

5.B.(2)(a)2, of SB LEAP-1B-73-0038, related to the pressure transducer, until the PSS unit has accumulated 15 hours or more of electrical power within the previous 90 days; or

(ii) Before further flight, apply electrical power to the PSS unit in accordance with the Accomplishment Instructions, paragraph 5.A.(3)(a)1, of SB LEAP-1B-73-0038, until the PSS unit has accumulated 15 hours or more of electrical power within the past 90 days.

(2) For an engine in service on the effective date of this AD that has accumulated 15 hours or more of electrical power applied to the PSS unit within the previous 90 days, within 5 flight cycles of the effective date of this AD, perform a one-time check for the maintenance messages listed in the Accomplishment Instructions, paragraph 5.B.(2)(a)2, of SB LEAP-1B-73-0038, related to the pressure transducer.

(3) For an engine not in service on the effective date of this AD that has accumulated fewer than 15 hours of electrical power applied to the PSS unit within the past 90 days, before further flight, apply electrical power to the PSS unit in accordance with the Accomplishment Instructions, paragraph 5.A.(3)(a)1, of SB LEAP-1B-73-0038, until the PSS unit has accumulated 15 hours or more of electrical power within the previous 90 days.

(4) For an engine not in service on the effective date of this AD that has accumulated 15 hours or more of electrical power applied to the PSS unit within the previous 90 days, before further flight, perform a check for the engine maintenance messages using the Accomplishment Instructions, paragraphs 5.A.(3)(b)1 through 5, of SB LEAP-1B-73-0038, related to the pressure transducer.

(5) After accumulating 15 hours of electrical power on the PSS unit as required by paragraph (g)(1)(ii) or (g)(3) of this AD, before further flight, perform a check for the engine maintenance messages using the Accomplishment Instructions, paragraphs 5.A.(3)(b)1 through 5, of SB LEAP-1B-73-0038, related to the pressure transducer.

(6) If any engine maintenance messages are found by the checks required by paragraph (g)(1)(i), (2), (4), or (5) of this AD, before further flight, replace the PSS unit with a PSS unit eligible for installation.

(h) Definitions

(1) For the purpose of this AD, an “in service” engine is any of the following:

(i) An engine installed on an airplane that was delivered prior to November 18, 2020, that, as of the effective date of this AD, has completed the Operational Readiness Flight in accordance with paragraph (m) of FAA AD 2020-24-02 (85 FR 74560, November 20, 2020); or

(ii) An engine installed on an airplane delivered after November 18, 2020.

(2) For the purpose of this AD, hours of electrical power on the PSS unit is the total amount of time that voltage was applied to the PSS unit either on-wing or on a bench in segments of no less than 15 minutes. If the voltage-time is not available, use the run time of the engine on which the PSS unit is installed.

(3) For the purpose of this AD, a “PSS unit eligible for installation” is any of the following:

(i) A PSS unit that is cleared in accordance with the criteria in the Accomplishment Instructions, paragraph 5.B.(3), of SB LEAP-1B-73-0038; or

(ii) A PSS unit with an S/N not listed in Additional Information, Paragraph 6.A. Table 1 of SB LEAP-1B-73-0038.

(i) Installation Prohibition

After the effective date of this AD, do not install on any engine a PSS unit unless it is a PSS unit eligible for installation as defined in paragraph (h)(3) of this AD.

(j) Credit for Previous Actions

You may take credit for the actions required by paragraphs (g)(1)(ii) and (g)(2) through (6) of this AD if you performed these actions before the effective date of this AD using CFM SB LEAP-1B-73-00-0038-01A-930A-D, Issue 001, dated 2021-04-23.

(k) Special Flight Permit

A special flight permit may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane for up to 5 flight cycles prior to accomplishing paragraph (g)(3) of this AD provided engine maintenance messages are checked prior to each flight using the Accomplishment Instructions, paragraphs 5.A.(3)(b)1-5, of SB LEAP-1B 73-0038, and no engine maintenance messages listed in the Accomplishment Instructions, paragraph 5.A.(3)(b)5, of SB LEAP-1B-73-0038, are detected. For all other requirements, special flight permits are prohibited.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. You may email your request to: ANE-AD-AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(m) Related Information

For more information about this AD, contact Mehdi Lamnyi, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238-7743; fax: (781) 238-7199; email: Mehdi.Lamnyi@faa.gov.

(n) 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 the AD specifies otherwise.

(i) CFM Service Bulletin (SB) LEAP-1B-73-00-0038-01A-930A-D, Issue 002-00, dated 2021-04-25, excluding FADEC Alliance SB LEAP-1B/73-012, Issue 001, dated 2021-04-23 (which is attached to this CFM SB).

(ii) [Reserved]

(3) For CFM International, S.A. service information identified in this AD, contact CFM International, S.A., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: (877) 432-3272; fax: (877) 432-3329; email: aviation.fleetsupport@ge.com.

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238-7759.

(5) 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 28, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-806]

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

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places four specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. These four specific substances fall within the definition of fentanyl-related substances set forth in the 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 four specified fentanyl-related substances will continue to be applicable permanently as a result of this action.

DATES: Effective date: May 4, 2021.

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

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

- Ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate (fentanyl carbamate);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)acrylamide (*ortho*-fluoroacryl fentanyl);
- *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (*ortho*-fluoroisobutyryl fentanyl); and
- *N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide (*para*-fluoro furanyl fentanyl).

The schedule I listing of these four 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 Controlled Substances Act (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 the Department of Health and Human Services (Assistant Secretary for HHS or 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 four 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 18, 2021 (86 FR 14707), DEA published a notice of proposed rulemaking (NPRM) to permanently control four specific fentanyl-related substances: fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 39, 62, 66, and 73 under paragraph (b) to Fentanyl carbamate, *ortho*-Fluoroacryl fentanyl, *ortho*-Fluoro isobutyryl fentanyl, and *para*-Fluoro furanyl 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 three of the four fentanyl-related substances (though the numbering for Fentanyl carbamate remains the same).

DEA and HHS Eight Factor Analyses

On March 2, 2021, HHS provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration (FDA), for fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl

fentanyl, and *para*-fluoro furanyl fentanyl and their salts. 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl. Please note that both the DEA and HHS 8-Factor analyses and the Assistant Secretary's March 2, 2021, 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-806."

Determination To Schedule Four 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 Four Specific Fentanyl-Related Substances in Schedule I." 86 FR 14707, March 18, 2021. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before April 19, 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 19, 2021.

Comments Received

DEA received 35 comments on the proposed rule to control fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl in schedule 1 of the CSA. Submissions were from individual or anonymous commenters. Twenty-one commenters provided support for the rule. Three other commenters supported the proposal, but it is not clear whether they were referring to these specific four fentanyl-related substances or the class of fentanyl-related substances that was the subject of DEA's February 6, 2018, temporary scheduling order and that was extended until May 6, 2021 by legislation (Pub. L. 116-114, Sec. 2). Eleven other commenters did not state a position on the rule. Rather, these 11 commenters expressed adverse health concerns, including mortality associated with fentanyl and fentanyl-related

substances, and were mostly pleas to help save lives from grieving parents who had lost a child due to an “accidental overdose of fentanyl” or “fentanyl poisoning.” These 11 comments are not germane to this rulemaking. Therefore, DEA will not respond to these comments.

Support of the Proposed Rule

Comment. Twenty-one commenters supported controlling fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl as schedule I controlled substances. These commenters indicated that permanent scheduling of these substances helps deter illicit manufacturing and trafficking of these substances. Further, commenters noted safety concerns with fentanyl, such as deaths, overdoses, addiction, 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 on these substances to help curb addiction and opioid overdose. In addition to supporting control of these four substances, a commenter, who is a member of grief groups for parents who have lost a child due to an accidental overdose (particular drugs or substances not specified by the commenter), noted the fentanyl epidemic and growth of these groups. Specifically, this commenter stated that members have grown from about 4,000 to 12,000 during the “pandemic”—which DEA interprets to mean, in context, the Coronavirus Disease 2019 (COVID-19) pandemic—with no sign of decline.

DEA Response. DEA appreciates the support for this rulemaking.

Comment. Three commenters supported the proposal, but it is not clear whether they were referring to these specific four fentanyl-related substances or the class of fentanyl-related substances. Two of these commenters mentioned the dangers to health and safety from fentanyl, the illicit trafficking of fentanyl and fentanyl-related substances, and their desires that the temporary ban on the class of fentanyl-related substances—which they noted expires in May 2021—be made permanent. One of the two specifically requested that Congress “pass the legislation” to extend the temporary ban, and the other requested DEA’s support in making the proposed temporary ban permanent. The third commenter did not mention the expiring legislation, and simply requested that efforts be continued to

maintain the ban on fentanyl and fentanyl-related substances.

DEA Response. DEA agrees with the commenters on the importance that this temporary ban be extended or made permanent. However, as one of the three commenters correctly notes, for the scheduling of fentanyl-related substances to be made permanent by legislative action, Congress (rather than DEA) would have to take such action.

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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl. DEA is therefore permanently scheduling these four 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) Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl have a high potential for abuse that is comparable to other schedule I substances such as acetyl fentanyl and furanyl fentanyl.

(2) Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl have no currently accepted medical use in treatment in the United States¹; and

¹ Although there is no evidence suggesting that fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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;

(3) There is a lack of accepted safety for use of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl under medical supervision. Based on these findings, the Acting Administrator concludes that fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 Fentanyl Carbamate, *Ortho*-Fluoroacryl Fentanyl, *Ortho*-Fluoro Isobutyryl Fentanyl, and *Para*-Fluoro Furanyl Fentanyl

Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl will continue² to be subject to the CSA’s schedule I 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, fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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.* Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl also must comply with the employee

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

² 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

² Fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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.

screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl fentanyl, also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle fentanyl carbamate, *ortho*-fluoroacryl fentanyl, *ortho*-fluoro isobutyryl fentanyl, and *para*-fluoro furanyl 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 four substances that has already been in effect for over three years. These four 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 four 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)(67) through (86) as paragraphs (b)(71) through (90);
b. Redesignate paragraphs (b)(62) through (66) as paragraphs (b)(65) through (69);
c. Redesignate paragraphs (b)(60) and (61) as paragraphs (b)(62) and (63);
d. Redesignate paragraphs (b)(39) through (59) as paragraphs (b)(40) through (60); and
e. Add new paragraphs (b)(39), (61), (64), and (70).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *
(b) * * *

(39) Fentanyl carbamate (ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate) 9851
(61) ortho-Fluoroacryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide) 9852
(64) ortho-Fluoroisobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) 9853
(70) para-Fluoro furanyl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide) 9854

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D. Christopher Evans,

Acting Administrator.

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DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE-2021-0001; EEEE500000 21XE1700DX EX1SF0000.EAQ000]

RIN 1014-AA48

Oil and Gas and Sulfur Operations on the Outer Continental Shelf—Civil Penalty Inflation Adjustment

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Final rule.

SUMMARY: This final rule adjusts the level of the maximum daily civil monetary penalty contained in the Bureau of Safety and Environmental

Enforcement (BSEE) regulations for violations of the Outer Continental Shelf Lands Act (OCSLA), in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance. The civil penalty inflation adjustment, using a 1.01182 multiplier, accounts for one year of inflation based on the Consumer Price Index (CPI-U) spanning from October 2019 to October 2020.

DATES: This rule is effective May 4, 2021.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background and Legal Authority

The OCSLA, at 43 U.S.C. 1350(b)(1), directs the Secretary of the Interior (Secretary) to adjust the OCSLA maximum daily civil penalty amount at least once every three years to reflect any increase in the Consumer Price Index (CPI) to account for inflation. On

November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114-74) (FCPIA of 2015). The FCPIA of 2015 required Federal agencies to adjust the level of civil monetary penalties found in their regulations with an initial “catch-up” adjustment through rulemaking, if warranted, and then to make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes. Agencies were required to publish the first annual inflation adjustments in the Federal Register by no later than January 15, 2017 and must publish recurring annual inflation adjustments by no later than January 15 of each subsequent year.

BSEE last updated the maximum daily civil penalty amounts in BSEE’s regulations for OCSLA violations by a final rule published and effective on March 4, 2020. (See 85 FR 12733). Consistent with OMB guidance, BSEE’s final rule implemented the inflation