For the Nuclear Regulatory Commission.

Pamela J. Shepherd-Vladimir,

Acting Chief Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2020–25875 Filed 11–24–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–565]

Schedules of Controlled Substances: Placement of cyclopentyl fentanyl, isobutyryl fentanyl, para-chloroisobutyryl fentanyl, para-methoxybutyryl fentanyl, and valeryl fentanyl in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places cyclopentyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide), isobutyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide), *para*-chloroisobutyryl fentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide), *para*-methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide), and valeryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide), 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. This action continues 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl.

DATES: Effective date: November 25, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

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 (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. 21 U.S.C. 811(a). This action was initiated on the Attorney General's own motion, as delegated to the Administrator of DEA (Administrator), and 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 the Drug Enforcement Administration (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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl.

Background

On February 1, 2018, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place cyclopentyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide), isobutyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide), *para*-chloroisobutyryl fentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide), *para*-methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide), and valeryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide), along with two other substances,[2] in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 83 FR 4580. 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 seven substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). On January 30, 2020, DEA published an order to extend the temporary schedule I status of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl by one year, or until February 1, 2021, pursuant to 21 CFR 811(h)(2). 85 FR 5321. Also, on that same date and in the same issue of the **Federal Register**, DEA simultaneously published a notice of proposed rulemaking (NPRM) to permanently control cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl in schedule I of the CSA. 85 FR 5356. Specifically, DEA proposed to add these five substances to the opiates list under 21 CFR 1308.11(b).

DEA and HHS Eight Factor Analyses

On November 12, 2019, the Assistant Secretary submitted HHS's scientific and medical evaluation and scheduling recommendation for cyclopropyl fentanyl, *para*-fluorobutyryl fentanyl, cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl to the former Acting Administrator.[3] 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl be controlled in schedule I of the CSA. In response, DEA conducted its own eight-factor analysis of cyclopentyl fentanyl, isobutyryl

[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] Those two other substances, ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(phenethylpiperidin-4-yl)acetamide) and *para*-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide, were subsequently permanently placed in schedule I on November 29, 2018 (83 FR 61320) and October 25, 2019 (84 FR 57323), respectively, pursuant to 21 U.S.C. 811(d)(1).

[3] Although HHS also provided information on cyclopropyl fentanyl and *para*-fluorobutyryl fentanyl, these two substances will not be discussed in this final rule since they were permanently placed in schedule I on October 25, 2019. 84 FR 57323.

fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl. DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–565) at *http://www.regulations.gov* under ''Supporting Documents.''

Determination To Schedule cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl

After a 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl into schedule I.'' This rule proposed to control cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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, in schedule I of the CSA. 85 FR 5356, January 30, 2020. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before March 2, 2020. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on or before March 2, 2020.

Comments Received

DEA received six comments on the proposed rule to permanently control cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl in schedule I of the CSA. The submissions were from individual or anonymous commenters. Two commenters provided support for the rule, and one commenter opposed the rule. Three other commenters either supported or opposed the proposal, but misunderstood it to be rescheduling fentanyl from schedule II to schedule I. As such, the latter three comments were outside the scope of this current scheduling action.

Comment: The two commenters provided different reasons for supporting the proposed rule. One commenter stated the proposed rule was beneficial and expressed displeasure with drug dealers, but did not elaborate further. The other commenter stated that according to the Centers for Disease Control and Prevention, abusing unregulated opioids represents a significant risk of opioid overdose to users. Additionally, the commenter stated that the opioid abuse epidemic is incurring not only financial, but also social and emotional damage. Lastly, this commenter stated that these five substances meet DEA's requirements for schedule I control, and noted they are structurally similar to the opioid fentanyl, lack FDA approval for treatment, and are of unknown quality and potency.

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

Comment: One commenter stated that DEA's proposal to only place five structural variants of fentanyl in schedule I is ''stupid'' and will not solve the problem when ''China imports *[sic]* four hundred variants'' (taken to be asserting that China exports 400 such variants of fentanyl to the United States). The commenter suggested that DEA determine every possible ''fentanyl variant'' and place them all in schedule I rather than control individual substances.

DEA Response: Similar to what this commenter suggested, the agency has undertaken a broad scheduling action for fentanyl-related substances. Specifically, on February 6, 2018, the former Acting Administrator of DEA published an order to temporarily schedule fentanyl-related substances, a class of substances as defined in the order, and their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers in schedule I. 83 FR 5188. This 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. The class of fentanyl-related substances that was the subject of the February 6, 2018, temporary scheduling order is currently listed in 21 CFR 1308.11(h)(30). Although the temporary scheduling of the fentanyl-related substances was scheduled to expire on February 6, 2020, Congress enacted a new law to extend the temporary scheduling of all of those fentanyl-related substances until May 6, 2021. (Pub. L. 116–114, Sec. 2).

As indicated above, the final rule being issued today applies to five fentanyl-related substances that were the subject of a February 1, 2018 temporary scheduling order (which was issued five days prior to the class-wide temporary scheduling of fentanyl-related substances). These five substances will now be listed in 21 CFR 1308.11(b), as specified in the text of the rule that appears below.

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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl. DEA is permanently scheduling cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl 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. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds the following:

(1) The abuse potential of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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, cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl have been shown to bind and act as mu-opioid receptor agonists;

(2) Cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that cyclopentyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide), isobutyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide), *para*-chloroisobutyryl fentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide), *para*-methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide), and valeryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide), 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. 21 U.S.C. 812(b)(1).

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

Requirements for Handling cyclopentyl fentanyl, isobutyryl fentanyl, para-chloroisobutyryl fentanyl, para-methoxybutyryl fentanyl, and valeryl fentanyl

Cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl will continue [5] 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) cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl, or who desires to handle cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl, 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.

2. *Security.* Cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling these five substances must also 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl is required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders (E.O.) 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug

[4] Although there is no evidence suggesting that cyclopentyl fentanyl, isobutyryl fentanyl, para-chloroisobutyryl fentanyl, para-methoxybutyryl fentanyl, and valeryl 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] Cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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 1, 2018 temporary scheduling order (83 FR 4580) and the subsequent one-year extension of that order (January 30, 2020, 85 FR 5321).

or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of E.O. 12866 and the principles reaffirmed in E.O. 13563.

This final rule does not meet the definition of an E.O. 13771 regulatory action. OMB has previously determined that formal rulemaking actions concerning the scheduling of controlled substances, such as this rule, are not significant regulatory actions under section 3(f) of E.O. 12866.

Executive Order 12988

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

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

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 (RFA), 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 1, 2018, DEA published an order to temporarily place cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl have already established and implemented the systems and processes required to handle these substances.

As discussed in the NPRM, there are 34 registrations authorized to handle one or more of the following substances: cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, or valeryl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 34 registrations represent 26 entities, of which eight are small entities. Therefore, DEA estimates eight small entities are affected by this rule.

A review of the 34 registrations indicates that all entities that currently handle cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl 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 eight affected 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 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.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in: ''an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.'' However, pursuant to the CRA, DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 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. Revise paragraphs (b)(22), (40), (56), and (59);

■ b. Add paragraph (b)(75);

■ c. Remove and reserve paragraphs (h)(23), and (h)(25) through (h)(28).

The revisions and addition read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(22) Cyclopentyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide)	9847
* * * * * * *	
(40) Isobutyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide)	9827
* * * * * * *	
(56) *para*-Chloroisobutyryl fentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide	9826

*	*	*	*	*	*	*	
(59) *para*-Methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide)							9837
*	*	*	*	*	*	*	
(75) Valeryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide)							9840

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–22757 Filed 11–24–20; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0747; FRL–10010–12–OAR]

RIN 2060–AU16

National Emission Standards for Hazardous Air Pollutants: Miscellaneous Coating Manufacturing Residual Risk and Technology Review

Correction

In rule document 2020–13439 beginning on page 49724 in the issue of August 14, 2020, make the following correction:

§ 63.8000 [Corrected]

■ On page 49742, in the first column, in § 63.8000(vi), in the 14th line ''August 15, 2022'' should read ''August 15, 2018''.

[FR Doc. C1–2020–13439 Filed 11–24–20; 8:45 am]

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 711

[EPA–HQ–OPPT–2018–0321; FRL–10016–96]

RIN 2070–AK33

Chemical Data Reporting; Final Extension of the 2020 Submission Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending the Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) regulations by extending the submission deadline for 2020 reports to January 29, 2021. This is the final extension for the 2020 submission period only. The CDR regulations require manufacturers (including importers) of certain chemical substances included on the TSCA Chemical Substance Inventory (TSCA Inventory) to report data on the manufacturing, processing, and use of the chemical substances.

DATES: This final rule is effective November 25, 2020.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0321, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West, William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Susan Sharkey, Data Gathering and Analysis Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8789; email address: *sharkey.susan@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import) chemical substances listed on the TSCA Inventory. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include but are not limited to:

- Chemical manufacturers (including importers) (NAICS codes 325 and 324110, *e.g.,* chemical manufacturing and processing and petroleum refineries).
- Chemical users and processors who may manufacture a byproduct chemical substance (NAICS codes 22, 322, 331, and 3344, *e.g.,* utilities, paper manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing).

B. What action is the Agency taking?

The current 2020 CDR submission period is from June 1 to November 30, 2020 (on April 9, 2020, EPA extended the September 30, 2020 deadline to November 30, 2020 (see 85 FR 19890)). EPA is issuing this amendment to extend the deadline for 2020 CDR submission reports until January 29, 2021. This is an extension for the 2020 submission period only: Subsequent submission periods (recurring every four years, next in 2024) are not being amended.

The Agency is taking this action in response to concerns raised by the regulated community about their ability to submit the required information within the prescribed period. Written requests to extend the CDR submission period have been received by the Agency starting in late-September. Copies of these letters are included in the docket (see **ADDRESSES**), and, at the time of drafting this document, include the following specific communications:

- Air Products and Chemicals, Inc. 2020 CDR 90-day Extension Request [Letter]. September 25, 2020. Certain information needed to inform submissions is stored off-site and reviewing in-person presents a logistical challenge because of the COVID–19 pandemic (administrative staff is currently on business-critical or work from home status). (Ref. 1.)
- American Chemistry Council (ACC). Request for an Extension to the TSCA Chemical Data Reporting (CDR)