



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-440]

Schedules of Controlled Substances: Temporary Placement of U-47700 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, 3,4-dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide (also known as U-47700), and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, 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 U-47700 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, U-47700.

DATES: This final order is effective on [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:

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. 21 U.S.C. 801-971. 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. 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 his intention to temporarily place a substance into schedule I of the CSA.¹ The Administrator transmitted the notice of intent to place U-47700 into schedule I on a

¹ 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.

temporary basis to the Assistant Secretary by letter dated April 18, 2016. The Assistant Secretary responded to this notice by letter dated April 28, 2016, 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 U-47700. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of U-47700 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). U-47700 is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for U-47700 under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of U-47700 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 temporarily schedule U-47700 was published in the *Federal Register* on September 7, 2016. 81 FR 61636.

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 U-47700, 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 updated three-factor analysis, and the Assistant Secretary's April 28, 2016, 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-2016-0016 (Docket Number DEA-440).

Factor 4. History and Current Pattern of Abuse

The recreational abuse of novel opioids continues to be a significant concern. These substances are distributed to users with often unpredictable outcomes. The novel synthetic opioid U-47700 has recently been encountered by law enforcement and public health officials and the adverse health effects and outcomes are documented in the scientific literature. Self-reporting by users describes the effects of U-47700 to be similar to other opioids. The negative effects documented in the scientific literature are also consistent with other opioids. 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 participating Federal, State, and local forensic laboratories across the country. The DEA utilizes NFLIS to monitor for drug trends. The first laboratory submission of U-47700 was recorded in October 2015; a total of 88 records were reported from State and local forensic laboratories between October 2015 – September 2016 according to NFLIS (query date: October 24, 2016).

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are repositied in STARLiMS; data from STARLiMS were queried on November 1, 2016. STARLiMS registered 45 reports containing U-47700 in 2016 from California, Connecticut, Florida, Maryland, Montana, North Dakota, New Jersey, New York, Tennessee, Texas, Virginia, West Virginia, and the District of Columbia. Through information collected from NFLIS, law enforcement reports, and email communications, the DEA is aware of the identification of U-47700 from toxicology reports and submitted evidence to forensic laboratories in several states, including Arkansas, California, Colorado, Connecticut, Florida, Georgia, Iowa, Kentucky, Missouri, Montana, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, and Wisconsin. These identifications occurred in 2015 and 2016.

Evidence suggests that the pattern of abuse of U-47700 parallels that of heroin, prescription opioid analgesics, and other novel opioids. Seizures of U-47700 have been encountered in powder form and in counterfeit tablets that mimic pharmaceutical opioids. U-47700 has also been encountered in glassine bags and envelopes and knotted corners of plastic bags. These clandestine forms of distribution demonstrate the abuse of this substance as a replacement for heroin or other opioids, either knowingly or unknowingly. Further, U-47700 has been encountered as a single substance as well as in combination with other substances, including heroin, fentanyl, and furanyl fentanyl in drug exhibits.

The scientific literature and information collected by DEA demonstrate U-47700 is being abused for its opioid properties. The distribution of U-47700 and the increased prevalence of abuse remain deeply concerning to the DEA.

Factor 5. Scope, Duration and Significance of Abuse

The scientific literature and reports collected by the DEA demonstrate U-47700 is being abused for its opioid properties. This abuse of U-47700 has resulted in morbidity and mortality (see updated DEA 3-Factor Analysis for full discussion). The DEA has received reports for at least 46 confirmed fatalities² associated with U-47700. The information on these deaths occurring in 2015 and 2016 was collected from email communications and toxicology and medical examiner reports and was reported from New Hampshire (1), New York (31), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1). The scientific literature notes additional fatal overdoses connected to U-47700. The population likely to abuse U-47700 appears to overlap with the populations abusing prescription opioid analgesics, other “designer opioids,” and heroin, as evidenced by drug use history documented in U-47700 fatal overdose cases. This observation is further supported by U-47700 being sold on the illicit market in glassine bags, some of which are marked with stamped logos, imitating the sale of heroin. Additionally, U-47700 has been found in counterfeit pills. Because abusers of U-47700 are likely to obtain this substance through non-regulated sources (i.e. on-line purchases or drug dealers), 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

² Due to a proofreading error, the number of fatalities listed in the U-47700 NOI, which was 15, is incorrect. The correct number, 46, has been added to this Final Order.

for the first time) U-47700 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.).

STARLiMS contains 45 reports in which U-47700 was identified in drug exhibits submitted in 2016. A query of NFLIS returned 88 records of U-47700 being identified in exhibits submitted to State and local forensic laboratories between October 2015 – September 2016. The DEA is not aware of any laboratory analyses of drug evidence identifying U-47700 prior to 2015, indicating that this synthetic opioid only recently became available as a replacement for other opioids that are commonly abused (i.e. oxycodone, heroin, fentanyl). U-47700 is available over the Internet and is marketed as a “research chemical.” The on-line sale and marketing of U-47700 are similar to other new psychoactive substances that have rapidly appeared on the recreational drug market and also resulted in negative consequences for the user.

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

U-47700 exhibits pharmacological profiles similar to that of morphine and other mu-opioid receptor agonists. Cases of intoxication are reported in the literature with morbidity and mortality associated with U-47700 use. The toxic effects of U-47700 in humans are demonstrated by overdoses and overdose fatalities associated with this substance, as reported in the scientific literature. Abusers of U-47700 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. Additionally, the potent opioid U-47700 may serve as a precursor to problematic opioid use and dependence.

Based on reports in the scientific literature and information received by the DEA, the abuse of U-47700 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 great. 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.

U-47700 has been associated with a number of fatalities and non-fatal overdoses as detailed in the scientific literature. The DEA has received information connecting U-47700 to at least 46 confirmed overdose deaths, occurring in 2015 and 2016 in New Hampshire (1), New York (31), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1).

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, importation, exportation, and abuse of U-47700 pose 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 U-47700 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 18, 2016, 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 U-47700 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 U-47700 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 final order, U-47700 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, U-47700 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 U-47700, and is not registered with the DEA, must submit an application for registration and may not continue to handle U-47700 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. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle U-47700, must surrender all quantities of currently held U-47700.

3. *Security.* U-47700 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].

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of U-47700 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 [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of U-47700 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 U-47700) 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 U-47700 pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, and 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 U-47700 must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Order Forms.* All DEA registrants who distribute U-47700 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].

9. *Importation and Exportation.* All importation and exportation of U-47700 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].

10. *Quota.* Only DEA registered manufacturers may manufacture U-47700 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].

11. *Liability.* Any activity involving U-47700 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 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 because it poses 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 the public safety and 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 final 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)(18) to read as follows:

§ 1308.11 Schedule I

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(h) * * *

(18) 3,4-Dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: U-47700).....(9547)

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Dated: November 7, 2016

Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2016-27357 Filed: 11/10/2016 8:45 am; Publication Date: 11/14/2016]