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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).

[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.

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

[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.

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 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,

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

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 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: 1/31/2018 8:45 am; Publication Date: 2/1/2018]