



Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-413F]

Schedules of Controlled Substances: Temporary Placement of Acetyl Fentanyl into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioid, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl), and its optical, positional, and geometric isomers, salts and salts of isomers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of this opioid substance into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, import, export, engage in research, or possess), or propose to handle, acetyl fentanyl.

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

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

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

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are

found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated her scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of the Administrator's intention to temporarily place a substance into schedule I of the CSA.¹

¹ Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this final order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, 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 Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

The Administrator transmitted the notice of intent to place acetyl fentanyl into schedule I on a temporary basis to the Assistant Secretary by letter dated April 7, 2015. The Assistant Secretary responded to this notice by letter dated April 29, 2015 (received by the DEA on May 05, 2015), and advised that based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for acetyl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of acetyl fentanyl into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C.

811(h)(4). Acetyl fentanyl is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for acetyl fentanyl under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the scheduling of acetyl fentanyl in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule acetyl fentanyl was published in the Federal Register on May 21, 2015. 80 FR 29227.

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 section 201(c) of the CSA, 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed into schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that

have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for acetyl fentanyl, summarized below, indicate that this synthetic opioid has 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 analysis is available in its entirety under the tab “Supporting and Related Material” of the public docket of this action at www.regulations.gov under Docket Number DEA-413F.

Factor 4. History and Current Pattern of Abuse

Clandestinely produced substances structurally related to the schedule II opioid analgesic fentanyl were trafficked and abused on the West Coast in the late 1970s and 1980s. These clandestinely produced fentanyl-like substances were commonly known as designer drugs, and recently, there has been a reemergence in the trafficking and abuse of designer drug substances, including fentanyl-like substances. Alpha-methylfentanyl, the first fentanyl analogue identified in California, was placed into schedule I of the CSA in September 1981. Following the control of alpha-methylfentanyl, the DEA identified several other fentanyl analogues (3-methylthiofentanyl, acetyl-alpha-methylfentanyl, beta-hydroxy-3-methylfentanyl, alpha-methylthiofentanyl, thiofentanyl, beta-hydroxyfentanyl, para-fluorofentanyl and 3-methylfentanyl) in submissions to forensic laboratories. These substances were temporarily controlled under schedule I of the CSA after finding that they posed an imminent hazard to public safety and were subsequently permanently placed into schedule I of the CSA.

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 State and local forensic laboratories across the country. The first laboratory submission of acetyl fentanyl was recorded in Maine in April 2013 according to NFLIS. NFLIS registered eight reports containing acetyl fentanyl in 2013 in Louisiana, Maine, and North Dakota; and 30 reports in 2014 in Florida, Illinois, Louisiana, Maine, New Jersey, Ohio, Oregon, Pennsylvania, and Virginia.

The System to Retrieve Information from Drug Evidence (STRIDE) is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from this database are from the DEA, other Federal agencies, and some local law enforcement agencies. Acetyl fentanyl was first reported to STRIDE in September 2013 from exhibits obtained through a controlled purchase in Louisiana. In October 2013, an exhibit collected from a controlled purchase of suspected oxycodone tablets in Rhode Island contained acetyl fentanyl as the primary substance. In 2014, STARLiMS (a web-based, commercial laboratory information management system that is in transition to replace STRIDE) and STRIDE reported eight additional seizures in Colorado, Florida, Georgia, and Washington.

In August 2013, the Centers for Disease Control and Prevention published an article in its Morbidity and Mortality Weekly Report documenting a series of 14 fatalities related to acetyl fentanyl that occurred between March and May 2013. In December 2013, another fatality associated with acetyl fentanyl was reported in Rhode Island for a total of 15 fatalities. In February 2014, the North Carolina Department of Health and Human Services issued a health advisory related to acetyl fentanyl following at least

three deaths related to this synthetic drug. Toxicologists at the North Carolina Office of the Chief Medical Examiner detected acetyl fentanyl in specimens associated with deaths that occurred in January 2014 in Sampson, Person, and Transylvania counties. In July and August 2014, four additional fatalities involving acetyl fentanyl were reported for a total of seven fatalities in North Carolina. Deaths involving acetyl fentanyl have also been reported in California (1), Louisiana (14), Oregon (1) and Pennsylvania (1).

A significant seizure of acetyl fentanyl occurred in April 2013 during a law enforcement investigation in Montreal, Canada. Approximately three kilograms of acetyl fentanyl in powder form and approximately 11,000 tablets containing acetyl fentanyl were seized. Given that a typical dose of acetyl fentanyl is in the microgram range, a three kilogram quantity could potentially produce millions of dosage units. In the United States, tablets that mimic pharmaceutical opioid products have been reported in multiple states, including Colorado, Florida, Georgia, Rhode Island, and Washington. Recent reports indicate that acetyl fentanyl in powder form is available over the Internet and has been imported to addresses within the United States.

Evidence also suggests that the pattern of abuse of fentanyl analogues, including acetyl fentanyl, parallels that of heroin and prescription opioid analgesics. For example, seizures of acetyl fentanyl have been encountered both in powder and in tablet form. It is also known to have caused many fatal overdoses, in which intravenous routes of administration and histories of drug abuse are documented.

Factor 5. Scope, Duration and Significance of Abuse

The DEA is currently aware of at least 39 fatalities associated with acetyl fentanyl. These deaths occurred in 2013 and 2014 from six states including California, Louisiana,

North Carolina, Oregon, Pennsylvania, and Rhode Island. STARLiMS and STRIDE, databases capturing drug evidence information from DEA forensic laboratories, have a total of 10 drug reports in which acetyl fentanyl was identified in six cases for analyzed drugs submitted from January 2010 – December 2014 from Colorado, Florida, Georgia, Louisiana, Rhode Island, and Washington. It is likely that the prevalence of acetyl fentanyl in opioid analgesic-related emergency room admissions and deaths is underreported since standard immunoassays cannot differentiate acetyl fentanyl from fentanyl.

The population likely to abuse acetyl fentanyl overlaps with the populations abusing prescription opioid analgesics and heroin. This is evidenced by the routes of administration and drug use history documented in acetyl fentanyl fatal overdose cases. Because abusers of acetyl fentanyl are likely to obtain the drug through illicit sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse health risks to its abusers. This risk is particularly heightened by the fact that acetyl fentanyl is a highly potent opioid (15.7 fold more potent than that of morphine as tested in mice using an acetic acid writhing method). Thus small changes in the amount and purity of the substance could potentially lead to overdose and death.

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

Acetyl fentanyl exhibits a pharmacological profile similar to that of fentanyl and other opioid analgesic compounds, and it is a potent opioid analgesic reported to be 1/3 as potent as fentanyl and 15.7 times as potent as morphine in mice tested in an acetic acid writhing method. In addition, studies also showed that the range between the effective dose (ED50) and the lethal dose (LD50) of acetyl fentanyl is narrower than that of

morphine and fentanyl, increasing the risk of fatal overdose. Thus, its abuse is likely to pose quantitatively greater risks to the public health and safety than abuse of traditional opioid analgesics such as morphine.

Based on the above pharmacological data, the abuse of acetyl fentanyl at least leads to the same qualitative public health risks as heroin, fentanyl, and other opioid analgesic compounds. The public health risks attendant to the abuse of heroin and opioid analgesics are well established. The abuse of opioid analgesics has resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

Acetyl fentanyl has been associated with numerous fatalities. At least 39 overdose deaths due to acetyl fentanyl abuse have been reported in six states in 2013 and 2014, California, Louisiana, North Carolina, Oregon, Pennsylvania, and Rhode Island. This indicates that acetyl fentanyl poses an imminent hazard to public safety.

Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety

Based on the data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of acetyl fentanyl poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed into schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for acetyl fentanyl indicate that this substance has a high potential for abuse, no currently accepted

medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 7, 2015, notified the Assistant Secretary of the DEA's intention to temporarily place this substance into schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl), into schedule I of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Because the Administrator hereby finds it necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard to the public safety, this final order temporarily scheduling acetyl fentanyl will be effective on the date of publication in the Federal Register, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

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

Requirements for Handling

Upon the effective date of this final order, acetyl fentanyl will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, 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, conducts instructional activities with, or possesses), or who desires to handle, acetyl 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, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles acetyl fentanyl, and is not registered with the DEA, must submit an application for registration and may not continue to handle acetyl fentanyl as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Security.* Acetyl 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 1301.71-1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

3. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of acetyl fentanyl must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

4. *Inventory.* Every DEA registrant who possesses any quantity of acetyl fentanyl on the effective date of this order must take an inventory of all stocks of this substance on hand as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d). Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including acetyl fentanyl) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

5. *Records.* All DEA registrants must maintain records with respect to acetyl fentanyl pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1307, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants authorized to handle acetyl fentanyl shall have 30 calendar days

from the effective date of this order to be in compliance with all recordkeeping requirements.

6. *Reports.* All DEA registrants who manufacture or distribute acetyl fentanyl must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, 1307, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

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

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

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

10. *Liability.* Any activity involving acetyl fentanyl not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued

before the expiration of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of 5 U.S.C. 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action final order is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Pursuant to the Congressional Review Act, “any rule for which an agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA’s need to move quickly to place this substance into schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with 5 U.S.C. 808(2), this order shall take effect immediately upon its publication.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Amend § 1308.11 by adding paragraph (h)(24) to read as follows:

§ 1308.11 Schedule I.

* * * *

(h) * * *

(24) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: acetyl fentanyl)

.....(9821).

* * * *

Dated: July 13, 2015.

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2015-17563 Filed: 7/16/2015 08:45 am; Publication Date: 7/17/2015]