 Convention, the United States is required, by scheduling under the CSA, to place appropriate controls on 4-FA to meet the minimum requirements of the treaty. Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for 4-FA, discussed in the above legal authority section, were not followed, DEA is utilizing the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control 4-FA. Such scheduling would satisfy the United States' international obligations.

### **DEA and HHS Eight Factor Analyses**

In a letter dated March 2, 2021, in accordance with 21 U.S.C. 811(b), and in response to DEA's September 6, 2019, request, the Department of Health and Human Services (HHS) provided to DEA a scientific and medical evaluation and scheduling recommendation for 4-FA. 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. 812(b)(1), that this substance warrants control in schedule I. Both DEA's and HHS' Eight-Factor analyses are 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-1180.

### **Notice of Proposed Rulemaking to Schedule 4-FA**

On June 3, 2025, DEA published a notice of proposed rulemaking (NPRM) to permanently control 4-FA in schedule I.<sup>3</sup> Specifically, DEA proposed to add 4-FA to the list of stimulant substances under 21 CFR 1308.11(f). The NPRM provided an opportunity for interested persons

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<sup>3</sup> Schedules of Controlled Substances: Placement of 4-Fluoroamphetamine in Schedule I, 90 FR 23477 (June. 3, 2025).

to file a request for hearing in accordance with DEA regulations on or before July 3, 2025. DEA did not receive any requests for such a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before July 3, 2025.

### **Comments Received**

DEA received nine comments in response to the NPRM for the placement of 4-FA into schedule I of the CSA. The submissions were from individuals or anonymous commenters. Two commenters supported the placement of 4-FA in schedule I of the CSA, five commenters were against the placement of 4-FA in schedule I of the CSA, and two commenters expressed statements that were neither for nor against the proposed rule (one of which noted 4-FA has helped them feel calmer).

*Support of Rulemaking:* DEA received two comments in support of the placement of 4-FA in schedule I.

*DEA Response:* DEA appreciates these comments in support of this rulemaking.

*Opposition to Rulemaking:* DEA received five comments against the placement of 4-FA in schedule I of the CSA. Of these comments, one asserted that 4-FA is already controlled under schedule II of the CSA under the Controlled Substances Analogue Act, and that criminal illicit use is already illegal. Three of these comments noted that placing 4-FA in schedule I would negatively impact the ability to do research. One commenter asserted 4-FA could be an effective treatment for PTSD and depression and should not be controlled until additional studies have been conducted. The following is DEA's response to the comments against the proposed rulemaking.

*DEA Response:* DEA appreciates these comments and would like to emphasize that 4-FA is not currently scheduled under the CSA and to provide further clarification regarding the control of 4-FA. 4-FA has been placed under international control. In order to comply with treaty obligations, DEA must place 4-FA under the most appropriate schedule, taking into consideration all appropriate scientific data. Additionally, as set forth in the NPRM, 4-FA has no

currently accepted medical use in treatment in the United States, nor were there any New Drug Applications. Therefore, 4-FA must be placed in schedule I of the CSA along with other substances which have no currently accepted medical use, lack accepted safety for use under medical supervision, and possess a high potential for abuse. With respect to research for potential medical use, the placement of substances in schedule I of the CSA does not preclude academic research on these substances.<sup>4</sup> Those wishing to conduct research on 4-FA must seek permission to do so with the DEA.<sup>5</sup>

### **Scheduling Conclusion**

After consideration of the public comments, 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 4-FA. As such, DEA is permanently scheduling 4-FA as a controlled substance under schedule I of the CSA. The permanent scheduling of 4-FA fulfills the United States' obligations as a party to the 1971 Convention.

### **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) 4-FA has a high potential for abuse that is comparable to other scheduled I and II substances, such as amphetamine, methamphetamine, and MDMA.

(2) 4-FA has no currently accepted medical use in treatment in the United States. In HHS' 2021 recommendation to control 4-FA, it was noted there are no approved New Drug

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<sup>4</sup> 21 U.S.C. 822(h); 21 U.S.C. 823(g)(2)(A); 21 U.S.C. 823(n).

<sup>5</sup> <https://apps.deadiversion.usdoj.gov/webforms2/spring/login?execution=e1s1>.

Applications for 4-FA and no known therapeutic applications for 4-FA in the United States.

DEA is not aware of any other evidence suggesting that 4-FA has a currently accepted medical use in treatment in the United States.<sup>6</sup>

(3) There is a lack of accepted safety for use of 4-FA under medical supervision. Because 4-FA has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined.

Based on these findings, the Administrator of DEA concludes that 4-FA, as well as its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule I of the CSA.

### **Requirements for Handling 4-FA**

4-FA is 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 of instructional activities or chemical analysis with, and possession 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

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<sup>6</sup> Pursuant to 21 U.S.C. 812(b)(1)(B), when placing a substance in schedule I, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 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 determine whether a drug or substance has a currently accepted medical use: (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' 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 4-FA or that the use of 4-FA is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied.

with, or possesses), or who desires to handle, 4-FA 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 4-FA and is not registered with DEA must submit an application for registration and may not continue to handle 4-FA, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. 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 4-FA 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. 4-FA 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.* 4-FA is 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, as of the effective date of this final scheduling action. Non-practitioners handling 4-FA 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 4-FA 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 4-FA 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 4-FA must take an inventory of 4-FA 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 4-FA) 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 4-FA) 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 4-FA, or products containing 4-FA, 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 4-FA to the Automated Reports and Consolidated Ordering 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 4-FA 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 4-FA 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 4-FA 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 of 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, 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.

*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 the substance 4-FA (chemical name: 1-(4-fluorophenyl)propan-2-amine), including its salts, isomers, and salts of isomers, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. 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 4-FA.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that 4-FA has high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. There appear to be no legitimate sources for 4-FA as a marketed drug 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 4-FA from legitimate suppliers. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

#### *Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.<sup>7</sup> This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this rule requires 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.

#### *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.

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<sup>7</sup> 44 U.S.C. 3501 through 3521.

*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.

**List of Subjects in 21 CFR Part 1308**

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

For the reasons set out above, 21 CFR part 1308 is amended 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. Amend § 1308.11 by:

- a. Redesignating paragraphs (f)(8) through (f)(13) as (f)(9) through (f)(14); and
- b. Adding a new paragraph (f)(8).

The addition reads as follows:

**§ 1308.11 Schedule I.**

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(8) 4-Fluoroamphetamine (4-FA, 1-(4-fluorophenyl)propan-2-amine, <i>para</i> -fluoroamphetamine)	1476
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**SIGNING AUTHORITY**

This document of the Drug Enforcement Administration was signed on January 8, 2026, by 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. 2026-00633 Filed: 1/14/2026 8:45 am; Publication Date: 1/15/2026]