and in compliance with requirements of the Office of the Federal Register, the undersigned Department of Commerce Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Commerce. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 29, 2020.

Asha Mathew,

Federal Register Liaison Officer, U.S. Department of Commerce.

[FR Doc. 2020–21897 Filed 9–30–20; 1:00 pm]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–633]

Schedules of Controlled Substances: Placement of Crotonyl Fentanyl in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration maintains the placement of crotonyl fentanyl ((*E*)-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbut-2-enamide), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action continues to impose 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 or conduct instructional activities with, or possess), or propose to handle crotonyl fentanyl.

DATES: Effective October 2, 2020.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs (''Single Convention''), March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151, as amended. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (''Commission'') adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (''Secretary-General''), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required ''by United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970,'' the Attorney General must issue an order permanently controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). 28 CFR 0.100.

Background

On February 6, 2018, DEA issued a temporary scheduling order, placing fentanyl-related substances, as defined in the order, in schedule I of the CSA. 83 FR 5188. That order was based on findings by the former Acting Administrator that the temporary scheduling of this class of substances was necessary to avoid an imminent hazard to the public safety; the order was codified at 21 CFR 1308.11(h)(30). On April 19, 2019, in the **Federal Register**, DEA provided the chemical name for crotonyl fentanyl, along with four other substances, identifying how these individual substances met the definition for fentanyl-related substances,[1] and, as such, were already covered by the February 2018 temporary order. 84 FR 16397. Regarding crotonyl fentanyl specifically, this substance was not otherwise controlled in any schedule (*i.e.,* listed under another Administration Substance Controlled Number) and is structurally related to fentanyl by the replacement of the *N*-propionyl group by another acyl group (*i.e.,* meets definition for modification E). On February 6, 2020, Congress extended the temporary control of fentanyl-related substances, as set forth in 21 CFR 1308.11(h)(30), until May 6, 2021. Public Law 116–114, sec. 2, 134 Stat. 103 (2020).

In November 2019, the Director-General of the World Health Organization recommended to the Secretary-General that crotonyl fentanyl and valeryl fentanyl be placed in Schedule I of the Single Convention, as these two substances have opioid mechanisms of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.,* crotonyl fentanyl is similar to drugs such as oxycodone and fentanyl; valeryl fentanyl is similar to drugs such as fentanyl), and have dependence and abuse potential. On May 7, 2020, the Secretary-General advised the Secretary of State of the United States, by letter, that during its 63rd session in March 2020, the Commission voted to place crotonyl fentanyl and valeryl fentanyl in Schedule I of the Single Convention (CND Mar/63/2 and Mar/63/3). Valeryl fentanyl is temporarily controlled in schedule I of the CSA until February 1, 2021 (85 FR 5321, Jan. 30, 2020), and it will not be discussed in this final order.[2]

Crotonyl Fentanyl

As discussed in the background section, crotonyl fentanyl is temporarily controlled in schedule I of the CSA, as it meets the definition of fentanyl-related substances, pursuant to 21 CFR 1308.11(h)(30). Accordingly, crotonyl fentanyl is scheduled as part of a class of substances.

Crotonyl fentanyl has a pharmacological profile similar to morphine, fentanyl, and other synthetic opioids that act as μ-opioid receptor agonists. For this reason, crotonyl fentanyl is abused for its opioid-like effects.

Law enforcement reports in the United States demonstrate the illicit use and distribution of this substance, which are similar to that of heroin and prescription opioid analgesics. 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. According to

[1] These four other substances (2′-fluoro *ortho*-fluorofentanyl, *ortho*-methyl acetylfentanyl, beta′-phenyl fentanyl, and thiofuranyl fentanyl) will not be discussed further in this final order.

[2] DEA issued a notice of proposed rulemaking to permanently control valeryl fentanyl in schedule I (85 FR 5356, Jan. 30, 2020) and is currently working to finalize that rule.

NFLIS,[3] there have been 143 reports containing crotonyl fentanyl since it was first reported in June 2017.

DEA is not aware of any claims or any medical or scientific literature suggesting that crotonyl fentanyl has a currently accepted medical use in treatment in the United States. In addition, the Department of Health and Human Services (HHS) advised DEA, by letter dated November 29, 2017, that there were no investigational new drug applications or approved new drug applications for fentanyl-related substances, a class that, as noted, includes crotonyl fentanyl.

DEA requested that HHS conduct a scientific and medical evaluation and a scheduling recommendation for several fentanyl-related substances, including crotonyl fentanyl, by letter dated April 3, 2019. In response to this request, HHS provided DEA a recommendation, dated July 2, 2020, to place crotonyl fentanyl in schedule I of the CSA. The recommendation from HHS is consistent with the placement of crotonyl fentanyl in Schedule I of the Single Convention in March 2020.

Normally, 21 U.S.C. 811(b) would require DEA to secure such an HHS recommendation as part of the regular scheduling process. As discussed above, however, DEA has authority under 21 U.S.C. 811(d)(1) to control substances that have been added to the Single Convention without making any findings otherwise required by 21 U.S.C. 811(a) or 812(b), and without following the procedures prescribed by 21 U.S.C. 811(a) and (b)—including 811(b)'s requirement that DEA secure an evaluation and recommendation from HHS. Thus, HHS's recommendation supports scheduling crotonyl fentanyl, but its scheduling does not depend on that recommendation.

Therefore, consistent with 21 U.S.C. 811(d)(1), DEA concludes that crotonyl fentanyl has no currently accepted medical use in treatment in the United States [4] and is most appropriately placed in schedule I of the CSA, the same schedule in which it currently resides. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to schedule crotonyl fentanyl pursuant to 21 U.S.C. 811(a).

This action establishes a specific listing for crotonyl fentanyl in schedule I of the CSA within 21 CFR 1308.11(b) (the opiates category of schedule I), and assigns an Administration Controlled Substances Number for the substance: As discussed above, crotonyl fentanyl was not previously listed in schedule I individually, but was instead temporarily controlled as part of the class of fentanyl-related substances controlled under 21 CFR 1308.11(h)(30). This action will allow DEA to establish an aggregate production quota for crotonyl fentanyl and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of crotonyl fentanyl who had previously been granted individual quotas for such purposes under the drug code for fentanyl-related substances.

Conclusion

In order to meet the United States' obligations under the Single Convention and because crotonyl fentanyl has no currently accepted medical use in treatment in the United States, the Acting Administrator has determined that crotonyl fentanyl, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible, should remain in schedule I of the CSA.

Requirements for Handling

Crotonyl fentanyl has been controlled as a schedule I controlled substance since February 6, 2018. With publication of the final order contained in this document, crotonyl fentanyl remains subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture of, distribution of, importation of, exportation of, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, crotonyl fentanyl must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Crotonyl fentanyl 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.* Crotonyl fentanyl is 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 through 1301.93. Non-practitioners handling crotonyl fentanyl must also comply with the employee screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of crotonyl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and must be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture crotonyl fentanyl 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 who possesses any quantity of crotonyl fentanyl has been required to keep an inventory of all stocks of this substance on hand as of February 6, 2018, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to crotonyl fentanyl pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Order Forms.* All DEA registrants who distribute crotonyl fentanyl must continue to comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of crotonyl fentanyl must continue to 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 crotonyl fentanyl not authorized by, or in violation of the CSA, 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

[3] NFLIS was queried on April 14, 2020. Data are still being collected for November 2019 to April 2020 due to the normal lag period for labs reporting to NFLIS.

[4] Although, as discussed above, there is no evidence suggesting that crotonyl fentanyl has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the Food and Drug Administration, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (March 26, 1992).

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB). This order is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. The action 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.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order (as compared to scheduling by rule pursuant to 21 U.S.C. 811(a)). Therefore, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute ''rule making'' under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 5 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States because it is being done pursuant to 21 U.S.C. 811(d)(1), which requires that the United States comply with its obligations under the specified international agreements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. 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 action is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This order 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, DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 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:

■ a. Redesignate paragraphs (b)(22) through (70) as (b)(23) through (71); and

■ b. Add new paragraph (b)(22).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(22) Crotonyl fentanyl ((*E*)-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbut-2-enamide)	9844

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–19305 Filed 10–1–20; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 1042

[EPA–HQ–OAR–2018–0638; FRL–10013–36–OAR]

RIN 2060–AU30

Amendments Related to Marine Diesel Engine Emission Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending the national marine diesel engine program with relief provisions to address concerns associated with finding and installing certified Tier 4 marine diesel engines in certain high-speed commercial vessels. This relief is in the form of additional lead time for qualifying engines and vessels.

DATES: This final rule is effective on November 2, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0638. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at Air and Radiation Docket and Information Center, EPA Docket Center, EPA/DC, EPA WJC West Building, 1301 Constitution Ave. NW, Room 3334, Washington, DC. Note that the EPA Docket Center and Reading Room were closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID–19. The Docket Center staff will continue to provide remote customer service via email, phone, and webform. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742. For further information on EPA Docket Center services and the current status, go to *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Alan Stout, Office of Transportation and Air Quality, Assessment and Standards Division (ASD), Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4805; email address: *stout.alan@epa.gov.*

SUPPLEMENTARY INFORMATION:

Does this action apply to me?

This action relates to marine diesel engines with rated power between 600 and 1,400 kW intended for installation on vessels flagged or registered in the United States, vessels that use those engines, and companies that manufacture, repair, or rebuild those engines and vessels.

Categories and business entities that might be affected by this rule include the following:

Category	NAICS code [a]	Examples of potentially affected entities
Industry	333618	Marine engine manufacturing.
Industry	336611	Shipbuilding and repairing.

[a] North American Industry Classification System (NAICS).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely covered by these rules. This table lists the types of entities that we are aware may be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your activities are regulated by this action, you should carefully examine the applicability criteria in the referenced regulations. You may direct questions regarding the applicability of this action to the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

I. Summary

EPA's 2008 Final Rule for Control of Emissions of Air Pollution from Locomotive Engines and Marine Compression-Ignition Engines Less than 30 Liters per Cylinder adopted Tier 4 emission standards for commercial marine diesel engines at or above 600 kilowatts (kW) (73 FR 37096, June 30, 2008). These standards, which were expected to require the use of exhaust aftertreatment technology, phased in from 2014 to 2017, depending on engine power.[1] After the Tier 4 standards were fully in effect for all engine sizes, some boat builders informed EPA that there were no certified Tier 4 engines available with suitable performance characteristics for the vessels they needed to build, specifically for high-speed commercial vessels that rely on engines with rated power between 600 and 1,400 kW that have high power density.

To address these concerns, EPA proposed, and through this rule is adopting, provisions to provide additional lead time for implementing the Tier 4 standards for engines used in certain high-speed vessels (84 FR 46909, September 6, 2019). We are also finalizing the proposed approaches for streamlining certification requirements to facilitate or accelerate certification of Tier 4 marine engines with high power density. These changes are reflected in amendments to 40 CFR. 1042.145, 1042.505, and 1042.901 that we are making in this final rule. Each of these elements is discussed in more detail in this final rule.

The September 2019 proposed rule also included provisions related to in-use fuel sulfur standards that apply for global marine fuel. We adopted those regulatory amendments to 40 CFR part 80 in a separate rule (84 FR 69335, December 18, 2019).

The regulatory changes EPA is adopting in this final rule are largely the same as we proposed, with a few adjustments to address concerns raised by commenters. Several commenters also suggested that we broaden the scope of the rule to provide additional relief—either for a longer period or for a wider range of vessels. We are considering further rulemaking action to address these concerns, as described in Section VII.

EPA adopted emission standards for marine diesel engines under Clean Air Act authority (42 U.S.C. 7401–7671q). The amendments in this rule are covered by that same authority.

[1] For engines up to 1,000 kW, compliance could be delayed for up to nine months, but no later than October 1, 2017.