the CO hazard presented by gas furnaces and boilers and the market for gas furnaces and boilers is forecast to grow. The rule establishes performance requirements to address the risk of CO poisoning associated with residential gas furnaces and boilers. The effective date provides a reasonable amount of time for manufacturers to comply with the rule and produce products that prevent the CO hazard. Given the deaths and injuries associated with CO leakage from gas furnaces and boilers, the Commission finds that the rule and its effective date are necessary to address the unreasonable risk of injury associated with gas furnaces and boilers.

F. Public Interest

The rule addresses an unreasonable risk of death and injuries presented from CO hazards associated with gas furnaces and boilers. Adherence to the requirements of the rule would reduce deaths and injuries from CO poisoning associated with gas furnaces and boilers; thus, the rule is in the public interest.

G. Voluntary Standards

If a voluntary standard addressing the risk of injury has been adopted and implemented, then the Commission must find that the voluntary standard is not likely to eliminate or adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely. The Commission determines that the relevant U.S. voluntary standards (ANSI Z21.13–2022, ANSI Z21.47–2021, and ANSI Z21.86–2016) do not contain performance requirements to protect against the known failure modes or conditions identified that have been associated with the production and leakage of CO into living spaces of U.S. residences resulting in numerous deaths and injuries, and thus do not adequately address the hazard of CO exposure from residential gas furnaces and boilers.

H. Reasonable Relationship of Benefits to Costs

The Commission determines the benefits expected from the rule bear a reasonable relationship to its costs. The rule significantly reduces the CO hazard associated with residential gas furnaces and boilers, and thereby reduces the societal costs of the resulting injuries and deaths. When costs are compared to benefits, the estimated costs of the rule are greater than the estimated benefits. Staff calculates net benefits (benefits less costs) to be −$245.74 million on annualized basis, discounted at three percent. The net benefits on per-unit basis are −$64.51, discounted at three percent. Alternatively, this can be described as the proposed rule being a net cost of −64.51 per gas furnace or boiler, which represents approximately three percent of the average price of a gas furnace or boiler. Overall, the proposed rule has a benefit-cost ratio of 0.59; in other words, for every $1 in cost of the proposed rule, there is a return of $0.59 in benefits from mitigated deaths and injuries. However, the rule is estimated to address 90–100 percent of deaths caused by the CO hazard associated with gas furnaces and boilers, resulting in potential total societal annualized benefits from the rule of $356.52 million, discounted at three percent. Staff conducted a sensitivity analysis that showed if by 2035 manufacturers were able to develop compliant gas furnaces and boilers with CO sensors that did not need replacement, and if the analysis took into account that a child's death is considered twice as costly as an adult death, the benefit-cost ratio would increase to 0.78.

I. Least-Burdensome Requirement That Would Adequately Reduce the Risk of Injury

The Commission considered four alternatives to the proposed rule: (1) continue to work and advocate for change through the voluntary standards process; (2) rely on the use of residential CO alarms; (3) continue to conduct education and information campaigns; and (4) rely on recalls. Although these alternatives may be less burdensome alternatives to the rule, the Commission determines that none of the alternatives would adequately reduce the risk of deaths and injuries associated with gas furnaces and boilers that is addressed by the rule.

Elina Lingappa,

Paralegal Specialist, Consumer Product Safety Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1143]

Schedules of Controlled Substances: Temporary Placement of *N*-Desethyl Isotonitazene and *N*-Piperidinyl Etonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule two synthetic benzimidazole-opioid substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act. When it is issued, the temporary scheduling order will impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances 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 these two specified substances.

DATES: October 25, 2023.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order [1] (in the form of a temporary amendment) to add the following two substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, to schedule I under the Controlled Substances Act (CSA):

- *N*-ethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as *N*-desethyl isotonitazene), and
- 2-(4-ethoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1*H*-benzimidazole (commonly known as either *N*-piperidinyl etonitazene or etonitazepipne).

The temporary scheduling order will be published in the **Federal Register** on or after November 24, 2023.

Legal Authority

The CSA provides the Attorney General (as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100) with the authority to temporarily place a substance in 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) while the substance is temporarily controlled under section 811(h), 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 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,

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

21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308.

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to place a substance in schedule I of the CSA temporarily (*i.e.,* to issue a temporary scheduling order). 21 U.S.C. 811(h)(4). The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[2] by letter dated April 3, 2023, regarding *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene. The Assistant Secretary responded to this notice by letter dated May 11, 2023, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene. The Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene currently are not listed in any schedule under the CSA, and no exemptions or approvals under 21 U.S.C. 355 are in effect for these substances.

To find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances. 21 U.S.C. 811(h)(3).

Substances 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 have 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).

[2] The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

Two Benzimidazole-Opioids: N-Desethyl Isotonitazene and N-Piperidinyl Etonitazene

The continued encounter of novel psychoactive substances (NPS) on the recreational drug market poses a threat to public safety. Following the class-wide scheduling of fentanyl-related substances, there has been an increase in the emergence of synthetic opioids that are not structurally related to fentanyl. Beginning in 2019, a new class of synthetic opioids known as benzimidazole-opioids, commonly referred to as ''nitazenes,'' emerged on the recreational drug market. This class of substances was first synthesized in the 1950s by CIBA Aktiengesellschaft in Switzerland, and it has a similar pharmacological profile to fentanyl, morphine, and other mu-opioid receptor agonists. Between August 2020 and April 2022, DEA temporarily controlled eight benzimidazole-opioids because they posed a threat to public safety. 87 FR 21556 (Apr. 12, 2022); 85 FR 51342 (Aug. 20, 2020). Recently, additional benzimidazole-opioids have been identified within the rapidly expanding class of ''nitazene'' compounds on the recreational drug market. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene are some of the recently encountered ''nitazene'' synthetic opioids identified on the illicit drug market.

The continued trafficking and identification of benzimidazole-opioids in toxicology cases pose a significant threat to public health and safety. Adverse health effects associated with the misuse and abuse of synthetic opioids have led to devastating consequences including death. Preclinical pharmacology data demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene have pharmacological profiles similar to those of the potent benzimidazole-opioids etonitazene and isotonitazene, schedule I opioid substances. *N*-Desethyl isotonitazene, an active metabolite of isotonitazene, has been positively identified in postmortem cases that involved isotonitazene. *N*-Piperidinyl etonitazene has been positively identified in at least three toxicology cases. As the United States continues to experience a high number of opioid-involved overdoses and mortalities, the introduction of new designer opioids further exacerbates the current opioid epidemic.

Available data and information for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene, summarized below, indicate that these substances have high potentials for abuse, no currently accepted medical uses in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–1143.

Factor 4. History and Current Pattern of Abuse

In the late 1950s, pharmaceutical research laboratories of the Swiss chemical company CIBA Aktiengesellschaft synthesized a group of structurally unique benzimidazole derivatives with analgesic properties; however, the research effort did not produce any medically approved analgesic products. These benzimidazole derivatives include schedule I substances, such as synthetic opioids clonitazene, etonitazene, and isotonitazene.

Since 2019, there has been an emergence of nitazene compounds on the illicit drug market, which have been positively identified in numerous cases of fatal overdose events. In August 2020, isotonitazene was placed in schedule I of the CSA (85 FR 51342). Subsequently, seven additional benzimidazole-opioids[3] have been placed in schedule I of the CSA (87 FR 21556).

Recently, two additional benzimidazole-opioids have emerged on the illicit drug market. Law enforcement officers have encountered *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in several solid forms (*e.g.,* powder and tablets). These substances are not approved pharmaceutical products and are not approved for medical use anywhere in the world. The Assistant Secretary in a letter to DEA dated May 11, 2023, stated that there are no FDA-approved NDAs or INDs for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in the United States; hence, there are no legitimate channels for these substances as marketed drug products.

The appearance of benzimidazole-opioids on the illicit drug market is similar to other designer opioid drugs that are trafficked for their psychoactive effects. These substances are likely to be abused in the same manner as schedule I opioids, such as etonitazene, isotonitazene, and heroin.

In 2022, *N*-desethyl isotonitazene was identified in counterfeit tablets in the United States and United Kingdom. Recent reporting by Center for Forensic

[3] Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene

Science Research and Education (CFSRE) indicates that in the United States, *N*-desethyl isotonitazene was identified in counterfeit oxycodone round blue tablets in Florida.[4] Further, in December 2022, *N*-desethyl isotonitazene was identified in samples called ''dope'' in the Philadelphia drug supply. *N*-Desethyl isotonitazene was also co-identified in ''dope'' samples containing xylazine, fentanyl, *para*-fluorofentanyl, and designer benzodiazepines (*e.g.,* flubromazepam and bromazolam).

In 2021, *N*-piperidinyl etonitazene emerged on the illicit synthetic drug market, as evidenced by its identification in toxicological analysis of biological samples.[5] In addition, there have been encounters of *N*-piperidinyl etonitazene in Europe. As reported in January 2022 by the European Monitoring Center for Drugs and Drug Addiction (EMCDDA), the European Union Early Warning System Network identified *N*-piperidinyl etonitazene in Germany in October 2021. As of January 23, 2023, a total of four European countries have reported identifications of *N*-piperidinyl etonitazene in powder form to the EMCDDA.[6]

Factor 5. Scope, Duration and Significance of Abuse

N-Desethyl isotonitazene and *N*-piperidinyl etonitazene, similar to etonitazene and isotonitazene (schedule I substances), have been described as potent synthetic opioids, and evidence suggests they are abused for their opioidergic effects. The abuse of these benzimidazole-opioids, similar to other synthetic opioids, has resulted in serious adverse health effects. Between October 2019 and January 2020, *N*-desethyl isotonitazene was positively identified in 13 postmortem samples and 64 driving-under-the-influence-of-drugs (DUID) cases involving isotonitazene in the United States. Although, *N*-desethyl isotonitazene has only been identified as a metabolite of isotonitazene in toxicology cases, the pharmacological profile of this substance demonstrates it is a highly potent synthetic opioid similar to etonitazene, isotonitazene, and fentanyl. As such, the identification of this substance as a parent drug in the recreational drug market is worrisome.

Data from law enforcement suggest that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are being abused in the United States as recreational drugs.[7] Since 2022, there have been three encounters reported to DEA's National Forensic Laboratory Information System (NFLIS)-Drug[8] (Federal, State, and local laboratories) database pertaining to the trafficking, distribution, and abuse of *N*-desethyl isotonitazene. These three encounters of *N*-desethyl isotonitazene were reported to NFLIS-Drug from two states: Florida (2) and Kansas (1).

Based on information collected from NFLIS-Drug, *N*-desethyl isotonitazene was identified in tablet form or as residue. Reporting from CFSRE show that *N*-desethyl isotonitazene was identified in a counterfeit oxycodone tablet in Florida,[9] suggestive that it might be presented as a substitute for heroin or fentanyl and likely abused in the same manner as either of those substances.

The lack of identification of *N*-piperidinyl etonitazene in NFLIS-Drug may be due to the rapid appearance of these benzimidazole-opioids and under reporting as forensic laboratories try to secure reference standards for this substance. However, *N*-piperidinyl etonitazene has been positively identified in toxicology cases in the United States and encountered by law enforcement in Europe.

The population likely to abuse these benzimidazole-opioids appears to be the same as those abusing prescription opioid analgesics, fentanyl, and other synthetic drugs. This is evidenced by the types of other drugs co-identified in biological samples and law enforcement encounters. Because abusers of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are likely to obtain these substances through unregulated sources, the identity, purity, and quantity of these substances are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well-characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[10] as of 2021, an estimated 9.2 million people aged 12 years or older misused opioids in the past year, including 8.7 million prescription pain reliever misusers and 1.1 million heroin users. In 2021, an estimated 5.6 million people had an opioid use disorder in the past year, which included 5.0 million people with a prescription pain reliever use disorder and 1.0 million people with heroin use disorder. This population abusing opioids is likely to be at risk of abusing *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene. Individuals who initiate (*i.e.,* use a drug for the first time) use of these benzimidazole-opioids are likely to be at risk of developing substance use disorder, overdose, and/or death, similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.). Law enforcement and toxicology reports demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are being illicitly distributed and abused.

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

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids on the illicit drug market. Data obtained from pre-clinical studies demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene exhibit pharmacological profiles similar to that of etonitazene, isotonitazene, and other mu-opioid receptor agonists. These two

[4] CFSRE NPS Discovery Public Alert 2023. Case Example—*N*-desethyl isotonitazene. January 2023.

[5] A partnership between the American College of Medical Toxicology (ACMT) and the Center for Forensic Science Research and Education (CFSRE) was established to comprehensively assess the role and prevalence of synthetic opioids and other drugs among suspected overdose events in the United States. CFSRE NPS Monograph. *N*-Piperidinyl etonitazene. November 22, 2021.

[6] Email communication with EMCDDA dated January 23, 2023.

[7] While law enforcement data are not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332 (Dec. 12, 2011).

[8] NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS-Drug, is currently 98.5 percent. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332. NFLIS-Drug data was queried on January 19, 2023.

[9] CFSRE NPS Discovery Public Alert January 2023. Accessed January 25, 2023.

[10] NSDUH, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.,* ever used), past year, and past month abuse or dependence. The 2021 NSDUH annual report is available at Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (*samhsa.gov*) (last accessed January 24, 2023).

benzimidazole-opioids bind to and act as an agonist at the μ-opioid receptors. It is well established that substances that act as mu-opioid receptor agonists have a high potential for addiction and can induce dose-dependent respiratory depression.

Consistent with any mu-opioid receptor agonist, the potential health and safety risks for users of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are high. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene have been positively identified in toxicology cases. The public health risks attendant to the abuse of mu-opioid receptor agonists are well established. These risks include large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. According to CDC provisional data, synthetic opioid-related overdose deaths in the United States increased from 57,834 in 2020 to 71,238 in 2021.[11] Overdose deaths involving opioids increased from an estimated 70,029 in 2020, to 80,816 in 2021. In 2021, according to Drug Abuse Warning Network (DAWN), preliminary findings indicate 1.03 million drug-related emergency department visits involved opioids (fentanyl, heroin, and other opioid pain medications taken alone or in combination with other opioids and/or other drugs).[12]

N-Piperidinyl etonitazene was detected in suspected opioid overdose cases in three patients from New Jersey over a period of three days in July 2021. Of those patients, two reported the use of cocaine; one reported the use of heroin and alprazolam. Similarly, according to a 2021 CFSRE report, *N*-piperidinyl etonitazene was co-identified with fentanyl in two cases and *para*-fluorofentanyl in one other case.[13]

Between October 2019 and January 2020, *N*-desethyl isotonitazene, an active metabolite of isotonitazene was identified in numerous toxicology cases involving isotonitazene. In DUID cases, *N*-desethyl isotonitazene was present in 64 samples containing isotonitazene and was found with isotonitazene in 13 postmortem samples. Although, *N*-desethyl isotonitazene was only identified as a metabolite of isotonitazene in these cases, the pharmacological profile of this substance demonstrate that it is a highly potent synthetic opioid similar to etonitazene, isotonitazene, and fentanyl. As such, the identification of this substance as a parent drug in the recreational drug market is worrisome.

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 uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene pose imminent hazards to public safety. DEA is not aware of any currently accepted medical uses for these substances in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I must 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 *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene indicate that these substances meet the three statutory criteria. As required by 21 U.S.C. 811(h)(4), the Administrator transmitted to the Assistant Secretary, via letter dated April 3, 2023, notice of her intent to place *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in schedule I on a temporary basis. HHS had no objection to the temporary placement of these substances in schedule I.

Conclusion

This Notice of Intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily schedule *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in schedule I of the CSA, and finds that placement of these substances in schedule I is necessary to avoid an imminent hazard to the public safety.

The temporary placement of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before November 24, 2023. Because the Administrator hereby finds this temporary scheduling order necessary to avoid an imminent hazard to the public safety, it will take effect on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). The Administrator intends to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon the temporary order's publication, *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene will then be subject to the CSA's schedule I regulatory controls and to administrative, civil, and criminal sanctions applicable to their manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession.

The CSA sets forth specific criteria for scheduling drugs or other substances. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures ''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 appropriate process and the government 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 Analyses

The CSA provides for expedited temporary scheduling actions where necessary to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h)(1), the Administrator, as delegated by the Attorney General, may, by order, temporarily place substances in schedule I. Such orders may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intent to

[11] 12 Month-ending August 2022 Provisional Number of Drug Overdose Deaths. Reported provisional data as of January 4, 2023. *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.* Accessed January 24, 2023.

[12] DAWN. Preliminary Findings from Drug-Related Emergency Department Visits, 2021. Preliminary Findings from Drug-Related Emergency Department Visits, 2021 (*samhsa.gov*). Accessed January 25, 2023.

[13] NPS Discovery Program at the Center for Forensic Science Research and Education: Monograph. *N*-Piperidinyl etonitazene Toxicology Analytical Report. November 22, 2021.

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, as delegated by the Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the **Federal Register** a Notice of Intent, 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. The APA expressly differentiates between orders and rules, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*'' 5 U.S.C. 551(6) (emphasis added). This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' and final decisions that conclude the scheduling process and are subject to judicial review. 21 U.S.C. 811(a) and 877. The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in section 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Even assuming that this Notice of Intent is subject to section 553 of the APA, the Administrator finds that there is good cause to forgo its notice-and-comment requirements, as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest given the manifest urgency to avoid an imminent hazard to the public safety.

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

Further, 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, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking. As discussed above, DEA is issuing this notice of intent pursuant to DEA's authority to issue a temporary scheduling order. 21 U.S.C. 811(h)(1). Therefore, in this instance, since DEA believes this temporary scheduling action is not a ''rule,'' it is not subject to the requirements of the Regulatory Flexibility Act when issuing this temporary action.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866, sec. 3(f), as amended by E.O. 14094, sec. 1(b), provides the definition of a ''significant regulatory action,'' requiring review by the Office of Management and Budget. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866.

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 E.O. 13132, 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, 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), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(62) and (63) to read as follows:

§ 1308.11 Schedule I

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(h) * * *

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(62) *N*-ethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: *N*-desethyl isotonitazene)	9760
(63) 2-(4-ethoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1*H*-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: *N*-piperidinyl etonitazene; etonitazepipne)	9761

Signing Authority

This document of the Drug Enforcement Administration was signed on October 16, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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