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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-460]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic opioid, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryl fentanyl *or* acryloylfentanyl), and its isomers, esters, ethers, salts and salts of isomers, esters, and ethers, into Schedule I. This action is based on a finding by the Administrator that the placement of acryl fentanyl 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, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, acryl fentanyl.

DATES: This temporary scheduling order is effective July 14, 2017, until July 15, 2019, unless it is extended for an additional year or a permanent scheduling proceeding is

completed. The DEA will publish a document in the *Federal Register* announcing an extension or permanence.

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

SUPPLEMENTARY INFORMATION:

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 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 scheduling¹ 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 scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

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

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.² The Administrator transmitted the notice of intent to place acryl fentanyl into Schedule I on a temporary basis to the Assistant Secretary by letter dated April 17, 2017. The Assistant Secretary responded to this notice by letter dated May 2, 2017, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for acryl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of acryl 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). Acryl fentanyl is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for acryl fentanyl under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of acryl fentanyl in Schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to issue a temporary order to schedule acryl fentanyl was published in the *Federal Register* on June 2, 2017. 82 FR 25564.

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

² 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.

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 acryl 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's three-factor analysis, and the Assistant Secretary's May 2, 2017, letter, are available in their entirety under the tab "Supporting Documents" of the public docket of this action at www.regulations.gov under FDMS Docket ID: DEA-2017-0005 (Docket Number DEA-460).

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. Acryl fentanyl has recently been encountered by law enforcement and public health officials and the adverse health effects and outcomes are demonstrated by fatal overdose

cases. The documented negative effects of acryl 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 May 5, 2017. STARLiMS registered 36 reports containing acryl fentanyl, from Alabama, Connecticut, Illinois, Indiana, Kentucky, Louisiana, Minnesota, Missouri, North Carolina, South Carolina, Tennessee, Texas, and West Virginia. According to STARLiMS, the first laboratory submission of acryl fentanyl occurred in July 2016 in Texas.

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. NFLIS registered 74 reports containing acryl fentanyl from state or local forensic laboratories in Arkansas, California, Connecticut, Iowa, Kentucky, Ohio, Pennsylvania, South Carolina, Texas, and Wisconsin (query date: May 5, 2017).³ The first report of acryl fentanyl was reported in Wisconsin in May 2016. The DEA is not aware of any laboratory identifications of acryl fentanyl prior to 2016.

Evidence suggests that the pattern of abuse of fentanyl analogues, including acryl fentanyl, parallels that of heroin and prescription opioid analgesics. Seizures of acryl fentanyl have been encountered in powder form, in solution, and packaged similar to that

³ Data are still being collected for February 2017 – April 2017 due to the normal lag period for labs reporting to NFLIS.

of heroin. Acryl fentanyl has been encountered as a single substance as well as in combination with other substances of abuse, including heroin, fentanyl, 4-fluoroisobutyryl fentanyl, and furanyl fentanyl. Acryl fentanyl has been connected to fatal overdoses, in which insufflation and intravenous routes of administration were documented.

Factor 5. Scope, Duration and Significance of Abuse

Reports collected by the DEA demonstrate acryl fentanyl is being abused for its opioid properties. This abuse of acryl fentanyl has resulted in morbidity and mortality (*see* DEA 3-Factor Analysis for full discussion). The DEA has received reports for at least 83 confirmed fatalities associated with acryl fentanyl. Information on these deaths, occurring as early as September 2016, was collected by the DEA from post-mortem toxicology and medical examiner reports. These deaths were reported from, and occurred in, Illinois (27), Maryland (22), New Jersey (1), Ohio (31), and Pennsylvania (2). NFLIS and STARLiMS have a total of 110 drug reports in which acryl fentanyl was identified in drug exhibits submitted to forensic laboratories in 2016 and 2017 from law enforcement encounters in Alabama, Arkansas, California, Connecticut, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Missouri, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, West Virginia, and Wisconsin. It is likely that the prevalence of acryl fentanyl in opioid analgesic-related emergency room admissions and deaths is underreported as standard immunoassays may not differentiate this substance from fentanyl.

The population likely to abuse acryl 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 acryl fentanyl fatal overdose cases and encounters of the substance by law enforcement officials. Because abusers of acryl fentanyl are likely to obtain this substance 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) acryl 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

Acryl fentanyl exhibits pharmacological profiles similar to that of fentanyl and other μ -opioid receptor agonists. The toxic effects of acryl fentanyl in humans are demonstrated by overdose fatalities involving this substance. Abusers of acryl fentanyl may not know the origin, identity, or purity of this substance, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone.

Based on information reviewed by the DEA, the misuse and abuse of acryl fentanyl leads 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.

Acryl fentanyl has been associated with numerous fatalities. At least 83 confirmed overdose deaths involving acryl fentanyl abuse have been reported from Illinois,

Maryland, New Jersey, Ohio, and Pennsylvania in 2016 and 2017. As the data demonstrates, the potential for fatal and non-fatal overdoses exists for acryl fentanyl; thus, acryl fentanyl poses 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 data and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of acryl fentanyl pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in treatment 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 acryl 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 17, 2017, notified the Assistant Secretary of the DEA's intention to temporarily place this substance into Schedule I. A notice of intent was subsequently published in the *Federal Register* on June 2, 2017. 82 FR 25564.

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 acryl 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 temporary order scheduling acryl 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. Permanent 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 permanent 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 permanent 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 temporary order, acryl fentanyl will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the

manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of Schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, acryl 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 July 14, 2017. Any person who currently handles acryl fentanyl, and is not registered with the DEA, must submit an application for registration and may not continue to handle acryl fentanyl as of July 14, 2017, 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 July 14, 2017 is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a Schedule I registration to handle acryl fentanyl, must surrender all quantities of currently held acryl fentanyl.

3. *Security.* Acryl 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 July 14, 2017.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of acryl fentanyl must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from July 14, 2017, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of acryl fentanyl on the effective date of this order must take an inventory of all stocks of this substance on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. 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 acryl 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.

6. *Records.* All DEA registrants must maintain records with respect to acryl fentanyl pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, 1317, and §1307.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute acryl fentanyl must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of July 14, 2017.

8. *Order Forms.* All DEA registrants who distribute acryl fentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 14, 2017.

9. *Importation and Exportation.* All importation and exportation of acryl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of July 14, 2017.

10. *Quota.* Only DEA registered manufacturers may manufacture acryl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of July 14, 2017.

11. *Liability.* Any activity involving acryl fentanyl not authorized by, or in violation of the CSA, occurring as of July 14, 2017, 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 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. 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 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.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, 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 this substance immediately to avoid an imminent hazard to the public safety. 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 the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

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) (17) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(17) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: acryl fentanyl, acryloylfentanyl).....(9811)

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Dated: July 10, 2017

Chuck Rosenberg

Acting Administrator.

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