appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or TCCA; or Airbus Canada Limited Partnership's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Related Information

For more information about this AD, contact Deep Gaurav, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on May 4, 2021 (86 FR 20266, April 19, 2021).

(i) Transport Canada Civil Aviation (TCCA) AD CF–2021–10, dated March 18, 2021.

(ii) [Reserved]

(4) For TCCA AD CF–2021–10, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.*

(5) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0313.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 22, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–08760 Filed 4–23–21; 11:15 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–476]

Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: In this rule, the Drug Enforcement Administration places 10 specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. These 10 specific substances all fall within the definition of fentanyl-related substances set forth in a February 6, 2018, temporary scheduling order. 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. 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, or possess), or propose to handle any of these 10 specified fentanyl-related substances will continue to be applicable permanently as a result of this action.

DATES: Effective date: April 27, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: This final rule imposes permanent controls on 10 specified fentanyl-related substances, which will continue to be listed in schedule I of the Controlled Substances Act (CSA). These 10 fentanyl-related substances are:

- *N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (2′-fluoro *ortho*-fluorofentanyl; 2′-fluoro 2-fluorofentanyl);
- *N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide (4′-methyl acetyl fentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (β′-phenyl fentanyl; *beta*′-Phenyl fentanyl; 3-phenylpropanoyl fentanyl);
- *N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*ortho*-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
- *N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl acetylfentanyl; 2-methyl acetylfentanyl);
- 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);
- *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*para*-methylfentanyl; 4-methylfentanyl);
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl); and
- *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl).

The schedule I listing of these 10 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible.

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 the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100) on his own motion. 21 U.S.C. 811(a). This action is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS (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 (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or proposes to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

Background

On February 6, 2018, pursuant to 21 U.S.C. 811(h)(1), DEA published a temporary scheduling order in the

Federal Register (83 FR 5188), 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. 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 10 specific substances already covered by that order, was set to expire on February 6, 2020. However, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress overrode and 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) (Feb. 6, 2020).

On March 3, 2021 (86 FR 12296), DEA published a notice of proposed rulemaking (NPRM) to permanently control 10 specific fentanyl-related substances: 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in schedule I of the CSA. Specifically, DEA proposed to add these substances to the opiates list under 21 CFR 1308.11(b), and assign paragraph numbers 17, 18, 41, 50, 61, 62, 64, 69, 75, and 83 under paragraph (b) to *beta*-Methyl fentanyl, *beta*′-Phenyl fentanyl, 2′-Fluoro *ortho*-fluorofentanyl, 4′-Methyl acetyl fentanyl, *ortho*-Fluorobutyryl fentanyl, *ortho*-Methyl acetylfentanyl, *ortho*-Methyl methoxyacetyl fentanyl, *para*-Methylfentanyl, Phenyl fentanyl, and Thiofuranyl fentanyl, respectively.

Since the publication of this NPRM, DEA issued a correcting amendment which updated the numbering of all listed opiates in paragraph (b). See 86 FR 16667, March 31, 2021. As a result, this final rule assigns different paragraph numbers under paragraph (b) than originally proposed, to nine of the ten substances (though the numbering for *ortho*-Methyl acetylfentanyl remains the same). In addition, after publication of the NPRM, DEA discovered that the NPRM inadvertently assigned a duplicate drug code to 2′-fluoro *ortho*-fluorofentanyl (9829). As such, with this final rule, DEA hereby corrects this error by assigning a new drug code (9855) for 2′-fluoro *ortho*-fluorofentanyl.

DEA and HHS Eight Factor Analyses

On July 2, 2020, HHS provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration (FDA), for 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl and their salts.[1] After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary recommended that these substances be placed in schedule I of the CSA. In response, DEA conducted its own eight-factor analysis of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. Please note that both the DEA and HHS 8-Factor analyses and the Assistant Secretary's July 2, 2020, letter are available in their entirety under the tab ''Supporting Documents'' of the public docket for this action at *http://www.regulations.gov* under Docket Number ''DEA–476.''

Determination To Schedule Ten 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 entitled ''Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I.'' 86 FR 12296, March 3, 2021. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before April 2, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before April 2, 2021.

[1] Although HHS also provided information on crotonyl fentanyl, this substance will not be discussed in this final rule since it was permanently placed in schedule I on October 2, 2020. 85 FR 62215.

Comments Received

DEA received ten comments on the proposed rule to control 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in schedule 1 of the CSA. One submission was from a public health group called The Partnership for Safe Medicines, which is made up of more than 45 non-profit organizations committed to the safety of prescription drugs and protection of consumers against counterfeit or unsafe medicines. Other submissions were from individual or anonymous commenters. Nine of the commenters provided support for the rule, and one commenter did not state a position on the rule.

Rather, the latter commenter inquired about DEA's concern with synthetic opioids versus natural substances, and the possibility of reducing opioid addiction risks by managing pain differently without the use of prescribed opioid medications. This comment is outside the scope of this rulemaking. As such, this rule will not provide a response to this comment.

Support of the Proposed Rule

Nine commenters supported controlling 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl as schedule I controlled substances. These commenters indicated support for permanent scheduling of these substances for the reasons such as similarity in their abuse potential to fentanyl, safety concerns with fentanyl, such as deaths, overdoses, addiction, and trafficking, and the involvement of fentanyl and fentanyl-related substances in the current public health crisis associated with the opioid abuse epidemic. Most commenters indicated that DEA needs to impose the permanent control to help curb addiction and opioid overdose.

In addition to supporting control of these 10 substances, a commenter highlighted the need for more specific guidelines for regulatory controls and administrative, civil, and criminal sanctions specific to these substances. In particular, this commenter desired that DEA ensure that vulnerable populations (*e.g.,* those addicted to or dependent on opioids) would not be

unduly punished by broad convictions or sentencing guidelines, and advocated for no mandatory minimums for subsequent convictions (after the first conviction) related to simple possession or ''low level handling'' of the 10 fentanyl-related substances.

DEA Response. DEA appreciates the support for this rulemaking. Regarding the comment for more specific guidelines related to regulatory control for these 10 substances, this comment is outside the scope of this rulemaking since sentencing guidelines are set by the CSA.

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 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. DEA is therefore permanently scheduling these 10 specific fentanyl-related substances as 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 outlines 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 Assistant Secretary and review of all other available data, the Acting Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a high potential for abuse that is comparable to other schedule I substances such as acetyl fentanyl and furanyl fentanyl.

(2) 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have no currently accepted medical use in treatment in the United States; [2] and

(3) There is a lack of accepted safety for use of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl under medical supervision. Based on these findings, the Acting Administrator concludes that 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl 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 continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 2′-Fluoro Ortho-Fluorofentanyl, 4′-Methyl Acetyl Fentanyl, β′-Phenyl Fentanyl, β-Methyl Fentanyl, Ortho-Fluorobutyryl Fentanyl, Ortho-Methyl Acetylfentanyl, Ortho-Methyl Methoxyacetyl Fentanyl, Para-Methylfentanyl, Phenyl Fentanyl, and Thiofuranyl Fentanyl

2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl will continue [3] to be subject to the CSA's regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importation, exportation, research, and conduct of instructional activities involving the handling of controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl 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.

2. *Security.* 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl 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 1301.71–1301.76. Non-practitioners handling 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl also must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture 2′-fluoro *ortho*-

[2] Although there is no evidence suggesting that 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl 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), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[3] 2′-Fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are covered by the February 6, 2018, temporary scheduling order, and are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 83 FR 5188.

fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl 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, 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 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Order Forms.* Every DEA registrant who distributes 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

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.

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 Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, 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). DEA estimates that all entities handling or planning to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have already established and implemented the systems and processes required to handle these substances which meet the definition of fentanyl-related substances.

There are currently 57 registrations authorized to handle the fentanyl-related substances as a class, which include 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 57 registrations represent 51 entities, of which eight are small entities. Therefore, DEA estimates eight small entities are affected by this final rule.

A review of the 57 registrations indicates that all entities that currently handle fentanyl-related substances, including 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 2′-fluoro *ortho*-fluorofentanyl, 4′-methyl acetyl

fentanyl, β′-phenyl fentanyl, β-methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. 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 eight affected small entities. Therefore, DEA has concluded that this rule will not have a significant effect 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 UMRA of 1995.

Congressional Review Act

This rule is not a ''major rule'' as defined in the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting the required reports to the Government Accountability Office, the House, and the Senate under the CRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of 10 substances that has already been in effect for over three years. These 10 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. 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 10 substances that has already been in effect for over three years, 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, 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.

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 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)(73) through (b)(76) as paragraphs (b)(83) through (b)(86);

■ b. Redesignate paragraphs (b)(66) through (b)(72) as paragraphs (b)(75) through (b)(81);

■ c. Redesignate paragraphs (b)(61) through (b)(65) as paragraphs (b)(69) through (b)(73);

■ d. Redesignate paragraphs (b)(57) through (b)(60) as paragraphs (b)(64) through (b)(67);

■ e. Redesignate paragraph (b)(56) as paragraph (b)(61);

■ f. Redesignate paragraphs (b)(46) through (b)(55) as paragraphs (b)(50) through (b)(59);

■ g. Redesignate paragraphs (b)(38) through (b)(45) as paragraphs (b)(41) through (b)(48);

■ h. Redesignate paragraphs (b)(19) through (b)(37) as paragraphs (b)(21) through (b)(39); and

■ i. Add new paragraphs (19), (20), (40), (49), (60), (62), (63), (68), (74), and (82).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * *

(19) *beta*-Methyl fentanyl (*N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide; also known as β-methyl fentanyl) 9856

(20) *beta*′-Phenyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide; also known as β′-phenyl fentanyl; 3-phenylpropanoyl fentanyl) 9842

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(40) 2′-Fluoro *ortho*-fluorofentanyl (*N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide; also known as 2′-fluoro 2-fluorofentanyl) 9855

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(49) 4′-Methyl acetyl fentanyl (*N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide) 9819

* * * * * * *

(60) *ortho*-Fluorobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide; also known as 2-fluorobutyryl fentanyl) 9846

* * * * * * *

(62) *ortho*-Methyl acetylfentanyl (*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl acetylfentanyl) 9848

(63) *ortho*-Methyl methoxyacetyl fentanyl (2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl methoxyacetyl fentanyl) 9820

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(68) *para*-Methylfentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide; also known as 4-methylfentanyl) 9817

*	*	*	*	*	*	*
(74) Phenyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide; also known as benzoyl fentanyl)						9841
*	*	*	*	*	*	*
(82) Thiofuranyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide; also known as 2-thiofuranyl fentanyl; thiophene fentanyl)						9839

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D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–08720 Filed 4–26–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 181

[Public Notice: 11408]

RIN 1400–AE98

Publication, Coordination, and Reporting of International Agreements

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Treaties and Other International Acts Series (TIAS) is the official treaty series of the United States and serves as evidence of the treaties, and international agreements other than treaties, in all courts of law and equity of the United States, and in public offices of the federal government and of the states, without any need of further authentication. Certain international agreements may be exempted from publication in TIAS, if the Department of State (the Department) provides notice in its regulations. This rule updates those regulations to clarify the scope of an existing exemption.

DATES: This rule is effective May 27, 2021.

FOR FURTHER INFORMATION CONTACT: Michael Mattler, Treaty Affairs, Office of the Legal Adviser, Department of State, Washington, DC 20520, (202) 647–1345, or at *treatyoffice@state.gov.*

SUPPLEMENTARY INFORMATION: This rule finalizes a proposed rule published by the Department of State on December 7, 2020. 85 FR 78813. The Department provided 60 days for comment; no relevant public comments were received.

Background

Pursuant to 1 U.S.C. 112a, the Secretary of State is required to cause to be published annually a compilation of all treaties and international agreements to which the United States is a party that were signed, proclaimed, or ''with reference to which any other final formality ha[d] been executed'' during the calendar year. The Secretary of State, however, may determine that publication of particular categories of agreements is not required if certain criteria are met (See 1 U.S.C. 112a(b)).

As explained in the NPRM, the Department is amending 22 CFR 181.8(a)(9) to read ''Agreements that have been given a national security classification pursuant to Executive Order No. 13526, its predecessors or successors, or are otherwise exempt from public disclosure pursuant to U.S. law.''

The scope of this new exemption includes agreements that have not been given a national security classification pursuant to Executive Order No. 13526, its predecessors or successors, but nonetheless are exempt from public disclosure pursuant to U.S. law. The principal category of agreements for which this clarification is relevant are agreements that are exempt from public disclosure pursuant to 10 U.S.C. 130c, which authorizes specified national security officials to withhold from public disclosure otherwise required by law sensitive information of foreign governments and international organizations.

Regulatory Analysis

Administrative Procedure Act

The Department issued the rule for comment in accordance with the Administrative Procedure Act (5 U.S.C. 553).

Regulatory Flexibility Act/Executive Order 13272: Small Business

This rulemaking is hereby certified as not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

Congressional Review Act

This rulemaking does not constitute a major rule, as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking.

The Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure nor would it significantly or uniquely affect small governments.

Executive Orders 12372 and 13132: Federalism and Executive Order 13175, Impact on Tribes

This rule will 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. Nor will the regulations have federalism implications warranting the application of Executive Orders 12372 and 13132. This rule will not have tribal implications, will not impose costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Executive Orders 12866 and 13563: Regulatory Review

This rule has been drafted in accordance with the principles of Executive Orders 12866 and 13563. This rule has been determined to be a significant rulemaking under section 3 of Executive Order 12866, but not economically significant. With respect to the costs and benefits of this rule, the Department notes that agreements addressed by the proposed clarification are, by definition, already exempt from public disclosure pursuant to U.S. law. The proposed rule is intended to provide greater clarity to the application of the existing rule rather than to effect a change in existing practices regarding the publication of agreements. For this reason, the Department does not anticipate any costs to the public from this rulemaking. Therefore, the Department believes that the benefits of this rulemaking outweigh any costs.

Executive Order 12988: Civil Justice Reform

This rule has been reviewed in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.