Country	Entity	License requirement	License review policy	**Federal Register** citation
	R2, Sharjah Airport Free Zone Street, Office 806, Sharjah, United Arab Emirates; *and* PO Box 120683, Saif-Zone, Sharjah, United Arab Emirates; *and* . SM-Office E1–1414D, Ajman Free Zone, Ajman, United Arab Emirates.			
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Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2023–26935 Filed 12–5–23; 11:15 am]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

Federal Old-Age, Survivors and Disability Insurance (1950–)

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 20 of the Code of Federal Regulations, Parts 400 to 499, revised as of April 1, 2023, in Appendix I to Subpart P of Part 404, in Part B, section 101.00, revise the first sentence of paragraph C.7.c. to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part B

* * * * *

101.00 Musculoskeletal Disorders.

* * * * *

C. * * *

7. * * *

c. For 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. * * *

[FR Doc. 2023–26983 Filed 12–6–23; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1036]

Schedules of Controlled Substances: Placement of Nine Specific Fentanyl-Related Substances 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 nine fentanyl-related substances, as identified in this final rule, 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, in schedule I of the Controlled Substances Act. These nine fentanyl-related substances are currently listed in schedule I pursuant to a temporary scheduling order. This action makes permanent the imposition of 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 with, or possess), or propose to handle these nine specific fentanyl-related controlled substances.

DATES: *Effective date:* December 7, 2023.

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 rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following nine controlled substances 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, in schedule I of the Controlled Substances Act (CSA):

- *meta*-fluorofentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide),
- *meta*-fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide),
- *para*-methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),
- 3-furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide),
- 2′,5′-dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide),
- isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide),
- *ortho*-fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),
- *alpha*′-methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide), and
- *para*-methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide).

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 (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);[1] or (3) on the petition of any interested party.[2] This action was initiated on the Attorney General's own motion, as delegated to the Administrator of the DEA (Administrator), and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (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 of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[2] 21 U.S.C. 811(a).

(Assistant Secretary) and an evaluation of all 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 or proposes to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl.

Background

On February 6, 2018, DEA published an order in the **Federal Register** (FR) (83 FR 5188) amending 21 CFR 1308.11(h), 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 and pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The nine 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 scheduling order was effective on the date of publication and was based on findings by the former Acting Administrator that the temporary scheduling of these substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). 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 these nine 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 (85 FR 20155), Congress extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103). This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024.

Comment: One commenter stated that fentanyl and the list of related substances is a hazard due to the overdose deaths that have been occurring. This commenter also referenced the National Institute on Drug Abuse, stating that fentanyl-related overdoses have been increasing in the United States. Lastly, this commenter stated that permanently placing fentanyl and the list of related substances in schedule I would improve public health and allow for regulation of these substances.

DEA Response: DEA appreciates the comments in support of this rulemaking. One clarification to note is that fentanyl remains a schedule II substance. This final rule only applies to the fentanyl-related substances that are listed in this final order.

Comment: One commenter stated the proposed rule would make it more difficult to produce and distribute these dangerous fentanyl-related substances, which would help combat the opioid epidemic in the United States. This commenter also referenced a news article by National Public Radio, stating that these nine fentanyl-related substances are not currently classified as controlled substances, making it easy to produce and distribute these substances without legal consequences. Lastly, this commenter recognized that this proposal could have significant impacts on the healthcare industry, such as increased oversight and regulation of fentanyl-related substances, which could prevent their misuse and abuse.

DEA Response: DEA appreciates the comments in support of this rulemaking. One clarification to note based on the comment above is that, by temporary order on February 6, 2018, DEA placed these nine fentanyl-related substances under schedule I. 83 FR 5188. That temporary order defined a fentanyl-related substance to mean any substance not otherwise controlled in any schedule (*i.e.,* not listed under another DEA Controlled Substance Code Number), and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), that is structurally related to fentanyl by one or more of five specified structural modifications. Therefore, these nine fentanyl-related substances are in fact already schedule I controlled substances.

The final rule being issued today applies to nine fentanyl-related substances that were the subject of a February 6, 2018, temporary scheduling order. These nine substances will now be listed in 21 CFR 1308.11(b), as specified in the text of the rule that appears below. This final rule should not have a significant impact on the healthcare industry because these nine fentanyl-related substances have no medical use and they have already been added as schedule I controlled substances since 2018.

Comment: One commenter discussed the direct and indirect effects on federal and state healthcare from this regulation. The commenter suggested that this regulation will boost federal oversight of manufacturing and disseminating harmful chemicals. In addition, this regulation would limit availability and expected use, ensure protection of residents, and increases confidence in the medical field. In addition, the commenter stated that is critical to restrict the use of ''fentanyl replicates'' to those who may need them for medical conditions. Lastly, the commenter stated that raising awareness of the risks of abusing these drugs benefits their prevention.

DEA Response: DEA appreciates the comments in support of this rulemaking. As mentioned previously, FDA has not approved a marketing application for a drug product containing any of these nine substances for any therapeutic indication. These substances have no medical use in the United States.

Comment: One commenter stated that this rule will affect federal healthcare because many federal agencies are trying to tackle the opioid crisis. The commenter discussed the rising number of pediatric deaths from fentanyl in 2021 and the surge in 2018 of fentanyl overdoses among older adolescents as well as in children younger than five. The commenter agrees with this final rule to schedule these fentanyl-related substances. The commenter also stated that fentanyl is highly addictive and that while fentanyl is prescribed for chronic pain or major surgery, it should be a last resort.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Comment: One commenter agreed with this final rule to make permanent these nine specific fentanyl-related substances rather than continuing multiple temporary extensions. Once finalized, the commenter stated that the federal government could act against anyone handling these substances since over 150 people die each day from a fentanyl-related drug overdose.

DEA Response: DEA appreciates the comments in support of this rulemaking. Again, DEA notes that fentanyl is a schedule II controlled substance that can be prescribed for approved medical uses. However, the nine fentanyl-related substances addressed in this rule are already

schedule I controlled substances and none of them have any medical use in the United States.

Comment: One commenter stated that fentanyl should be placed in schedule I. The commenter compared this substance to marijuana, which is a schedule I drug and thought it was mind-blowing that fentanyl was not a schedule I substance. It was suggested that the rising number of deaths, the risk to public health, abuse potential, and dependency should classify fentanyl as a schedule I.

DEA Response: DEA appreciates this comment. As stated previously, fentanyl remains a schedule II substance. Fentanyl has approved medical uses in the United States. This final rule only applies to the fentanyl-related substances that are listed in this final order.

Scheduling Conclusion

After consideration of the relevant matter presented through public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl. DEA is permanently scheduling these nine 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. The CSA also specifies the findings required to place a drug or other substance in any particular schedule.[3] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds the following:

(1) The abuse potential of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl is associated with each substance's pharmacological similarity to other schedule I and II mu-opioid receptor agonist substances which have a high potential for abuse. Similar to morphine (schedule II), fentanyl (schedule II), and several schedule I opioid substances that are structurally related to fentanyl, these nine fentanyl-related substances have been shown to bind and act as mu-opioid receptor agonists;

(2) *meta*-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, have no currently accepted medical use in treatment in the United States;[4] and

(3) There is a lack of accepted safety for use of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl under medical supervision.

Based on these findings, the Administrator concludes that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, 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, warrant control in schedule I of the CSA.[5]

This final rule does not affect the scheduling of fentanyl itself, which remains a schedule II controlled substance.

Requirements for Handling Meta-Fluorofentanyl, Meta-Fluoroisobutyryl Fentanyl, Para-Methoxyfuranyl Fentanyl, 3-Furanyl Fentanyl, 2′,5′-Dimethoxyfentanyl, Isovaleryl Fentanyl, Ortho-Fluorofuranyl Fentanyl, Alpha′-Methyl Butyryl Fentanyl, and Para-Methylcyclopropyl Fentanyl

Meta-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl will continue, on a permanent basis,[6] 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) *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, or who desires to handle these nine substances, is required to 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. meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-

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

[4] Although there is no evidence suggesting that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

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.

57 FR 10499 (1992).

[5] 21 U.S.C. 812(b)(1).

[6] *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and/or *para*-methylcyclopropyl fentanyl have been subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h), by virtue of the February 6, 2018 temporary scheduling order (83 FR 5188) and the subsequent statutory extension of that order through December 31, 2024 (Pub. L. 117–328, Division O, Title VI, Sec. 601).

dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl 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. meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl 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 these nine substances must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels and labeling for commercial containers of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, must be in compliance with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl 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 *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl 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 *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl 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 *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1301.74(b) and (c), 1301.76(b), 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding these substances 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 *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl 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 (E.O.) 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB). This action makes no change in the status quo, as *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are already listed as a schedule I controlled substances.

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 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. 601–602, 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. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have already established and implemented the systems and processes required to handle these substances.

As discussed in the NPRM, there are 108 registrations authorized to handle one or more of the following substances: *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 108 registrations represent a maximum of 95 small entities. Therefore, DEA conservatively estimates as many as 95 small entities are affected by this rule.

A review of the 108 registrations indicates that all entities that currently handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, also handle other schedule I controlled substances and have established and implemented (or maintain) the systems and processes required to handle these substances. Therefore, DEA anticipates that 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 small entities. Therefore, 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 million 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.

Paperwork Reduction Act of 1995

This final rule does not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. Also, this final rule does not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this final rule does 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.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. Pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of nine substances that has already been in effect. These nine substances all fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order (83 FR 5188). Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024.[7] The February 2018 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of the fentanyl-related substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Because this rule finalizes the control status of nine substances that has already been in effect, it does not alter the legal obligations of any person who handles these substances. Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, since this rule does not change the current scheduling status and corresponding legal obligations, DEA is making the rule effective on the date of publication in the **Federal Register**, as any delay in the effective date is unnecessary and would be contrary to the public interest.

[7] Public Law 117–328, Division O, Title VI, Sec. 601.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 29, 2023, by Administrator Anne Milgram. 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

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 21 CFR 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)(10) through (94) to read as follows:

Old paragraph	New paragraph
(b)(10) through (33)	(b)(11) through (34).
(b)(34) through (43)	(b)(36) through (45).
(b)(44) through (47)	(b)(47) through (50).
(b)(48) through (50)	(b)(52) through (54).
(b)(51) through (66)	(b)(57) through (72).
(b)(67) through (74)	(b)(74) through (81).
(b)(75) through (94)	(b)(84) through (103).

■ b. Add new paragraphs (b)(10), (35), (46), (51), (55), (56), (73), (82), and (83);

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *	
(10) *alpha'*-Methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide)	9864
* * * * * * *	
(35) 2′,5′-Dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide)	9861
* * * * * * *	
(46) 3-Furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide)	9860
* * * * * * *	
(51) Isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide)	9862
* * * * * * *	
(55) *meta*-Fluorofentanyl *(N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide)	9857
(56) *meta*-Fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide)	9858
* * * * * * *	
(73) *ortho*-Fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)	9863
* * * * * * *	
(82) *para*-Methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide	9859
(83) *para*-Methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide)	9865

* * * * *

[FR Doc. 2023–26694 Filed 12–6–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 42

[Public Notice: 12224]

RIN 1400–AE83

Immigrant Visas

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (''Department'') is amending its regulation governing immigrant visas by removing the section which allows a consular officer to conduct an informal evaluation of the family members of an immigrant visa applicant to identify potential grounds of ineligibility. The existing regulation was promulgated in 1952, at a time when a consular officer could more readily assess a family member's potential qualification for a visa without a formal visa application. Assessing eligibility for an immigrant visa is now a more complex task and not one which can be accomplished accurately with an informal evaluation.

DATES: This final rule is effective on January 8, 2024.

FOR FURTHER INFORMATION CONTACT: Claire Kelly, Office of Visa Services, Bureau of Consular Affairs, Department of State; telephone (202) 485–7586, *VisaRegs@state.gov.*

SUPPLEMENTARY INFORMATION: The Department published a notice of proposed rulemaking, Public Notice 11604 at 88 FR 16384 (Mar. 17, 2023) (hereafter ''proposed rule''), with a request for comments, proposing to amend Part 42 of Title 22 of the Code of Federal Regulations. The rule will eliminate 22 CFR 42.68 in its entirety. The regulatory amendment was discussed in detail in the proposed rule, and that discussion is adopted by reference in this final rule. The Department received two responsive comments, both in support of eliminating 22 CFR 42.68. The Department is now promulgating a final rule with no changes from the proposed rule. This rule results in no change for applicants, as the authority granted by 22 CFR 42.68 was no longer used by consular officers.[1]

Analysis of Comments

The proposed rule was published in the **Federal Register** on March 17, 2023. The comment period closed May 16, 2023. The Department received two responsive comments, both in favor of the proposed elimination of 22 CFR 42.68, and one non-responsive comment.

One of the two responsive comments advocated for replacing 22 CFR 42.68 with ''supportive and accessible eligibility screenings for noncitizens seeking visas,'' while the other comment only expressed its support for the proposed elimination. The Department has considered these comments. Considering the complexity required to evaluate a noncitizen's eligibility for a visa, and limited resources to reliably assess eligibility absent a visa application, the Department is unable to offer any eligibility screenings. Noncitizens who wish to receive a nonimmigrant or immigrant visa must formally apply for a visa to allow a consular officer to assess their eligibility for the visa.

[1] *See* the proposed rule for further discussion.

Regulatory Findings

A. Administrative Procedure Act

As this rule involves amending visa policy, which is a foreign affairs function of the United States, it is exempt from both the delayed effective date and notice and comment requirements of 5 U.S.C. 553 per subsection (a)(1). Notwithstanding the applicability of the foreign affairs exception to this rule, the Department, for its own benefit, sought public comment on the proposed elimination of 22 CFR 42.68. *See, e.g., Hoctor* v. *U.S. Dep't of Agric.,* 82 F.3d 165, 171–72 (7th Cir. 1996) (observing that there is nothing in the APA that forbids an agency's use of notice-and-comment procedures even if not required under the APA, and that courts should attach no weight to an agency's varied approaches involving similar rules). Though this rule is not subject to 5 U.S.C. 553(d), the Department is also choosing to delay the effective date of this rule for 30 days.

B. Regulatory Flexibility Act

As this rulemaking is not required to be published for notice and comment under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory