Issued in Des Moines, Washington, on May 2, 2019.

Victor Wicklund,

Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–490]

Schedules of Controlled Substances: Placement of Furanyl Fentanyl, 4-Fluoroisobutyryl Fentanyl, Acryl Fentanyl, Tetrahydrofuranyl Fentanyl, and Ocfentanil in Schedule I; Correction

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule; correcting amendment.

SUMMARY: The Drug Enforcement Administration is correcting a final order that appeared in the **Federal Register** on November 29, 2018. The document issued an action maintaining the placement of furanyl fentanyl, 4-fluoroisobutyryl fentanyl, acryl fentanyl, tetrahydrofuranyl fentanyl, and ocfentanil, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, in schedule I of the Controlled Substances Act. A drafting oversight in the amendatory instructions did not correctly update the prefatory language on isomers to reflect the change in the paragraph number for the designation of 3-methylthiofentanyl.

DATES: Effective Date: May 8, 2019.

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

SUPPLEMENTARY INFORMATION: On May 29, 1987, the Drug Enforcement Administration (DEA) placed six substances, including 3-methylthiofentanyl, into schedule I of the Controlled Substances Act. 52 FR 20070. At that time, the introductory text was revised to clearly indicate that optical and geometric isomers of 3-methylthiofentanyl were controlled. On January 8, 1988, paragraph (b)(34), the listing for 3-methylthiofentanyl, was redesignated to (b)(35), but the introductory text was not revised. 53 FR 500. On May 16, 2016, paragraph (b)(35), the listing for 3-methylthiofentanyl, was redesignated to (b)(36), but the introductory text was not revised. 81 FR 22023. On June 7, 2017, paragraph (b)(36), the listing for 3-methylthiofentanyl, was redesignated to (b)(37), but the introductory text was not revised. 82 FR 26349. On April 20, 2018, paragraph (b)(37), the listing for 3-methylthiofentanyl, was redesignated to (b)(38), but the introductory text was not revised. 83 FR 17486. On November 29, 2018, paragraph (b)(38), the listing for 3-methylthiofentanyl, was redesignated to (b)(41), the present listing for 3-methylthiofentanyl, and a further error was introduced by modifying the reference to (b)(34) in the preamble to (b)(39), due to a drafting fault. 83 FR 61320.

Previously, the prefatory language has identified 3-methylthiofentanyl by paragraph number. However, the paragraph numbers have changed frequently over time, as new substances are identified and added to the list of schedule I substances in § 1308.11(b). In order to avoid similar oversights or confusion in the future, this correction changes the designation to reference 3-methylthiofentanyl by name rather than by paragraph number.

Because this final rule is limited to a technical correction for accuracy and does not substantively alter any regulation, and is therefore insignificant in nature and impact, and inconsequential to the public, the Agency finds good cause that notice and public procedure are unnecessary to the promulgation of this correction. 5 U.S.C. 553(b)(B). The Agency also finds that this technical correction merely clarifies or explains the existing regulation and is therefore an interpretive rule that does not require notice and comment rulemaking. 5 U.S.C. 553(b)(A); *see also Reno-Sparks Indian Colony* v. *EPA,* 336 F.3d 899, 909–10 (9th Cir. 2003) (stating that a Technical Correction ''was interpretive because it does not change existing substantive law'' and thus could be promulgated ''by foregoing notice and comment procedures'').

Because, as described above, this final rule is limited to a technical correction for accuracy and does not substantively alter any regulation, and is therefore insignificant in nature and impact, and inconsequential to the public, the Agency finds good cause to make this final rule effective upon the date of publication and to forego thirty days prior notice. *See* 5 U.S.C. 553(d)(3). In addition, pursuant to 5 U.S.C. 553(d)(2), interpretive rules do not require thirty days prior notice before they may become effective. Therefore, because this technical correction is an interpretive rule, it may be made effective immediately. 5 U.S.C. 553(d)(2).

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. Revise the introductory text of § 1308.11(b) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) *Opiates.* Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of 3-methylthiofentanyl only, the term isomer includes the optical and geometric isomers):

* * * * *

Dated: May 3, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–09477 Filed 5–7–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–484]

Schedules of Controlled Substances: Placement of beta-Hydroxythiofentanyl in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places *beta*-hydroxythiofentanyl (*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*-phenyl-propanamide, including its isomers, esters, ethers,

salts, and salts of isomers, esters and ethers, in schedule I of the Controlled Substances Act. This rule continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle *beta*-hydroxythiofentanyl.

DATES: This final rule is effective May 8, 2019.

FOR FURTHER INFORMATION CONTACT: Lynnette M. Wingert, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated by the former Acting Administrator of the Drug Enforcement Administration (DEA) on his own motion and an evaluation of all other relevant data by the DEA, and is supported by a recommendation from the Assistant Secretary for Health of the HHS (Assistant Secretary). This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle *beta*-hydroxythiofentanyl.

Background

On May 12, 2016, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place *beta*-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 81 FR 29492. That temporary order was effective on the date of publication, and was based on findings by the Acting Administrator of the DEA that the temporary scheduling of *beta*-hydroxythiofentanyl was necessary to avoid an imminent hazard to public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA [2] requires that the temporary control of this substance expire two years from the effective date of the scheduling order, which was May 12, 2018. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling of that substance may be extended for up to one year. *Id.* Accordingly, on May 10, 2018, the DEA extended the temporary scheduling of *beta*-hydroxythiofentanyl by one year, until May 12, 2019. 83 FR 21834. On May 10, 2018, the DEA published a notice of proposed rulemaking (NPRM) to permanently control *beta*-hydroxythiofentanyl in schedule I of the CSA. 83 FR 21826.

DEA and HHS Eight Factor Analyses

On April 27, 2018, the HHS provided the DEA with a scientific and medical evaluation and scheduling recommendation for *beta*-hydroxythiofentanyl entitled ''Basis for the recommendation to place β-hydroxythiofentanyl and its isomers, esters, ethers, salts and salts of isomers, esters and ethers into Schedule I of the Controlled Substances Act (CSA).'' After considering the eight factors in 21 U.S.C. 81l(c), including consideration of the substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision, the Assistant Secretary of the HHS recommended that *beta*-hydroxythiofentanyl be controlled in schedule I of the CSA. In response, the DEA conducted its own eight-factor analysis of *beta*-hydroxythiofentanyl and concluded that this substance warrants control in schedule I of the CSA. Both the DEA and HHS 8-Factor analyses are available in their entirety under the tab ''Supporting Documents'' of the public docket for this action at *http://www.regulations.gov* under Docket Number ''DEA–484.''

Determination to Schedule *beta*-Hydroxythiofentanyl

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the former Acting Administrator of the DEA published a NPRM entitled ''Schedules of Controlled Substances: Placement of *beta*-Hydroxythiofentanyl into Schedule I,'' proposing to control *beta*-hydroxythiofentanyl. 83 FR 21826, May 10, 2018. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before June 11, 2018. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal up to June 11, 2018. All of the comments received are summarized below, along with the DEA's response.

Comments Received

The DEA received 25 comments on the proposed rule to control *beta*-hydroxythiofentanyl in schedule I of the CSA. Ten commenters were in favor of controlling *beta*-hydroxythiofentanyl as a schedule I controlled substance, and one commenter was in favor of controlling *beta*-hydroxythiofentanyl as a schedule II controlled substance. One commenter supporting the rule submitted responses nine times (generating eight duplicative responses). Six commenters submitted responses that were outside the scope of the action.

Support of the Proposed Rule

Ten commenters supported controlling *beta*-hydroxythiofentanyl as a schedule I controlled substance. One commenter urged the DEA to maintain the status of *beta*-hydroxythiofentanyl as a schedule I controlled substance. Another commenter stated it is concerning that the DEA was unable to permanently control *beta*-hydroxythiofentanyl as a schedule I substance within the two year time frame. Three commenters stated that because *beta*-hydroxythiofentanyl has no approved medical use, it should be controlled as a schedule I substance. Specifically, one commenter stated that placing *beta*-hydroxythiofentanyl in a different schedule within the CSA would foster recreational use of this substance. Further, four commenters noted that *beta*-hydroxythiofentanyl and other fentanyl derivatives pose significant health risk to the public. Specifically, one commenter stated that fentanyl and its derivatives have been found in numerous samples of other street drugs such as heroin and cocaine and classifying *beta*-hydroxythiofentanyl as a schedule I controlled substance illustrates the true

[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, March 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.

[2] 21 U.S.C. 811(h)(2).

stance of the government in protecting the public.

DEA Response: The DEA agrees with the comments in support for this rulemaking. With regard to the comment related to the timeliness of permanent control of *beta*-hydroxythiofentanyl by the DEA, the DEA is in compliance with the provisions of a temporary scheduling action. Section 201(h)(2) of the CSA [3] requires that the temporary control of a substance expires two years from the effective date of the scheduling order. The Administrator may, during the pendency of proceedings under subsection 21 U.S.C. 811(a)(1), extend the temporary scheduling for up to one year.

Comments Suggesting Placement in Schedule II

One commenter stated that *beta*-hydroxythiofentanyl similar to fentanyl should be placed in schedule II of the CSA because it is an analog of fentanyl and has some medical use in the United States.

DEA Response: The Assistant Secretary, through a letter dated January 13, 2016, notified the former Acting Administrator of the DEA that *beta*-hydroxythiofentanyl is not the subject of any approved new drug application (NDA) or investigational new drug application (IND). According to HHS, there is no approved drug product containing *beta*-hydroxythiofentanyl. HHS concluded that *beta*-hydroxythiofentanyl lacks accepted medical use in the United States. If a controlled substance has no such currently accepted medical use, it must be placed in schedule I.[4]

Other Comments

One commenter expressed concerns about the roles of phones in classroom and wants smart phones out of public schools. Another commenter highlighted the gap in medical education system and emphasized the need for physicians to handle difficulties associated with prescription drug abuse. Another commenter stated that words matter when handling complex issues like powerful prescription drugs. Three commenters misinterpreted *beta*-hydroxythiofentanyl as fentanyl and expressed that access to their fentanyl medications, especially the fentanyl transdermal patch, should not be denied.

DEA Response: The comment about phones in classrooms and the comment that words matter when handling powerful prescription drugs are unrelated to this scheduling action.

With regard to the gap in medical education system and the need to educate physicians to tackle prescription drug abuse, the DEA has worked aggressively to improve its communication and cooperation with registrant medical professionals by maintaining an open dialogue with national associations such as the American Medical Association, Federation of State Medical Boards, and other groups to address diversion problems and educate the medical community on improving prescribing practices. In May 2018, the DEA initiated a nationwide program to train individual practitioners through Practitioner Diversion Awareness Conferences (PDACs) throughout the country. In addition to the PDAC training, the DEA has also sent correspondence to 1.3 million prescribers nationwide, alerting them of the Centers for Disease Control and Prevention (CDC) recommendation (part of CDC's Prescribing Guideline for Chronic Pain) for opioid prescribing for acute pain and alerted practitioners to a free training webinar available from CDC. The DEA is also working on similar correspondence to alert these same practitioners about resources available from the Substance Abuse and Mental Health Services Administration (SAMHSA) to locate substance abuse treatment providers in their state.

This rule will not affect patient access to FDA-approved fentanyl medications (such as the fentanyl transdermal patch) because the rule is limited to *beta*-hydroxythiofentanyl, a synthetic opioid with no currently accepted medical use in treatment in the United States.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of *beta*-hydroxythiofentanyl. As such, the DEA is scheduling *beta*-hydroxythiofentanyl as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis, recommendation of the Assistant Secretary for HHS, and review of all other available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

1. *beta*-Hydroxythiofentanyl has a high potential for abuse;

2. *beta*-Hydroxythiofentanyl has no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of *beta*-hydroxythiofentanyl under medical supervision.

Based on these findings, the Acting Administrator of the DEA concludes that *beta*-hydroxythiofentanyl (*N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling *beta*-Hydroxythiofentanyl

Upon the effective date of this final rule, *beta*-hydroxythiofentanyl will continue [5] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) *beta*-hydroxythiofentanyl, or who desires to handle *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.

2. *Disposal of stocks. beta*-Hydroxythiofentanyl must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security. beta*-Hydroxythiofentanyl is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.93.

[3] 21 U.S.C. 811(h)(2).

[4] *See* Notice of Denial of Petition, 66 FR 20038 (Apr. 18, 2001) (''Congress established only one schedule—schedule I—for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.' '').

[5] *beta*-Hydroxythiofentanyl is currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 81 FR 29492, May 12, 2016.

4. *Labeling and Packaging.* All labels and labeling for commercial containers of *beta*-hydroxythiofentanyl must comply with 21 U.S.C. 825 and 958(e) and must conform with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture *beta*-hydroxythiofentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant whose registration currently authorizes handling *beta*-hydroxythiofentanyl and who possesses any quantity of *beta*-hydroxythiofentanyl on the effective date of this final rule must maintain an inventory of all stocks of *beta*-hydroxythiofentanyl on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Any person who becomes registered with the DEA on or after the effective date of this final rule must take an initial inventory of all stocks of *beta*-hydroxythiofentanyl on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *beta*-hydroxythiofentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. Records and Reports. Every DEA registrant must maintain records and submit reports with respect to *beta*-hydroxythiofentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

8. Order Forms. Every DEA registrant who distributes *beta*-hydroxythiofentanyl must comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

9. Importation and Exportation. All importation and exportation of *beta*-hydroxythiofentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. Liability. Any activity involving *beta*-hydroxythiofentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

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

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this final rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On May 12, 2016, the DEA published a final order to temporarily place *beta*-hydroxythiofentanyl in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). On May 10, 2018, the DEA published a temporary scheduling order extending the temporary placement of *beta*-hydroxythiofentanyl in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). Accordingly, all entities that currently handle or plan to handle *beta*-hydroxythiofentanyl have already established and implemented the systems and processes required to handle this substance. There are currently 20 registrations authorized to handle *beta*-hydroxythiofentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 20 registrations represent 18 entities, of which 14 are small entities. Therefore, the DEA estimates 14 small entities are affected by this rule.

A review of the 20 registrations indicates that all entities that currently handle *beta*-hydroxythiofentanyl also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle *beta*-hydroxythiofentanyl. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 14 affected small entities. Therefore, the DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* the DEA has determined and certifies that this action will not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This final rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

Determination To Make Rule Effective Immediately

The DEA is making the rule effective on the date of publication in the **Federal Register** as allowed under the good cause exception in 5 U.S.C. 553(d)(3). This final rule amends the regulations to permanently control *beta*-hydroxythiofentanyl in schedule I of the CSA. This action continues control of the substance as it is currently controlled until May 12, 2019 by virtue of the temporary scheduling order (83 FR 21834, May 10, 2018). The May 2018 temporary scheduling order extended temporary control of the substance, which was first established in the May 10, 2016, final order. 81 FR 29492. That May 2016 final order was effective on the date of publication, and was based on findings by the Acting Administrator of the DEA that the temporary scheduling of *beta*-hydroxythiofentanyl was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Therefore, the DEA believes it is unnecessary and contrary to the public interest to delay the effectiveness of this final rule by 30 days.

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 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(16) through (65) as (b)(17) through (66);

■ b. Add new paragraph (b)(16); and

■ c. Remove and reserve paragraph (h)(3).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(16) *N*-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-*N*-phenylpropionamide (Other name: *beta*-Hydroxythiofentanyl) 9836

* * * * *

Dated: May 2, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–09479 Filed 5–7–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2019–0306]

Special Local Regulation; Regattas and Marine Parades in the COTP Lake Michigan Zone—Harborfest Dragon Boat Race; South Haven, MI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation on the Black River in South Haven, Michigan for the Harborfest Dragon Boat Race on June 15, 2019. This action is necessary and intended to protect the safety of life and property on navigable waters prior to, during, and immediately after the boat race. During the enforcement period listed below vessels and persons are prohibited from transiting through, mooring, or anchoring within the special local regulation unless authorized by the Captain of the Port Lake Michigan or a designated representative. The operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.903 will be enforced from 7 a.m. through 6 p.m. on June 15, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email marine event coordinator MSTC Kaleena Carpino, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI; telephone (414) 747–7148, email *D09-SMB-SECLakeMichigan-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.903 from 7 a.m. through 6 p.m. on June 15, 2019. This special local regulation encompasses the waters of the Black River in South Haven, MI within the following coordinates starting at 42°24′13.6″ N, 086°16′41″ W; then southeast 42°24′12.6″ N, 086°16′40″ W; then northeast to 42°24′19.2″ N, 086°16′26.5″ W; then northwest to 42°24′20.22″ N, 086°16′27.4″ W; then back to point of origin. (NAD 83). As specified in 33 CFR 100.901, no vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander. This action is being taken to provide for the safety of life and property on navigable waterways prior to, during, and immediately after the boat race.

Pursuant to 33 CFR 100.903, Harborfest Dragon Boat Race; South Haven, MI, entry into, transiting, or anchoring within the special local regulation during an enforcement period is prohibited unless authorized by the Captain of the Port Lake Michigan, or a designated on-scene representative. Those seeking permission to enter the special local regulation may request permission from the Captain of Port Lake Michigan via channel 16, VHF–FM or at (414) 747–7182. If you are the operator of a vessel in the regulated area during the enforcement period you must comply with directions from the Patrol