into 16 CFR part 1112. The test method is reasonably available to interested parties, and interested parties may obtain a copy of the test method from CPSC National Product Testing and Evaluation Center, 5 Research Place, Rockville, MD 20850; *www.cpsc.gov.* The test method is also available on the CPSC website. *https://cpsc.gov/Business-Manufacturing/Testing-Certification/Lab-Accreditation/Test-Methods/.* A copy of the test method can also be inspected at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814, telephone 301–504–7923.

### F. Effective Date

The APA generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). The NPR proposed a 30-day effective date because the rule allows testing to continue under the existing testing method by testing laboratories that meet certain criteria for a period of up to two years after the publication of a final rule. However, to avoid possible confusion if the effective date for this rule differed from the effective date for the underlying phthalates rule, we are setting the effective date for the rule on April 25, 2018, the same date the phthalates rule takes effect. This is consistent with past practice setting the effective date for NORs for durable nursery products under section 104 of the CPSIA and updates to the mandatory toy standard ASTM F963 on the same date the underlying rule takes effect.

### G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the APA, or any other statute, unless the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603 and 605. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The Commission certified, in the NPR, that the rule would not have a significant impact on a substantial number of small entities because the revised testing method is substantially the same as the method that laboratories are already using, qualified testing laboratories should be able to adopt the new method without difficulty, and the 2-year window allowed to amend the accreditation scope documents would allow testing laboratories to time the amendments with their periodic reassessments by their accreditation bodies, which should result in minimal (if any) additional cost. The Commission did not receive any public comments that addressed the potential impact on small entities, nor has the Commission staff become aware of any new information that would change its previous determination regarding the impact on small entities.

### H. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

### List of Subjects in 16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Incorporation by reference, Reporting and recordkeeping requirements, Third party conformity assessment body.

For the reasons discussed in the preamble, the Commission amends title 16 CFR chapter II, as follows:

## PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for part 1112 continues to read as follows:

**Authority:** 15 U.S.C. 2063; Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008).

■ 2. Amend § 1112.15 by:
■ a. Revising the introductory text to paragraph (b)(31);
■ b. Revising paragraph (b)(31)(i); and
■ c. Revising paragraph (c)(3)(i).

The revisions read as follows:

**§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?**

* * * * *

(b) * * *

(31) 16 CFR part 1307, Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. For its accreditation to be accepted by the Commission to test for phthalates in children's toys and child care articles, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope:

(i) CPSC Test Method CPSC–CH–C1001–09.4, ''Standard Operating Procedure for Determination of Phthalates'';

* * * * *

(c) * * *

(3) * * *

(i) CPSC–CH–C1001–9.4, ''Standard Operating Procedure for Determination of Phthalates'', January 17, 2018;

* * * * *

**Alberta E. Mills,**

*Acting Secretary, U.S. Consumer Product Safety Commission.*

[FR Doc. 2018–01452 Filed 1–31–18; 8:45 am]

**BILLING CODE 6355–01–P**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1308

**[Docket No. DEA–475]**

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

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Temporary amendment; temporary scheduling order.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule seven fentanyl-related substances in schedule I. These seven substances are: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide (valeryl fentanyl), *N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*para*-fluorobutyryl fentanyl), *N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*para*-methoxybutyryl fentanyl), *N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (*para*-chloroisobutyryl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide (isobutyryl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide (cyclopentyl fentanyl), and *N*-(2-fluorophenyl)-2-methoxy-*N*-(1-phenethylpiperidin-4-yl)acetamide (ocfentanil). This action is based on a finding by the Administrator that the placement of these seven synthetic opioids in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to

schedule I controlled substances will be imposed 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, valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil.

**DATES:** This temporary scheduling order is effective February 1, 2018, until February 1, 2020. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

**SUPPLEMENTARY INFORMATION:**

## Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling [1] for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

## Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Administrator transmitted notice of his intent to place valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil in schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated October 20, 2017. The Assistant Secretary responded to this notice of intent by letter dated November 8, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of these seven substances in schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). Valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for these seven substances under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil was published in the **Federal Register** on December 13, 2017. 82 FR 58575.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil, summarized below, indicate that these synthetic opioids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis and the Assistant Secretary's November 8, 2017 letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov* under FDMS Docket ID: DEA–2017–0016–0001 (Docket Number DEA–475).

## Factor 4. History and Current Pattern of Abuse

The recreational abuse of fentanyl-related substances continues to be a significant concern. These substances are distributed to users, often with unpredictable outcomes. Evidence suggests that the pattern of abuse of these fentanyl-related substances parallels that of heroin and prescription opioid analgesics. Valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil are fentanyl-related substances that have been encountered by law enforcement and/or reported in the scientific literature by public health officials. Adverse health effects and outcomes related to the abuse of fentanyl-related substances have been documented in previous temporary

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this document adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the 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 the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

scheduling actions (see DEA 3-Factor Analysis).

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. Data from STRIDE and STARLiMS were queried on November 2, 2017. STARLiMS registered the following reports: valeryl fentanyl (15), *para*-fluorobutyryl fentanyl (5), isobutyryl fentanyl (116), and cyclopentyl fentanyl (1). These identifications were made beginning in 2015.

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state and local forensic laboratories across the country. NFLIS was queried on November 3, 2017 [3] and the following substances (number of drug reports) were identified from state and local forensic laboratories since 2015: valeryl fentanyl (69), *para*-fluorobutyryl fentanyl (220), *para*-methoxybutyryl fentanyl (1), and isobutyryl fentanyl (4). The identification in other countries of *para*-fluorobutyryl fentanyl (Poland and Sweden), *para*-methoxybutyryl fentanyl (Sweden), ocfentanil (Belgium and Switzerland), cylcopentyl fentanyl (Sweden), and *para*-chloroisobutyryl fentanyl (Sweden) in toxicological samples associated with fatal and non-fatal overdoses was reported in the scientific literature.

**Factor 5. Scope, Duration and Significance of Abuse**

Fentanyl-related substances have recently re-emerged on the illicit market (*see* DEA 3-Factor Analysis for full discussion). Valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil have been identified in evidence submitted to law enforcement and/or reported in the scientific literature by public health forensic laboratories.

The identification of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil in forensic evidence indicates that these substances are intended to be replacements for controlled synthetic opioids, heroin, and/or prescription opioids. Because abusers of these fentanyl-related substances obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (*i.e.,* use a drug for the first time) abuse of these substances are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine).

**Factor 6. What, if Any, Risk There Is to the Public Health**

With no legitimate medical use in the United States, valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil have emerged on the illicit drug market. Substances within this chemical structural class have demonstrated pharmacological profiles similar to that of fentanyl and other μ-opioid receptor agonists (see DEA 3-Factor Analysis). The abuse of these fentanyl-related substances poses significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone. The toxic effects of substances within this structural class in humans are demonstrated by overdose fatalities described in previous scheduling actions.

Based on information received by the DEA, the misuse and abuse of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil lead to, at least, the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are high. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

**Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety**

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information, summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these seven substances in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, by letter dated October 20, 2017, notified the Assistant Secretary of the DEA's intention to temporarily place these substances in schedule I. A notice of intent was subsequently published in the **Federal Register** on December 13, 2017. 82 FR 58575.

**Conclusion**

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, and herein sets forth the grounds for his determination that it is necessary to temporarily schedule valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil in schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds it necessary to temporarily place these synthetic opioids in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil is effective on

[3] Data are still being collected for July 2017–October 2017 due to the normal lag period for labs reporting to NFLIS.

the date of publication in the **Federal Register**, and is in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

**Requirements for Handling**

Upon the effective date of this temporary order, valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil must be registered with the 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, as of February 1, 2018. Any person who currently handles valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil, and is not registered with the DEA, must submit an application for registration and may not continue to handle valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil as of February 1, 2018, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after February 1, 2018, is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil, must surrender all currently held quantities of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil.

3. *Security.* Valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of February 1, 2018.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from February 1, 2018, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, 1317, and § 1307.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil must submit reports pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304 and 1312, as of February 1, 2018.

8. *Order Forms.* All DEA registrants who distribute valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil must comply with order form requirements pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305, as of February 1, 2018.

9. *Importation and Exportation.* All importation and exportation of valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, and ocfentanil must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312, as of February 1, 2018.

10. *Quota.* Only DEA registered manufacturers may manufacture valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil in accordance with a quota assigned pursuant to 21 U.S.C. 826, and

in accordance with 21 CFR part 1303, as of February 1, 2018.

11. *Liability.* Any activity involving valeryl fentanyl, *para*-fluorobutyryl fentanyl, *para*-methoxybutyryl fentanyl, *para*-chloroisobutyryl fentanyl, isobutyryl fentanyl, cyclopentyl fentanyl, or ocfentanil not authorized by, or in violation of, the CSA, occurring as of February 1, 2018, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

**Regulatory Matters**

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of 5 U.S.C. 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action 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. Therefore, in accordance with Executive Order 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, ''any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.'' 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances in schedule I because they pose an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

**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, the DEA amends 21 CFR part 1308 as follows:

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(23) through (29) to read as follows:

**§ 1308.11 Schedule I.**

* * * * *

(h) * * *

| | |
|---|---|
| (23) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: valeryl fentanyl) | (9804) |
| (24) *N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: *para*-fluorobutyryl fentanyl) | (9823) |
| (25) *N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: *para*-methoxybutyryl fentanyl) | (9837) |
| (26) *N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: *para*-chloroisobutyryl fentanyl) | (9826) |
| (27) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: isobutyryl fentanyl) | (9827) |
| (28) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: cyclopentyl fentanyl) | (9847) |
| (29) *N*-(2-fluorophenyl)-2-methoxy-*N*-(1-phenethylpiperidin-4-yl)acetamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: ocfentanil) | (9832) |

Dated: January 26, 2018.

**Robert W. Patterson,**

*Acting Administrator.*

[FR Doc. 2018–02008 Filed 1–31–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2018–0033]**

### Drawbridge Operation Regulation; New Jersey Intracoastal Waterway, Beach Thorofare, Margate City, NJ

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Margate Boulevard/Margate Bridge which carries Margate Boulevard across the New Jersey Intracoastal Waterway, Beach Thorofare, mile 74.0, at Margate City, NJ. The deviation is necessary to facilitate bridge maintenance. This deviation allows the bridge to remain in the closed-to-navigation position.

**DATES:** The deviation is effective from 7 a.m. on Monday, February 26, 2018, through 7 p.m. on Monday, March 12, 2018.

**ADDRESSES:** The docket for this deviation, [USCG–2018–0033] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6557, email *Michael.R.Thorogood@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** The Ole Hansen and Sons, Inc., owner and operator of the Margate Boulevard/Margate Bridge that carries Margate Boulevard across the New Jersey Intracoastal Waterway, Beach Thorofare, mile 74.0, at Margate City, NJ, has requested a temporary deviation from the current operating schedule to facilitate maintenance of the structural steel and replacement of the structural steel support column of the double bascule drawbridge. The bridge has a vertical clearance of 14 feet above mean high water in the closed position and unlimited clearance in the open position. The current operating schedule is set out in 33 CFR 117.5. Under this temporary deviation, the bridge will be in the closed-to-navigation position between 7 a.m. on February 26, 2018, through 7 p.m. on March 12, 2018.

The Beach Thorofare is used by a variety of vessels including recreational vessels. The Coast Guard has carefully coordinated the restrictions with waterway users in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternative route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge, so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: January 26, 2018.

**Hal R. Pitts,**

*Bridge Program Manager, Fifth Coast Guard District.*

[FR Doc. 2018–01981 Filed 1–31–18; 8:45 am]

**BILLING CODE 9110–04–P**

## POSTAL REGULATORY COMMISSION

### 39 CFR Part 3010

**[Docket No. RM2016–6; Order No. 4393]**

### Mail Preparation Changes

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission adopts a final rule concerning mail preparation changes. This Order amends an existing Commission rule.

**DATES:** *Effective* March 5, 2018.

**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202–789–6820.

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**



**I. Introduction**

In this Order, the Commission adopts a final rule concerning mail preparation changes. The final rule adopted by this Order amends an existing Commission rule located at 39 CFR part 3010.[1] The rule as adopted incorporates suggestions presented by commenters that include slight modifications to the rule as proposed, but do not materially affect its substance.

**II. Background**

The Commission is charged with enforcing its price cap rules, which require that the Postal Service make reasonable adjustments to its billing determinants to account for the effects of classification changes such as the introduction, deletion, or redefinition of rate cells. *See* 39 CFR 3010.23(d)(2). Under § 3010.23(d)(2), these classification changes can include changes to mail preparation requirements made by the Postal Service. In Docket No. R2013–10R, the Commission articulated a standard governing when mail preparation changes result in the deletion or redefinition of rate cells under § 3010.23(d)(2) of the price cap rules.[2]

After setting forth the standard applied to mail preparation requirements, the Commission instituted the present rulemaking ''to create rules for the process and timeframes for the regulation of mail preparation requirement changes.'' [3] As discussed below, the Commission issued an initial proposed rule that was

[1] On December 1, 2017, the Commission issued a Notice of Proposed Rulemaking in Docket No. RM2017–3 that proposed replacing provisions of 39 CFR part 3010 with new rules in new subparts. The Commission issues this rule in part 3010 and any changes to the rule's location in the CFR will be made in the Docket No. RM2017–3 rulemaking. *See* Docket No. RM2017–3, Notice of Proposed Rulemaking for the System for Regulating Rates and Classes for Market Dominant Products, December 1, 2017 (Order No. 4258). The notice of proposed rulemaking was published in the **Federal Register** on December 11, 2017. *See* 82 FR 58280.

[2] Docket No. R2013–10R, Order Resolving Issues on Remand, January 22, 2016 (Order No. 3047). For a complete history of the underlying proceedings and the facts regarding the change to Full Service Intelligent Mail barcoding (IMb) which precipitated the need for a standard, *see* Docket No. R2013–10, Order on Price Adjustments for Market Dominant Products and Related Mail Classification Changes, November 21, 2013, at 5–35 (Order No. 1890); Order No. 3047; Docket No. R2013–10R, Order Resolving Motion for Reconsideration of Commission Order No. 3047, July 20, 2016 (Order No. 3441).

[3] Order No. 3047 at 21. *See also id.* at 59 (''The Commission intends to also issue a rulemaking to establish procedural rules setting forth the process governing mail preparation changes that require price cap compliance.'').