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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-434F]

Schedules of Controlled Substances: Temporary Placement of Butyryl Fentanyl and Beta-Hydroxythiofentanyl into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioids, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutyramide, also known as *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide, (butyryl fentanyl) and *N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide, also known as *N*-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-*N*-phenylpropanamide, (beta-hydroxythiofentanyl), and their isomers, esters, ethers, salts and salts of isomers, esters and ethers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of butyryl fentanyl and beta-hydroxythiofentanyl into 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, butyryl fentanyl and beta-hydroxythiofentanyl.

DATES: This final order is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she 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 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 her 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 into schedule I of the CSA.[1] The Administrator transmitted the notice of intent to place butyryl fentanyl and beta-hydroxythiofentanyl into schedule I on a temporary basis to the Assistant Secretary by letter dated December 21, 2015. The Assistant Secretary responded to this notice by letter dated January 13, 2016, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for butryl fentanyl or beta-hydroxythiofentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of butryl fentanyl or beta-hydroxythiofentanyl into 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). Neither butryl fentanyl nor beta-hydroxythiofentanyl is currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for butryl fentanyl or beta-hydroxythiofentanyl under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of butryl fentanyl and beta-hydroxythiofentanyl in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule butryl fentanyl and beta-hydroxythiofentanyl was published in the *Federal Register* on March 23, 2016. 81 FR 15485.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to

[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), 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.

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 into 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 butryl fentanyl and beta-hydroxythiofentanyl, 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 January 13, 2016, 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-2016-0005 (Docket Number DEA-434).

Factor 4. History and Current Pattern of Abuse

Clandestinely produced substances structurally related to the schedule II opioid analgesic fentanyl were trafficked and abused on the West Coast in the late 1970s and 1980s. These clandestinely produced fentanyl-like substances were commonly known as designer drugs, and recently there has been a reemergence in the trafficking and abuse of designer drug substances, including fentanyl-like substances. Alpha-methylfentanyl, the

first fentanyl analogue identified in California, was placed into schedule I of the CSA in September 1981. 46 FR 46799. Following the control of alpha-methylfentanyl, the DEA identified several other fentanyl analogues (3-methylthiofentanyl, acetyl-alpha-methylfentanyl, beta-hydroxy-3-methylfentanyl, alpha-methylthiofentanyl, thiofentanyl, beta-hydroxyfentanyl, para-fluorofentanyl, and 3-methylfentanyl) in submissions to forensic laboratories. These substances were temporarily controlled[2] in 1985-1987 under schedule I of the CSA after finding that they posed an imminent hazard to public safety and were subsequently permanently placed in schedule I of the CSA. On July 17, 2015, acetyl fentanyl was temporarily controlled under schedule I of the CSA after a finding by the Administrator that it posed an imminent hazard to public safety. 80 FR 42381.

Prior to October 1, 2014, the System to Retrieve Information from Drug Evidence (STRIDE) collected the results of drug evidence analyzed at DEA laboratories and reflected evidence submitted by the DEA, other federal law enforcement agencies, and some local law enforcement agencies. STRIDE data were queried through September 30, 2014, by date submitted to federal forensic laboratories. Since October 1, 2014, STARLiMS (a web-based, commercial laboratory information management system) has replaced STRIDE as the DEA 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 December 21, 2015. The National Forensic Laboratory Information System (NFLIS) is a program of the DEA that collects drug identification results from drug cases analyzed by other federal, state, and local

[2] 50 FR 43698, 51 FR 42834, 50 FR 11690, 51 FR 15474, and 51 FR 4722. [The temporary scheduling of para-fluorofentanyl was extended in 1987, at 52 FR 7270.

forensic laboratories. NFLIS reports from other federal, state, and local forensic laboratories were queried on December 22, 2015.[3]

The first laboratory submission of butyryl fentanyl was recorded in Kansas in March 2014 according to NFLIS. STRIDE, STARLiMS, and NFLIS registered seven reports containing butyryl fentanyl in 2014 in Illinois, Kansas, Minnesota, and Pennsylvania; 81 reports of butyryl fentanyl were recorded in 2015 in California, Connecticut, Florida, Indiana, North Dakota, New York, Ohio, Oregon, Tennessee, Virginia, and Wisconsin. A total of three reports of beta-hydroxythiofentanyl were recorded by STARLiMS, all of which were reported in 2015 from Florida. As of December 22, 2015, beta-hydroxythiofentanyl had not been reported in NFLIS; however, this substance was identified in June 2015 by a forensic laboratory in Oregon.

Evidence also suggests that the pattern of abuse of fentanyl analogues, including butyryl fentanyl and beta-hydroxythiofentanyl, parallels that of heroin and prescription opioid analgesics. Seizures of butyryl fentanyl have been encountered in tablet and powder form. Butyryl fentanyl was identified on bottle caps and spoons and residue was detected within glassine bags, on digital scales, and on sifters which demonstrates the abuse of this substance as a replacement for heroin or other opioids, either knowingly or unknowingly. Butyryl fentanyl has been encountered as a single substance as well as in combination with other illicit substances, such as acetyl fentanyl, heroin, cocaine, or methamphetamine. Like butyryl fentanyl, beta-hydroxythiofentanyl has been encountered in both tablet and powder form. Both butyryl fentanyl and beta-

[3] Data are still being reported for September–November 2015 due to normal lag time for laboratories to report to NFLIS.

hydroxythiofentanyl have caused fatal overdoses, in which intravenous routes of administration are documented.

Factor 5. Scope, Duration and Significance of Abuse

The DEA is currently aware of at least 40 confirmed fatalities associated with butyryl fentanyl and 7 confirmed fatalities associated with beta-hydroxythiofentanyl. The information on these deaths occurring in 2015 was collected from toxicology and medical examiner reports and was reported from four states—Florida (7, beta-hydroxythiofentanyl), Maryland (1, butyryl fentanyl), New York (38, butyryl fentanyl), and Oregon (1, butyryl fentanyl). STRIDE, STARLiMS, and NFLIS have a total of 88 drug reports in which butyryl fentanyl was identified in drug exhibits submitted in 2014 and 2015 from California, Connecticut, Florida, Illinois, Indiana, Kansas, Minnesota, North Dakota, New York, Ohio, Oregon, Pennsylvania, Tennessee, Virginia, and Wisconsin. STARLiMS has a total of three drug reports in which beta-hydroxythiofentanyl was identified in drug exhibits submitted in 2015 from Florida. It is likely that the prevalence of butyryl fentanyl and beta-hydroxythiofentanyl in opioid analgesic-related emergency room admissions and deaths is underreported as standard immunoassays cannot differentiate these substances from fentanyl.

The population likely to abuse butyryl fentanyl and beta-hydroxythiofentanyl overlaps with the populations abusing prescription opioid analgesics and heroin. This is evidenced by the routes of administration and drug use history documented in butyryl fentanyl and beta-hydroxythiofentanyl fatal overdose cases. Because abusers of these fentanyl analogues are likely to obtain these substances through illicit sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse

health risks to abusers of butyryl fentanyl and beta-hydroxythiofentanyl. Individuals who initiate (i.e. use an illicit drug for the first time) butyryl fentanyl or beta-hydroxythiofentanyl abuse 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, etc.).

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

Butyryl fentanyl and beta-hydroxythiofentanyl exhibit pharmacological profiles similar to that of fentanyl and other mu-opioid receptor agonists. Due to limited scientific data, their potency and toxicity are not known; however, the toxic effects of both butyryl fentanyl and beta-hydroxythiofentanyl in humans are demonstrated by overdose fatalities involving these substances. Abusers of these fentanyl analogues may not know the origin, identity, or purity of these substances, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone.

Based on the documented case reports of overdose fatalities, the abuse of butyryl fentanyl and beta-hydroxythiofentanyl leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. 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.

Butyryl fentanyl and beta-hydroxythiofentanyl have been associated with numerous fatalities. At least 40 confirmed overdose deaths involving butyryl fentanyl abuse have been reported in Maryland (1), New York (38), and Oregon (1) in 2015. At least seven confirmed overdose fatalities involving beta-hydroxythiofentanyl have been reported in

Florida in 2015. This indicates that both butyryl fentanyl and beta-hydroxythiofentanyl pose an imminent hazard to the public safety.

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 data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of butyryl fentanyl and beta-hydroxythiofentanyl pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these 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 into 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 butyryl fentanyl and beta-hydroxythiofentanyl 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, through a letter dated December 21, 2015, notified the Assistant Secretary of the DEA's intention to temporarily place these substances into schedule I.

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, herein sets forth the grounds for his determination that it is necessary to temporarily schedule butyryl fentanyl and beta-

hydroxythiofentanylinto schedule I of the CSA, and finds that placement of these synthetic opioids into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Because the Administrator hereby finds it necessary to temporarily place these synthetic opioids into schedule I to avoid an imminent hazard to the public safety, this final order temporarily scheduling butyryl fentanyl and beta-hydroxythiofentanyl will be effective on the date of publication in the *Federal Register*, and will be 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 final order, butyryl fentanyl and beta-hydroxythiofentanyl will become 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, butyryl fentanyl and beta-hydroxythiofentanyl 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 [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles butyryl fentanyl and beta-hydroxythiofentanyl, and is not registered with the DEA, must submit an application for registration and may not continue to handle butyryl fentanyl or beta-hydroxythiofentanyl as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], 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 this substance in a manner not authorized by the CSA on or after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful and those in possession of any quantity of this substance 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 butyryl fentanyl and beta-hydroxythiofentanyl, must surrender all quantities of currently held butyryl fentanyl and beta-hydroxythiofentanyl.

3. *Security*. Butyryl fentanyl and beta-hydroxythiofentanyl 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 [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

4. *Labeling and packaging*. All labels, labeling, and packaging for commercial containers of butyryl fentanyl and beta-hydroxythiofentanyl 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 [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

5. *Inventory*. Every DEA registrant who possesses any quantity of butyryl fentanyl and beta-hydroxythiofentanyl on the effective date of this order must take an inventory of all stocks of this substance 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 butyryl fentanyl and beta-hydroxythiofentanyl) 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 butyryl fentanyl and beta-hydroxythiofentanyl pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, and 1312, 1317 and §1307.11. Current DEA registrants authorized to handle butyryl fentanyl and beta-hydroxythiofentanyl 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 butyryl fentanyl and beta-hydroxythiofentanyl must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Order Forms*. All DEA registrants who distribute butyryl fentanyl and beta-hydroxythiofentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Importation and Exportation*. All importation and exportation of butyryl fentanyl and beta-hydroxythiofentanyl must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

10. *Quota*. Only DEA registered manufacturers may manufacture butyryl fentanyl and beta-hydroxythiofentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

11. *Liability*. Any activity involving butyryl fentanyl and beta-hydroxythiofentanyl not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], 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 an expedited 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 Congressional Review Act, "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 because they pose a public health risk. 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 into schedule I because they pose an imminent hazard to 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 final 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), unless otherwise noted.

2. Amend § 1308.11 by adding paragraphs (h)(26) and (27) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(26) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: butyryl fentanyl)…….....(9822)

(27) *N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: beta-hydroxythiofentanyl) …….....…….…...…..…(9836)

Dated: May 6, 2016

Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2016-11219 Filed: 5/11/2016 8:45 am; Publication Date: 5/12/2016]