in which it is approved. Once approved, a TEM IPA is effective until December 31 of the first year in which it is effective or until December 31 of the year in which the TEM IPA representative notifies NMFS in writing that the TEM IPA is no longer in effect, whichever is later. A TEM IPA may not expire mid-year. No party may leave a TEM IPA once it is approved, except as allowed under paragraph (d)(3) of this section.

(d) *NMFS review of a proposed TEM IPA.*—(1) *Approval.* A TEM IPA will be approved by NMFS if the TEM IPA meets the following requirements:

(i) Complies with the submission requirements of paragraphs (b) and (c) of this section; and

(ii) Contains the information required in paragraph (b) of this section.

(2) *Amendments to a TEM IPA.* Amendments in writing to an approved TEM IPA may be submitted to NMFS at any time and will be reviewed under the requirements of paragraph (b) of this section. An amendment to an approved TEM IPA is effective when NMFS notifies the TEM IPA representative in writing of NMFS approval.

(3) *Disapproval.* (i) NMFS will disapprove a proposed TEM IPA or a proposed amendment to a TEM IPA:

(A) If the proposed TEM IPA fails to meet any of the requirements of paragraph (b) of this section; or

(B) If a proposed amendment to a TEM IPA would cause the TEM IPA to no longer comply with the requirements of paragraph (b) of this section.

(ii) [Reserved]

(4) *Initial Administrative Determination (IAD).* If NMFS identifies deficiencies in the proposed TEM IPA, NMFS will notify the applicant in writing that the proposed TEM IPA will not be approved. The TEM IPA representative will be provided one 30-day period to address, in writing, all deficiencies identified by NMFS. Additional information or a revised TEM IPA received by NMFS after the expiration of the 30-day period specified by NMFS will not be considered. NMFS will evaluate any additional information submitted by the TEM IPA representative within the 30-day period. If the Regional Administrator determines that the additional information addresses the deficiencies in the proposed TEM IPA, the Regional Administrator will approve the proposed TEM IPA under paragraph (d) of this section. However, if NMFS determines that the proposed TEM IPA does not comply with the requirements of paragraph (b) of this section, NMFS will issue an IAD providing the reasons for disapproving the proposed TEM IPA.

(5) *Appeal.* A TEM IPA representative who receives an IAD disapproving a proposed TEM IPA may appeal under the procedures set forth at 15 CFR part 906. If the TEM IPA representative fails to timely file an appeal of the IAD pursuant to 15 CFR part 906, the IAD will become the final agency action. If the IAD is appealed and the final agency action approves the proposed TEM IPA, the TEM IPA will be effective as described in paragraph (c) of this section.

(6) *Pending approval.* While appeal of an IAD disapproving a proposed TEM IPA is pending, proposed parties to the TEM IPA subject to the IAD, which are not currently parties to an approved TEM IPA, are not authorized to participate in trawl EM category.

(e) *Public release of a TEM IPA and performance metrics.* Each fishing year NMFS will release to the public and publish on the NMFS Alaska Region website:

(1) *Approvals.* Approved TEM IPAs and Approval Memos;

(2) *Parties.* List of parties to each approved TEM IPA; and

(3) *Names.* Names of vessels covered by each approved TEM IPA that:

(i) On average, harvesting pollock catch in excess of 300,000 pounds (136 mt) per fishing trip in the GOA;

(ii) Harvest bycatch in quantities that exceed MRAs; and

(iii) Vessels' performance under the TEM IPA and any restrictions, penalties, or performance criteria imposed under the TEM IPA by vessel name.

(f) *TEM IPA Annual Report.* The representative of each approved TEM IPA must submit a written annual report to the Council at the address specified in § 679.61(f). The Council will make the annual report available to the public.

(1) *Submission deadline.* The TEM IPA Annual Report must be received by the Council no later than May 15 of the following fishing year.

(2) *Information requirements.* The TEM IPA Annual Report must contain the following information:

(i) A comprehensive description of the incentive measures in effect in the previous year;

(ii) A description of how these incentive measures affected individual vessels;

(iii) An evaluation of whether incentive measures were effective in limiting changes in vessel behavior including the effectiveness of:

(A) Measures to discourage participating vessels, on average, from harvesting pollock catch in excess of 300,000 pounds (136 mt) per fishing trip in the GOA;

(B) Measures that incentivize participating vessels to avoid exceeding MRAs established in § 679.20(e) applicable to non-EM vessels;

(C) Restrictions, penalties, or performance criteria that were imposed to prevent vessels from consistently exceeding catcher vessel harvest limit for pollock in the GOA or MRAs relative to non-EM vessels by vessel name (see §§ 679.7(b)(2) and 679.20(e));

(D) The frequency of vessels exceeding the catcher vessel harvest limit for pollock in the GOA and MRA limits relative to non-EM vessels (see §§ 679.7(b)(2) and 679.20(e)); and

(E) Identification of, and the TEM IPA's response to, vessels directed fishing in conflict with harvest specifications or directed fishing for Steller Sea Lion forage species within closed Steller Sea Lion protection areas.

(iv) A description of any amendments to the TEM IPA that were approved by NMFS since the last annual report and the reasons that the amendments to the TEM IPA were requested.

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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: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule two synthetic benzimidazole-opioid substances, as identified in this order, in schedule I of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these two substances in schedule I is necessary to avoid imminent hazard to the public safety. This order imposes 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 with, or possess) or propose to handle these two specified controlled substances.

DATES: This temporary scheduling order is effective July 29, 2024, until July 29, 2026. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., 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 Drug Enforcement Administration (DEA) issues 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).

Legal Authority

Under 21 U.S.C. 811(h)(1), the Attorney General, as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100, has the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the evaluation requirements of 21 U.S.C. 811(b), if the Administrator finds that such action is necessary to avoid an imminent hazard to the public safety.[2] 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.[3]

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, 21 U.S.C. 355.[4]

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

[2] 21 U.S.C. 811(h)(1).

[3] 21 U.S.C. 811(h)(2).

[4] 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).[5] The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[6] 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 (IND) or approved new drug applications (NDA) 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.

DEA has taken into consideration the Assistant Secretary's comments as required by subsection 811(h)(4). DEA has found the control of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent (NOI) to temporarily schedule *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene on October 25, 2023.[7] That NOI discussed findings from DEA's three-factor analysis dated January 2023, which DEA made available on *www.regulations.gov*.

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.[8] Consideration of these factors includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances.[9]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[10] 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.[11]

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,[12] 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.[13]

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''

[5] 21 U.S.C. 811(h)(4).

[6] 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).

[7] 88 FR 73293 (Oct. 25, 2023).

[8] 21 U.S.C. 811(h)(3).

[9] *Id.*

[10] 21 U.S.C. 811(h)(1).

[11] 21 U.S.C. 812(b)(1).

[12] On February 6, 2018, pursuant to 21 U.S.C. 811(h), the then Acting Administrator of Drug Enforcement Administration temporarily placed fentanyl-related substances in schedule I of the Controlled Substances Act (CSA) (83 FR 5188) to avoid an imminent hazard to public safety. Through the Temporary Reauthorization and Study of Emergency Scheduling of Fentanyl Analogues Act, Public Law 116–114, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. This temporary order was subsequently extended multiple times, most recently through the Consolidated Appropriations Act of 2023, Public Law 117–328, which extended the order until December 31, 2024.

[13] Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, flunitazene, Metodesnitazene, Metonitazene, *N*-Pyrrolidino etonitazene, and Protonitazene in Schedule I, 87 FR 21556 (Apr. 12, 2022); Schedules of Controlled Substances: Temporary Placement of Isotonitazene in Schedule I, 85 FR 51342 (Aug. 20, 2020).

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.[14] *N*-Desethyl isotonitazene, an active metabolite of isotonitazene, has been positively identified in at least ten toxicology cases.[15] *N*-Piperidinyl etonitazene has been positively identified in at least three toxicology cases.[16] 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,[17] and a lack of accepted safety for use under medical supervision. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene have been positively identified 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 Thus, the Administrator concludes that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene meet the statutory requirements to be temporarily placed in schedule I under the CSA. 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[18] have been placed in schedule I of the CSA.

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. 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 Science Research and Education (CFSRE) indicates that in the United States, *N*-desethyl isotonitazene was identified in counterfeit oxycodone round blue tablets in Florida. Further, in December 2022, *N*-desethyl isotonitazene was co-identified in ''dope'' samples containing xylazine, fentanyl, *para*-fluorofentanyl, and designer benzodiazepines (*e.g.,* flubromazepam and bromazolam).[19]

In 2021, *N*-piperidinyl etonitazene emerged on the illicit synthetic drug market, as evidenced by its identification in toxicological analysis of biological samples.[20] In addition, there have been encounters of *N*-piperidinyl etonitazene in Europe. As reported in January 2022 by the European Monitoring Center for Drugs

[14] DEA–VA Interagency Agreement. ''In Vitro Receptor and Transporter Assays for Abuse Liability Testing for the DEA by the VA''. Binding and Functional Activity at Delta, Kappa and Mu Opioid Receptors. 2022.

[15] Walton SE, Krotulski AJ, Logan BK. A Forward-Thinking Approach to Addressing the New Synthetic Opioid 2-Benzylbenzimidazole Nitazene Analogs by Liquid Chromatography-Tandem Quadrupole Mass Spectrometry (LC–QQQ–MS). J Anal Toxicol. 2022 Mar 21;46(3):221–231.

[16] Calello DP, Aldy K, Jefri M, Nguyen TT, Krotulski A, Logan B, Brent J, Wax P, Walton S, Manini AF; ToxIC Fentalog Study Group. Identification of a novel opioid, *N*-piperidinyl etonitazene (etonitazepipne), in patients with suspected opioid overdose. Clin Toxicol (Phila). 2022 Sep;60(9):1067–1069.

[17] When finding that placing a substance in schedule I on a temporary basis is necessary to avoid imminent hazard to the public, 21 U.S.C. 811(h) does not require DEA to consider whether the substance has a currently accepted medical use in treatment in the United States. Nonetheless, there is no evidence suggesting that *N*-desethyl isonitazene and etonitazepipne have a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand,* 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that the HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this temporary scheduling action, there is no evidence that health care providers have widespread experience with medical use of N-desethyl isonitazene and etonitazepipne, or that the use of N-desethyl isonitazene and etonitazepipne is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

[18] Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. *See* 87 FR 21556 (Apr. 12, 2022).

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

[20] 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.

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.[21]

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 as a metabolite of isotonitazene in 13 postmortem samples and 64 driving-under-the-influence-of-drugs (DUID) in the United States. However, beginning in 2023, *N*-desethyl isotonitazene has been identified in 10 toxicology cases.[22] The pharmacological profile of *N*-desethyl isotonitazene 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.[23] Since 2022, there have been 14 reports to DEA's National Forensic Laboratory Information System (NFLIS)-Drug[24] (Federal, State, and local laboratories) database pertaining to the trafficking, distribution, and abuse of *N*-desethyl isotonitazene (n = 5) and *N*-piperidinyl etonitazene (n = 9). These five encounters of *N*-desethyl isotonitazene were reported to NFLIS-Drug from Pennsylvania (2), Florida (2) and Kansas (1). Encounters of *N*-piperidinyl etonitazene occurred in Tennessee (8) and Pennsylvania (1).

Based on information collected from NFLIS-Drug, *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene were identified in tablet form or as residue. Reporting from CFSRE show that *N*-desethyl isotonitazene was identified in a counterfeit oxycodone tablet in Florida,[25] suggesting that it might be present as a substitute for heroin or fentanyl and likely abused in the same manner as either of those substances.

The population likely to be harmed by these benzimidazole-opioids appears to be the same as that harmed by prescription opioid analgesics, fentanyl, and other synthetic drugs.[26] This is evidenced by the types of other drugs co-identified in biological samples and law enforcement reports. Law enforcement and toxicology reports demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are being illicitly distributed and abused. Because users 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. 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.).

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.[27] These two benzimidazole-opioids bind to and act as an agonist at the mu-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.

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.[28]

The pharmacological profile of this substance demonstrates 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.

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

[22] CFSRE NPS Opioids Trend Report, 2023 Q1 and Q2. Accessed September 15, 2023.

[23] 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).

[24] 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 Schedules of Controlled Substances:* Placement of Carisoprodol Into Schedule IV, 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data was queried on October 2, 2023.

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

[26] According to the most recent data from the National Survey on Drug Use and Health, as of 2022, an estimated 8.9 million people aged 12 years or older misused opioids in the past year, including 8.5 million prescription pain reliever misusers and 1.0 million heroin users. This population abusing opioids is likely to be at risk of abusing *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene.

[27] DEA–VA Interagency Agreement. ''In Vitro Receptor and Transporter Assays for Abuse Liability Testing for the DEA by the VA''. Binding and Functional Activity at Delta, Kappa and Mu Opioid Receptors. 2022. Unpublished data.

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

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. DEA subsequently published a NOI in the **Federal Register** on October 25, 2023.[29]

Conclusion

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.

This temporary placement of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in schedule I of the CSA 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.[30]

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.[31] 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.[32] Temporary scheduling orders are not subject to judicial review.[33]

Requirements for Handling

Upon the effective date of this temporary order, *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, possession of, and engagement in research and conduct of instructional activities or chemical analysis with, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (possesses, manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with) or desires to handle, *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must be registered with 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 29, 2024. Any person who thereafter handles *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene and is not registered with DEA must submit an application for registration and may not continue to handle *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene as of July 29, 2024, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 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 these substances in a manner not authorized by the CSA on or after July 29, 2024 is unlawful, and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is unable to obtain a schedule I registration to handle *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must surrender all currently held quantities of these substances.

3. *Security. N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.93, as of July 29, 2024.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene must comply with 21 U.S.C. 825 and 958(e) and 21 CFR part 1302. Current DEA registrants will have 30 calendar days from July 29, 2024 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene on the effective date of this order must take an inventory of all stocks of these substances 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 will have 30 calendar days from the effective date of this order to comply with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene) 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 *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR parts 1304, 1312, and 1317, and section 1307.11. Current DEA registrants authorized to handle these two substances shall have 30 calendar days from the effective date of this order to comply with all recordkeeping requirements.

7. *Reports.* All DEA registrants must submit reports with respect to *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, 1312, and 1317, and sections 1301.74(c) and 1301.76(b), as of July 29, 2024. Manufacturers and distributors must also submit reports regarding these substances to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 29, 2024.

9. *Importation and Exportation.* All importation and exportation of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of July 29, 2024.

10. *Quota.* Only DEA-registered manufacturers may manufacture *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in accordance

[29] Schedules of Controlled Substances: Temporary Placement of *N*-Desethyl Isotonitazene and *N*-Piperidinyl Etionitazene in Schedule I, 88 FR 73293 (Oct. 25, 2023).

[30] 21 U.S.C. 811(h)(1) and (2).

[31] 21 U.S.C. 811.

[32] 21 U.S.C. 877.

[33] 21 U.S.C. 811(h)(6).

with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of July 29, 2024.

11. *Liability.* Any activity involving *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene not authorized by or in violation of the CSA, occurring as of July 29, 2024, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

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 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.[34]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, DEA believes the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this temporary scheduling order. 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.

Assuming for the sake of argument that this action 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 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. 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, 13563, and 14094, 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.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 16, 2024, 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

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 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), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(68) and (69) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

[34] 21 U.S.C. 811(h)(1).

*	*	*	*	*	*	*	
(68) *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
(69) 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
*	*	*	*	*	*	*	

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[FR Doc. 2024–16391 Filed 7–26–24; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0658]

RIN 1625–AA00

Safety Zone; Demolition of Lock and Dam 3, Monongahela River Mile Marker 23.5 to 24.5, Elizabeth, PA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary interim rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Monongahela River from mile marker 23.5 to mile marker 24.5 in Elizabeth, PA. This rule is substantially similar to a temporary safety zone published on June 27, 2024. We must establish this temporary safety zone because of the continuation of lock and dam demolition. This regulation will prohibit entry of vessels or persons into the safety zone to protect personnel, vessels, and the marine environment from potential hazards during demolition activities planned from August 1, 2024, through December 31, 2024.

DATES: This rule is effective from August 1, 2024, through December 31, 2024. Comments and related material must be received by the Coast Guard on or before September 27, 2024.

ADDRESSES: We encourage you to submit comments identified by docket number USCG–2024–0658 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Eyobe Mills, Marine Safety Unit, Pittsburgh, U.S. Coast Guard, at telephone 412–221–0807, email *Eyobe.D.Mills@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The similar rule published at 89 FR 53491 on June 27, 2024. The Coast Guard is issuing this interim temporary rule without prior notice and opportunity to comment pursuant to the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to public interest. The notice allowing the demolition project to proceed and providing updated timelines for the project was only recently finalized and provided to the Coast Guard, which did not give the Coast Guard enough time to publish an NPRM, take public comments, and issue a final rule before ethe existing regulation expires. Timely action is needed to respond to the potential safety hazards associated with demolition of the lock and dam, which involves the use of explosives. It would be impracticable and contrary to the public interest to publish an NPRM because we must establish the safety zone to protect the safety of the waterway users, demolition crew, other personnel associated with the project, and the public. A delay of the project to accommodate a full notice and comment period would delay necessary operations, result in increased costs, and delay the completion date of the demolition project and subsequent opening of the navigation channel. We must establish this safety zone by August 1, 2024, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the reasons stated in the preceding paragraph, delaying the effective date of this rule is impracticable and contrary to public interest because timely action is needed to respond to the potential safety hazards associated with the demolition of the lock and dam starting August 1, 2024.

Although this regulation is published as an interim rule without prior notice, public comment is nevertheless desirable to ensure that the regulation is both workable and reasonable. Accordingly, persons wishing to comment may do so by submitting written comments as set out under **ADDRESSES** in this preamble. Commenters should include their names and addresses, identify the docket number for the regulation, and give reasons for their comments. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this temporary interim rule under the authority in 46 U.S.C. 70034. The Captain of the Port Pittsburgh (COTP) has determined that potential hazards associated with this lock and dam demolition will be a safety concern for anyone on the Monongahela River within mile marker 23.5 through 24.5. The use of explosives and other activities involved in demolishing the lock and dam involve inherent risk. To minimize risk to personnel, vessels, property, and the marine environment, no vessel may moor, anchor, transit, or otherwise be present in the designated safety zone at any time during the periods of enforcement unless receiving prior permission from the COTP or their designated representative.

This temporary interim rule is needed to protect personnel, vessels, and the