0-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1457]

Schedules of Controlled Substances: Placement of Seven Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places seven fentanyl-related substances, as identified in this final rule, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers in schedule I of the Controlled Substances Act. The regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle these seven specific controlled substances will continue to apply as a result of this action.

DATES: Effective [INSERT 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:

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

- *para*-chlorofentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide),
- *ortho*-chlorofentanyl (*N*-(2-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide),
- *meta*-fluorofuranyl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),
- *ortho*-methylcyclopropyl fentanyl (*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide),
- *beta*-methylacetyl fentanyl (*N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)acetamide),
- tetrahydrothiofuranyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrothiophene-2-carboxamide),
- *para*-fluoro valeryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)pentanamide).

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on her own motion, at the request of the Secretary of Health and Human Services (HHS), or on the petition of an interested party.[1] This action is supported by, *inter alia*, a recommendation from the then-Assistant Secretary for Health of HHS (Assistant Secretary for HHS or Assistant Secretary) and an evaluation of all other relevant data by DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts

[1] 21 U.S.C. 811(a).

instructional activities or chemical analysis with, or possesses) or proposes to handle these seven substances.

Background

On February 6, 2018, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the *Federal Register* temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety.[2] The seven substances named in this final rule meet the existing definition of fentanyl-related substances as they are not otherwise controlled in any other schedule (i.e., not included under another DEA Controlled Substance Code Number) and are structurally related to fentanyl by one or more of the five modifications listed under the definition. That temporary order was effective upon the date of publication.

Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as the seven specific substances already covered by that order, was set to expire on February 6, 2020. However, on February 6, 2020, as explained in DEA's April 10, 2020, correcting amendment[3], Congress extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act.[4] This temporary order was subsequently extended multiple times, most recently on March 15, 2025, which extended the order until September 30, 2025.[5] Also, on December 30, 2024, the then-DEA Administrator extended the temporary order in a separate action.[6] On the same day, the then-Administrator, on her own motion pursuant to 21 U.S.C. 811(a), initiated scheduling proceedings and published a notice of proposed rulemaking (NPRM) to permanently control these seven specific fentanyl-related substances in

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[2] *Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I*, 83 FR 5188 (Feb. 6, 2018).
[3] *Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I; Correction***,** 85 FR 20155 (Apr. 10, 2020).
[4] Pub. L. 116-114, sec. 2, 134 Stat. 103.
[5] Pub. L. 119-4, sec. 3105, 139 Stat. 9.
[6] *See* Schedules of Controlled Substances: Extension of Temporary Placement of Seven Specific Fentanyl-Related Substances in Schedule I of the Controlled Substances Act, 89 FR 106311 (Dec. 30, 2024).

schedule I of the CSA.[7] Specifically, DEA proposed to add these substances to the opiates list under 21 CFR 1308.11(b).

DEA and HHS Eight Factor Analyses

On October 25, 2024, the then-Assistant Secretary submitted HHS's scientific and medical evaluation and scheduling recommendation for *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl and their salts to the then-Administrator, which recommended placing these seven specific fentanyl-related substances and their salts in schedule I of the CSA. In accordance with 21 U.S.C. 811(c), upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data and conducted its own eight-factor analysis of the abuse potential of these seven fentanyl-related substances.[8]

Determination to Permanently Schedule Seven Specific Fentanyl-Related Substances

After review of the available data, including the scientific and medical evaluation and the scheduling recommendations from HHS, DEA published an NPRM in the *Federal Register* on December 30, 2024, which proposed the placement of seven specific fentanyl-related substances in schedule I of the CSA.[9] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before January 29, 2025. DEA did not receive a hearing request. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before January 29, 2025. DEA did not receive any comment on the proposed rule to control these seven specific fentanyl-related substances in schedule I of the CSA.

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[7] *See* Schedules of Controlled Substances: Placement of Seven Specific Fentanyl-Related Substances in Schedule I, 89 FR 106384 (Dec. 30, 2024). After the publication of the NPRM, Congress enacted the HALT Fentanyl Act, Pub. L. 119-26 (July 16, 2025), which, among other things, permanently places fentanyl-related substances as a class into schedule I of the CSA.

[8] Both the DEA 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-1457."

[9] *See* Schedules of Controlled Substances: Placement of Seven Specific Fentanyl-Related Substances in Schedule I, 89 FR 106384 (Dec. 30, 2024)

Scheduling Conclusion

After consideration of the scientific and medical evaluation and accompanying scheduling recommendation of HHS, and DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse for *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl. DEA is therefore permanently scheduling these seven fentanyl-related substances as schedule I controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V, and outlines the findings required to place a drug or other substance in any particular schedule.[10] After consideration of the analysis and recommendation of the then-Assistant Secretary for HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C.811(a) and 21 U.S.C.812(b)(1), finds that:

(1) *para*-Chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl, similar to morphine and fentanyl, are mu-opioid receptor agonists. These seven fentanyl-related substances have analgesic effects that are mediated by mu-opioid receptor agonism. Substances that produce mu-opioid receptor agonist effects in the central nervous system are considered as having a high potential for abuse (e.g. morphine and fentanyl). Pharmacological data obtained from drug discrimination studies on these seven fentanyl-related substances show they fully substituted for the discriminative stimulus effects of morphine.

(2) There is no Food and Drug Administration (FDA)-approved drug application for *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, or *para*-

[10] 21 U.S.C. 812(b).

fluoro valeryl fentanyl in the United States. Further, there are no adequate and well-controlled clinical studies for any of these substances, and there are no well-defined finished dosage forms for any of these fentanyl-related substances. There are no known therapeutic applications for these seven fentanyl-related substances, and thus they have no currently accepted medical use in the United States.[11]

(3) There is a lack of accepted safety for use of *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl under medical supervision. Because these seven substances have no FDA-approved medical use and have not been investigated as new drugs, their safety for use under medical supervision has not been determined. Therefore, there is a lack of accepted safety for use of these seven substances under medical supervision.

Based on these findings, the Administrator of DEA concludes that *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl, including

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[11] Pursuant to 21 U.S.C 812(b)(1)(B), when placing a drug or substance in schedule I of the CSA, 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 a drug or substance to determine whether a drug or substance has a currently medical use: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 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 applied the traditional five-part test 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 providers 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). In its eight-factor assessment, HHS determined that these seven fentanyl-related substances did not satisfy this two-part test. Therefore, since both DEA and HHS have determined that these seven fentanyl-related substances do not satisfy the five-part test, and HHS has determined that these seven fentanyl-related substances do not satisfy the additional two-part test, DEA concludes that *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl do not have a currently accepted medical use.

their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, warrant continued control in schedule I of the CSA.[12]

Requirements for Handling *para*-Chlorofentanyl, *ortho*-Chlorofentanyl, *meta*-Fluorofuranyl fentanyl, *ortho*-Methylcyclopropyl fentanyl, *beta*-Methylacetyl fentanyl, Tetrahydrothiofuranyl fentanyl, and *para*-Fluoro valeryl fentanyl

As discussed above, these seven fentanyl-related substances are currently subject to a temporary scheduling order, which added them to schedule I. *para*-Chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl will continue to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl must be registered 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. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* *para*-Chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl

[12] 21 U.S.C. 812(b)(1).

fentanyl, and *para*-fluoro valeryl fentanyl 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.* *para*-Chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71 through 1301.76. Non-practitioners handling these seven substances also must comply with the screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and Packaging.* All labels and labeling for commercial containers of *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl must have 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 pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl,

ortho-methylcyclopropyl fentanyl*, beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958(e) 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 with respect to *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl*, beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317. Manufacturers and distributors would be required to submit reports regarding *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl*, beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl 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 *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl*, beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl 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 *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl*, beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability*. Any activity involving *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl*, beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl 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 done "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 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 Deregulations, or E.O. 14294, Fighting 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 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, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601-612, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances, as defined in the order, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). However, as explained in DEA's April 10, 2020, correcting amendment,[13] Congress extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act.[14] This temporary order was subsequently extended multiple times, most recently on March 15, 2025, which extended the order until September 30, 2025.[15] Also, on December 30, 2024, the then-DEA Administrator extended the temporary order to these seven fentanyl-related substances in a separate action.[16] Thus, DEA estimates that all entities handling or planning to handle *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl have already established and implemented systems and processes required to handle these substances which meet the definition of fentanyl-related substances.

There are currently 170 registrations authorized to specifically handle the fentanyl-related substances as a class, which include one or more of the following substances: *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. Some of these entities are likely to be large entities. However,

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[13] *Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I; Correction*, 85 FR 20155 (Apr. 10, 2020).
[14] Pub. L. 116-114, sec. 2, 134 Stat. 103.
[15] Pub. L. 119-4, sec. 3105, 139 Stat. 9.
[16] *See* Schedules of Controlled Substances: Extension of Temporary Placement of Seven Specific Fentanyl-Related Substances in Schedule I of the Controlled Substances Act, 89 FR 106311 (Dec. 30, 2024).

since DEA does not have information of registrant size, DEA conservatively assumes all of the 170 registrants affected by this rule are small entities.

A review of the 170 registrations indicates that all entities that currently handle *para*-chlorofentanyl, *ortho*-chlorofentanyl, *meta*-fluorofuranyl fentanyl, *ortho*-methylcyclopropyl fentanyl, *beta*-methylacetyl fentanyl, tetrahydrothiofuranyl fentanyl, and *para*-fluoro valeryl fentanyl also handle other schedule I controlled substances and have established and implemented (or maintained) systems and processes required to handle these substances. Therefore, DEA anticipates this final rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 170 affected small entities. Consequently, DEA has concluded that this final rule will 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. 1501 *et seq.*, DEA has determined and certifies 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 the UMRA of 1995.

Paperwork Reduction Act of 1995

This rule would not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.[17] Also, this rule would 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,

[17] 44 U.S.C. 3501–3521.

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.

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, 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. Redesignate paragraphs (b)(104) through (110) as paragraphs (b)(111) through (117);

b. Redesignate paragraphs (b)(87) through (103) as paragraphs (b)(93) through (109);

c. Redesignate paragraphs (b)(84) through (86) as paragraphs (b)(89) through (91);

d. Redesignate paragraphs (b)(82) and (83) as paragraphs (b)(86) and (87);

e. Redesignate paragraphs (b)(76) through (81) as paragraphs (b)(79) through (84);

f. Redesignate paragraphs (b)(59) through (75) as paragraphs (b)(61) through (77);

g. Redesignate paragraphs (b)(21) through (58) as paragraphs (b)(22) through (59);

h. Add new paragraphs (b)(21), (60), (78), (85), (88), (92), and (110); and

i. Remove and reserve paragraphs h(70) through h(76).

The additions to read as follows:

§ 1308.11 Schedule I.

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(b) * * *

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(21) *beta*-methylacetyl fentanyl (*N*-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)acetamide)	9868
* * * * * * *	
(60) *meta*-fluorofuranyl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)	9871
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(78) *ortho*-chlorofentanyl (*N*-(2-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide	9828
* * * * * * *	
(85) *ortho*-methylcyclopropyl fentanyl (*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide)	9849
* * * * * * *	
(88) *para*-chlorofentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide)	9818
* * * * * * *	
(92) *para*-fluoro valeryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)pentanamide)	9870
* * * * * * *	
(110) tetrahydrothiofuranyl fentanyl (also known as: tetrahydrothiophene fentanyl) (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrothiophene-2-carboxamide)	9869
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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on September 8, 2025, by Administrator Terrance 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. 2025-18103 Filed: 9/17/2025 8:45 am; Publication Date: 9/18/2025]