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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA- 507]

Schedules of Controlled Substances: Placement of Cyclopropyl Fentanyl, Methoxyacetyl fentanyl, *ortho*-Fluorofentanyl, and *para*-Fluorobutyryl 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 the substances cyclopropyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopropanecarboxamide), methoxyacetyl fentanyl (2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide), *ortho*-fluorofentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide), and *para*-fluorobutyryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide), including their 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, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201(d)(1) of the Controlled Substances Act (CSA) (21 U.S.C. 811(d)(1)) states that, 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 shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [section 201(a) (21 U.S.C. 811(a)] or section [202(b) (21 U.S.C. 812(b)) of the Act] and without regard to the procedures prescribed by [section 201 (a) and (b) (21 U.S.C. 811(a) and (b)]." If a substance is added to one of the schedules of the Single Convention on Narcotic Drugs (1961), then, in accordance with article 3, paragraph 7 of the Convention, as a signatory Member State, the United States is obligated to control the substance under its national drug control legislation, the CSA. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

Background

On May 23, 2019, the Secretary-General of the United Nations send a letter to the Secretary of State of the United States advising him that during the 62nd session of the Commission on Narcotic Drugs, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl were added to Schedule I of the Single Convention on Narcotic Drugs (1961). This letter was prompted by a decision at the 62nd session of the Commission on Narcotic Drugs in March 2019 to schedule cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl under Schedule I of the Single Convention on Narcotic Drugs. As a signatory Member State to the Single Convention on Narcotic Drugs, the United States is obligated to control cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl under its national drug control legislation, the CSA, in the schedule deemed most appropriate to carry out its international obligations. 21 U.S.C. 811(d)(1).

Cyclopropyl Fentanyl, Methoxyacetyl Fentanyl, *ortho*-Fluorofentanyl, and *para*-Fluorobutyryl Fentanyl

Cyclopropyl fentanyl (83 FR 469, January 4, 2018), methoxyacetyl fentanyl and *ortho*-fluorofentanyl (82 FR 49504, October 26, 2017), and *para*-fluorobutyryl fentanyl (83 FR 4580, February 1, 2018) were temporarily controlled in schedule I of the CSA upon finding that they pose an imminent hazard to the public safety. These substances share pharmacological profiles similar to morphine, fentanyl, and other synthetic opioids which act as μ-opioid receptor agonists. For this reason, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl are abused

for their opioid-like effects. Law enforcement and public health reports demonstrate the illicit use and distribution of these substances, which are similar to that of heroin and prescription opioid analgesics.

Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl were identified in law enforcement encounters in the United States. 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 NFLIS,[1] cyclopropyl fentanyl (first reported in 2016) was identified in 2,461 exhibits submitted to forensic laboratories, methoxyacetyl fentanyl (first reported in 2017) was identified in 1,718 exhibits, *ortho*-fluorofentanyl (first reported in 2016) was identified in 13 exhibits, and *para*-fluorobutyryl fentanyl (first reported in 2015) was identified in 309 exhibits.

The DEA is not aware of any claims or any medical or scientific literature suggesting that cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, or *para*-fluorobutyryl fentanyl have a currently accepted medical use in treatment in the United States. In addition, the Department of Health and Human Services (HHS) advised the DEA, by letters dated September 6, 2017 (cyclopropyl fentanyl), July 14, 2017 (methoxyacetyl fentanyl), June 9, 2017 (*ortho*-fluorofentanyl), and November 8, 2017 (*para*-fluorobutyryl fentanyl) that there were no investigational new drug applications or approved new drug applications for these substances.

The DEA requested that HHS conduct a scientific and medical evaluation and a

[1] NFLIS was queried on June 7, 2019. Data are still being collected for January 2019 – June 2019 due to the normal lag period for labs reporting to NFLIS.

scheduling recommendation for methoxyacetyl fentanyl and *ortho*-fluorofentanyl (by letter dated April 18, 2018) and cyclopropyl fentanyl and *para*-fluorobutyryl fentanyl (by letter dated November 5, 2018). Regardless of these requests and any potential responses from HHS, the DEA is not required under 21 U.S.C. 811(d)(1) to make any findings otherwise required by 21 U.S.C. 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 U.S.C. 811(a) and (b). The Acting Administrator advised HHS, by letter dated September 6, 2019, that the DEA no longer requires scientific and medical evaluations and scheduling recommendations for cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl. These evaluations are no longer required due to the placement of these substances in Schedule I of the Single Convention on Narcotic Drugs (1961) in March 2019. Therefore, consistent with the framework of 21 U.S.C. 811(d), the DEA concludes that cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl have no currently accepted medical use in treatment in the United States and are most appropriately placed in schedule I of the CSA, the same schedule in which they currently reside. Further, while the DEA temporarily scheduled these substances under 21 CFR 1308.11(h), a paragraph reserved for the temporary listing of substances subject to emergency scheduling, this order moves these substances to 21 CFR 1308.11(b). As explained above, because control is required under the Single Convention on Narcotic Drugs (1961), the DEA will not be initiating regular rulemaking proceedings to schedule these substances pursuant to 21 U.S.C. 811(a).

Conclusion

In order to meet the United States' obligations under the Single Convention on Narcotic Drugs (1961) and because cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl have no currently accepted medical use in treatment in the United States, the Acting Administrator of the DEA has determined that these substances should remain in schedule I of the CSA.

Requirements for Handling

Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl have been controlled as schedule I controlled substances since January 4, 2018, October 26, 2017, October 26, 2017, and February 1, 2018, respectively. With publication of the final order contained in this document, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl remain subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, engagement in research, conduct of instructional activities, 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, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl 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.* Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl 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*. Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl are subject to schedule I security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93.

4. *Labeling and packaging*. All labels, labeling, and packaging for commercial containers of cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl 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.* A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 is required in order to manufacture cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl.

6. *Inventory*. Every DEA registrant who possesses any quantity of cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl was required to keep an inventory of all stocks of these substances on hand as of January 4, 2018, October 26, 2017, October 26, 2017, and February 1, 2018, respectively, 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 cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl 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 cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl must 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 cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl 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 cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl 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 Order 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in Executive Order 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 Executive Order 13771 regulatory action.

Executive Order 12988, Civil Justice Reform

This action 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 action does not have federalism implications warranting the application of Executive Order 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 Executive Order 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 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.*

To the extent that 21 U.S.C. 811(d)(1) directs that if control is required by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, scheduling actions shall be issued by order (as compared to scheduling pursuant to 21 U.S.C. 811(a) by rule), the 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 21 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States given that this action is being done in accordance with 21 U.S.C. 811(d)(1)'s requirement 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, the 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, 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:

a. Redesignate paragraphs (b)(51) through (b)(66) as (b)(55) through (70);

b. Redesignate paragraphs (b)(41) through (b)(50) as (b)(43) through (52);

c. Redesignate paragraphs (b)(22) through (40) as (b)(23) through (41);

d. Add new paragraphs (b)(22), (42), (53), and (54); and

e. Remove and reserve paragraphs (h)(19), (21), (22), and (24).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(22) Cyclopropyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopropanecarboxamide) 9845

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(42) Methoxyacetyl fentanyl (2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide) 9825

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(53) *ortho*-Fluorofentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide); other name: 2-fluorofentanyl) 9816

(54) *para*-Fluorobutyryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide).....9823

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Dated: October 19, 2019.

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Uttam Dhillon,
Acting Administrator.

[FR Doc. 2019-23348 Filed: 10/24/2019 8:45 am; Publication Date: 10/25/2019]