



Billing Code 4410-09-P

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**[Docket No. DEA-473]**

**Schedules of Controlled Substances: Temporary Placement of *ortho*-Fluorofentanyl, Tetrahydrofuranyl Fentanyl, and Methoxyacetyl Fentanyl into Schedule I**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Proposed amendment; notice of intent.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule the synthetic opioids, *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*ortho*-fluorofentanyl or 2-fluorofentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl), and 2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (methoxyacetyl fentanyl), into Schedule I. This action is based on a finding by the Administrator that the placement of these synthetic opioids into Schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to Schedule I controlled substances under the Controlled Substances Act on the manufacture, distribution, reverse

distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of these synthetic opioids.

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

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

**SUPPLEMENTARY INFORMATION:** This notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) to add *ortho*-fluorofentanyl, tetrahydrofuranfentanyl, and methoxyacetyl fentanyl to Schedule I under the Controlled Substances Act.<sup>1</sup> The temporary scheduling order will be published in the *Federal Register*, but will not be issued before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

#### **Legal Authority**

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid 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.

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<sup>1</sup> Though DEA has used the term “final order” with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a “temporary scheduling order.” No substantive change is intended.

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); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

## **Background**

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.<sup>2</sup> The Administrator transmitted notice of his intent to place *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl in Schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter. Notice for these actions was transmitted on the following dates: May 19, 2017 (*ortho*-fluorofentanyl) and July 5, 2017 (tetrahydrofuranlyl fentanyl and methoxyacetyl fentanyl). The Assistant Secretary responded by letter dated June 9, 2017 (*ortho*-fluorofentanyl) and July 14, 2017 (tetrahydrofuranlyl fentanyl and methoxyacetyl fentanyl), and advised that based on a review by the Food and Drug Administration (FDA), there are currently no

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<sup>2</sup> 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.

investigational new drug applications or approved new drug applications for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the CSA. *ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl under section 505 of the FDCA, 21 U.S.C. 355.

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 consider three of the eight factors set forth in 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in Schedule I. 21 U.S.C. 811(h)(1). Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

***ortho*-Fluorofentanyl, Tetrahydrofuranyl Fentanyl, and Methoxyacetyl Fentanyl**

The recent identification of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in drug evidence and the identification of these substances in

association with fatal overdose events indicate that these substances are being abused for their opioid properties. No approved medical use has been identified for *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, or methoxyacetyl fentanyl, nor have they been approved by the FDA for human consumption.

Available data and information for *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl, 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 is available in its entirety under "Supporting and Related Material" of the public docket for this action at [www.regulations.gov](http://www.regulations.gov) under Docket Number DEA-473.

#### **Factor 4. History and Current Pattern of Abuse**

The recreational abuse of fentanyl-like substances continues to be a significant concern. These substances are distributed to users, often with unpredictable outcomes. *ortho*-Fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl have recently been encountered by law enforcement and public health officials. Adverse health effects and outcomes are demonstrated by fatal overdose cases involving these substances. The documented negative effects of *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl are consistent with those of other opioids.

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are repositied in

STARLiMS. Data from STRIDE and STARLiMS were queried on June 19, 2017.

STARLiMS registered four reports containing *ortho*-fluorofentanyl from California and five reports containing tetrahydrofuranlyl fentanyl from Florida and Missouri. According to STARLiMS, the first laboratory submissions of *ortho*-fluorofentanyl and tetrahydrofuranlyl fentanyl occurred in April 2016, and March 2017, respectively.

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. Data from NFLIS was queried on June 20, 2017. NFLIS registered three reports containing *ortho*-fluorofentanyl from state or local forensic laboratories in Virginia.<sup>3</sup> According to NFLIS, the first report of *ortho*-fluorofentanyl was reported in September 2016. NFLIS registered two reports containing tetrahydrofuranlyl fentanyl from state or local forensic laboratories in New Jersey and was first reported in January 2017. The identification of methoxyacetyl fentanyl in drug evidence submitted in April 2017 was reported to DEA from a local laboratory in Ohio.<sup>4</sup> The DEA is not aware of any laboratory identifications of *ortho*-fluorofentanyl prior to 2016 or identifications of tetrahydrofuranlyl fentanyl or methoxyacetyl fentanyl prior to 2017.

Evidence suggests that the pattern of abuse of fentanyl analogues, including *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl, parallels that of heroin and prescription opioid analgesics. Seizures of *ortho*-fluorofentanyl,

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<sup>3</sup> Data are still being collected for March 2017 – June 2017 due to the normal lag period for labs reporting to NFLIS.

<sup>4</sup> Email from Cuyahoga County Medical Examiner's Office, to DEA (May 8, 2017 02:29 p.m. EST) (on file with DEA).

tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been encountered in powder form similar to fentanyl and heroin and have been connected to fatal overdoses.

#### **Factor 5. Scope, Duration and Significance of Abuse**

Reports collected by the DEA demonstrate *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are being abused for their opioid properties. Abuse of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have resulted in mortality (*see* DEA 3-Factor Analysis for full discussion). The DEA collected post-mortem toxicology and medical examiner reports on 13 confirmed fatalities associated with *ortho*-fluorofentanyl which occurred in Georgia (1), North Carolina (11), and Texas (1), two confirmed fatalities associated with tetrahydrofuranyl fentanyl which occurred in New Jersey (1) and Wisconsin (1), and 2 confirmed fatalities associated with methoxyacetyl fentanyl which occurred in Pennsylvania. It is likely that the prevalence of these substances in opioid related emergency room admissions and deaths is underreported as standard immunoassays may not differentiate fentanyl analogues from fentanyl.

*ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been identified in drug evidence collected by law enforcement. NFLIS and STARLiMS have a total of seven drug reports in which *ortho*-fluorofentanyl was identified in drug exhibits submitted to forensic laboratories in 2016 from law enforcement encounters in California and Virginia and seven drug reports in which tetrahydrofuranyl fentanyl was identified in drug exhibits submitted to forensic laboratories in 2017 from law enforcement encounters in Florida, Missouri, and New Jersey. The identification of

methoxyacetyl fentanyl in drug evidence submitted in April 2017 was reported to DEA from Ohio.

The population likely to abuse *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl overlaps with the population abusing prescription opioid analgesics, heroin, fentanyl, and other fentanyl-related substances. This is evidenced by the routes of drug administration and drug use history documented in *ortho*-fluorofentanyl and tetrahydrofuranlyl fentanyl fatal overdose cases. Because abusers of *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl are likely to obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (i.e. use a drug for the first time) *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, or methoxyacetyl fentanyl 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**

*ortho*-Fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl exhibit pharmacological profiles similar to that of fentanyl and other  $\mu$ -opioid receptor agonists. The toxic effects of *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl in humans are demonstrated by overdose fatalities involving these substances. Abusers of *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl 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 information received by the DEA, the misuse and abuse of *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl lead to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are high. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

*ortho*-Fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl have been associated with numerous fatalities. At least 13 confirmed overdose deaths involving *ortho*-fluorofentanyl abuse have been reported from Georgia (1), North Carolina (11), and Texas (1). At least two confirmed overdose deaths involving tetrahydrofuranlyl fentanyl have been reported from New Jersey (1) and Wisconsin (1). At least two confirmed overdose deaths involving methoxyacetyl fentanyl have been reported from Pennsylvania. As the data demonstrates, the potential for fatal and non-fatal overdoses exists for *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and methoxyacetyl fentanyl and these substances 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 available data and information, summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of *ortho*-fluorofentanyl, tetrahydrofuranlyl fentanyl, and

methoxyacetyl fentanyl pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl 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 letters dated May 19, 2017 (*ortho*-fluorofentanyl) and July 5, 2017 (tetrahydrofuranyl fentanyl and methoxyacetyl fentanyl), notified the Assistant Secretary of the DEA's intention to temporarily place these substances in Schedule I.

### **Conclusion**

This notice of intent provides the 30-day notice pursuant to section 201(h)(1) of the CSA, 21 U.S.C. 811(h)(1), of DEA's intent to issue a temporary scheduling order. In accordance with the provisions of section 201(h)(3) of the CSA, 21 U.S.C. 811(h)(3), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in Schedule I of the CSA, and finds that placement of these synthetic opioids into Schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

The temporary placement of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Because the Administrator hereby finds that it is necessary to temporarily place *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling these substances will be effective on the date that order is published 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). It is the intention of the Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon publication of the temporary order, *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a Schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular 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 regular 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 regular 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).

### **Regulatory Matters**

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 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 section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 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.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the

DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Assistant Secretary in response to notice that DEA transmitted to the Assistant Secretary pursuant to section 811(h)(4).

Further, the DEA believes that this notice of intent 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 (RFA). 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 section 553 of 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.

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.

#### **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 hereby provides notice of its intent to temporarily amend 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. In § 1308.11, add paragraphs (h)(19) through (21) to read as follows:

**§ 1308.11 Schedule I**

\* \* \* \* \*

(h) \* \* \*

(19) *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: *ortho*-fluorofentanyl, 2-fluorofentanyl).....(9816)

(20) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrofuran-2-carboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: tetrahydrofuranyl fentanyl).....(9843)

(21) 2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: methoxyacetyl fentanyl).....(9825)

Dated: August 26, 2017

Chuck Rosenberg,  
*Acting Administrator.*

[FR Doc. 2017-19283 Filed: 9/11/2017 8:45 am; Publication Date: 9/12/2017]