By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–21231 Filed 9–6–16; 8:45 am]

BILLING CODE 6750–01–P

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: Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule the synthetic opioid, 3,4-dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide (also known as U–47700), 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 synthetic opioid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. Any final 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, possession, importation, exportation, research, and conduct of, instructional activities of this synthetic opioid.

DATES: September 7, 2016.

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

SUPPLEMENTARY INFORMATION: Any final order will be published in the **Federal Register** and may not be effective prior to October 7, 2016.

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 providing 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, each 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 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 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 notice of his intent to place U–47700 in schedule I on a 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. 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 public safety.

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 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).

U–47700

The substance U–47700 was first described in 1978 in the patent literature. Publications in the scientific literature in the early 1980's found that U–47700 behaved similarly to morphine in animal models. No approved medical

[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.

use has been identified for this synthetic opioid, nor has it been approved by the FDA for human consumption. The recent identification of U–47700 in drug evidence and the identification of this substance in association with fatal overdose events indicate that this substance is being abused for its morphine-like properties. In addition, U–47700 is available for purchase over the Internet and is marketed as a ''research chemical.'' Labels which state ''not for human consumption'' or ''for research purposes only'' have been encountered and are likely used in an effort to circumvent statutory restrictionson controlled substance analogues. 21 U.S.C. 813.

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 three-factor analysis is available in its entirety under the public docket of this action as a supporting document at *www.regulations.gov* under Docket Number DEA–440.

Factor 4. History and Current Pattern of Abuse

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 submissions of U–47700 were recorded in the first quarter of 2016; 10 records were reported from January–March 2016 according to NFLIS (query date: 06/20/2016).

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 reposited in STARLiMS; data from STARLiMS were queried on April 12, 2016. STARLiMS registered one report containing U–47700 in 2016 from Montana. Through information collected from law enforcement reports and personal communications,[2] [3] the DEA is aware of the identification of U–47700 from toxicology reports and submitted evidence to forensic laboratories in several states, including New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Texas, and Wisconsin. These identifications occurred in 2015 and 2016.

Evidence suggests that the pattern of abuse of synthetic opioids, including U–47700, parallels that of heroin and prescription opioid analgesics. 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, which demonstrates the abuse of this substance as a replacement for heroin or other opioids, either knowingly or unknowingly. U–47700 has been encountered as a single substance as well as in combination with other substances, including heroin, fentanyl, and furanyl fentanyl.

Factor 5. Scope, Duration and Significance of Abuse

The DEA is currently aware of at least 15 confirmed fatalities associated with U–47700. The information on these deaths occurring in 2015 and 2016 was collected from personal communications and toxicology and medical examiner reports and was reported from New Hampshire (1), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1). The population likely to abuse U–47700 appears to overlap with the populations abusing prescription opioid analgesics and heroin, as evidenced by drug use history documented in U–47700 fatal overdose cases. This 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. Because abusers of U–47700 are likely to obtain this substance through non-regulated sources, the identity, purity, and quantity is uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (*i.e.* use an illicit drug 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 a report in which U–47700 was identified in drug exhibits submitted in 2016 from Montana. A query of NFLIS returned 10 records of U–47700 being identified in exhibits submitted to Federal, State and local forensic laboratories in the first quarter of 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'' which allows this substance to be easily obtainable.

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. Due to limited scientific data, the potency and toxicity of U–47700 are not known; however, the toxic effects of U–47700 in humans are demonstrated by overdose fatalities associated with this substance. Abusers of U–47700 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 the documented case reports of overdose fatalities, the abuse of U–47700 leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. 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 fatalities. At least 15 confirmed overdose deaths involving U–47700 occurred in 2015 and 2016 in New Hampshire (1), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1). This indicates that U–47700 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 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 U–47700 poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for U–47700 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

[2] Email from North Carolina Department of Health and Human Services, to DEA (April 13, 2016 09:54 a.m. EST) (on file with DEA).

[3] Email from Erie County, Central Police Services, to DEA (March 22, 2016 10:12 a.m. EST) (on file with DEA).

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 in schedule I.

Conclusion

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). 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 set forth the grounds for his determination that it is necessary to temporarily schedule U–47700 in schedule I of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling this substance 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 scheduling process. 21 U.S.C. 811(h) (1) and (2). It is the intention of the Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. U–47700 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 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 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 will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

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 (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 (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.

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 proposes to 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 paragraph (h)(21).

The addition reads as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(21) 3,4-Dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: U–47700). (9547)

* * * * *

Dated: August 31, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–21477 Filed 9–6–16; 8:45 am]

BILLING CODE 4410–09–P