airplane must comply with the exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Gulfstream Model GVI airplane will incorporate the following novel or unusual design feature:

An oxygen distribution system that provides a shared source of oxygen between the flightcrew and passengers to provide supplemental and therapeutic oxygen.

Discussion

There are no specific regulations that address the design and installation of required passenger or crew oxygen systems that share a supply source with an optional oxygen system used specifically for therapeutic applications. Therapeutic oxygen systems have been previously certified and were generally considered an extension of the passenger oxygen system for the purpose of defining the applicable regulations. As a result, existing requirements, such as 14 CFR 25.1309, 25.1441(b) and (c), 25.1451, and 25.1453, in the Gulfstream GVI airplane's certification basis applicable to this project, provide some design standards appropriate for oxygen system installations. In addition, § 25.1445 includes standards for oxygen distribution systems when oxygen is supplied to crew and passengers. If a common source of supply is used, § 25.1445(a)(2) requires a means to separately reserve the minimum supply required by the flight crew.

Section 25.1445 is intended to protect the flightcrew by ensuring that an adequate supply of oxygen is available to complete a descent and landing following a loss of cabin pressure. When the regulation was written, the only passenger oxygen system designs were supplemental oxygen systems intended to protect passengers from hypoxia in the event of a decompression. Existing passenger oxygen systems did not include design features that would allow the flightcrew to control oxygen to passengers during flight. There are no similar requirements in § 25.1445 when oxygen is supplied from the same source to passengers for use during a decompression, and for discretionary or first-aid use any time during the flight. In the design, the crew, passenger, and therapeutic oxygen systems use the same source of oxygen. These special conditions contain additional design requirements for the equipment involved in this dual therapeutic oxygen plus supplemental gaseous oxygen installation.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Gulfstream Model GVI airplane. Should Jet Aviation AG apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. T00015AT to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 40113, 44701, 44702, and 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Gulfstream Aerospace Corporation Model GVI airplanes, as modified by Jet Aviation AG.

The distribution system for the passenger therapeutic oxygen system must be designed and installed to meet the following requirements:

(1) When oxygen is supplied to passengers for both supplemental and therapeutic purposes, the distribution system must be designed for either—

(a) A source of supplemental oxygen for protection following a loss of cabin pressure, and a separate source for therapeutic purposes; or

(b) A common source of supply with means to separately reserve the minimum supply required by the passengers for supplemental use following a loss of cabin pressure.

Issued in in Kansas City, Missouri, on August 13, 2025.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2025–15630 Filed 8–14–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1337]

Schedules of Controlled Substances: Temporary Placement of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Drug Enforcement Administration issues this temporary order to schedule two benzimidazole-opioids in schedule I of the Controlled Substances Act. DEA bases this action on a finding that placing these substances in schedule I is necessary to avoid imminent hazard to 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, or possess) or propose to handle these substances.

DATES: This temporary order is effective August 15, 2025, until August 15, 2027. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

ADDRESSES: 8701 Morrissette Drive, Springfield, Virginia 22152.

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.

As required by 5 U.S.C. 553(b)(4), a summary of this rule may be found in the docket for this rulemaking at *www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) issues a temporary scheduling order [1]

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the

the form of a temporary amendment) to add the following 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, to schedule I under the Controlled Substances Act (CSA):

- 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (commonly known as, *N*-pyrrolidino metonitazene or metonitazepyne), and
- 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (commonly known as, *N*-pyrrolidino protonitazene or protonitazepyne).

Legal Authority

Under 21 U.S.C. 811(h)(1), 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 evaluation requirements of 21 U.S.C. 811(b), if she finds that such action is necessary to avoid an imminent hazard to the public safety.[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]

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to temporarily place a substance in schedule I of the CSA (*i.e.,* to issue a temporary scheduling order).[5] By letter dated March 24, 2025, the then-Acting Administrator transmitted the required notice to place *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I on a temporary basis to the Acting Assistant Secretary for Health of HHS (Assistant Secretary).[6] On June 11, 2025, the Acting Assistant Secretary responded to this notice and advised DEA 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*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene. The Acting Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I of the CSA. *N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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.[7]

DEA has taken into consideration the Acting Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). DEA has found the control of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene on September 17, 2024.[8] That NOI discussed findings from DEA's three-factor analysis dated August 2024, 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.[9] Considerations of these factors includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene.[10] Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[11] Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States,[12] and a lack of accepted safety for use under medical supervision.[13]

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.

[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] By letter dated December 7, 2023, the then-Administrator transmitted the required notice to place *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I on a temporary basis to the Acting Assistant Secretary for Health of HHS. On December 22, 2023, the then-Assistant Secretary responded to this notice and advised DEA that based on a review by the FDA, there are currently no investigational new IND or approved NDA for *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene. The then-Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I of the CSA.

[8] Schedules of Controlled Substances: Temporary Placement of *N*-Pyrrolidino Metonitazene and *N*-Pyrrolidino Protonitazene in Schedule I, 89 FR 75979 (Sept. 17, 2024).

[9] 21 U.S.C. 811(h)(3).

[10] 21 U.S.C. 811(h)(3).

[11] 21 U.S.C. 811(h)(1).

[12] When finding schedule I placement 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*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene 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 applied the traditional five-part test and concluded the test was not satisfied. 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 providers 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 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 order, there is no evidence that health care providers have widespread experience with medical use of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene or that the use of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied. By letter dated December 22, 2023, and June 11, 2025, DEA has been advised by HHS that there are currently no approved new drug applications or investigational new drug applications for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene. Additionally, HHS communicated no objections to the temporary placement of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene into Schedule I of the CSA.

[13] 21 U.S.C. 812(b)(1).

Two Benzimidazole-Opioids: *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene

The continued encounter of novel synthetic opioids on the recreational drug market poses a threat to public safety. 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 has a similar pharmacological profile to fentanyl, morphine, and other mu-opioid receptor agonists. Between August 2020 and March 2024, DEA temporarily controlled ten benzimidazole-opioids because they posed a threat to public safety.[14] *N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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 poses 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have pharmacological profiles similar to those of the potent benzimidazole-opioids metonitazene and protonitazene, schedule I opioid substances. *N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have been positively identified in at least 26 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene, 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–1337.

Factor 4. History and Current Pattern of Abuse

Since 2019, there has been an emergence of benzimidazole-opioid compounds on the illicit drug market, which have been positively identified in numerous cases of fatal overdose events. The benzimidazole-opioids were originally synthesized and studied in the 1950s by the pharmaceutical research laboratories of the Swiss chemical company Chemical Industries Basel. The research produced 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.

In August 2020, isotonitazene was placed in schedule I of the CSA (85 FR 51342). Subsequently, nine additional benzimidazole-opioids[15] have been placed in schedule I of the CSA (87 FR 21556 and 89 FR 60817). Recently, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have emerged on the illicit drug market. Law enforcement officers have encountered *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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 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 2023, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene emerged on the illicit synthetic drug market as evidenced by their identification in forensic drug seizures and in biological samples.[16] Based on NFLIS-Drug data, law enforcement encounters of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene were found in combination with other substances of abuse such as heroin, designer benzodiazepines, cocaine, fentanyl, methamphetamine, and xylazine.

Factor 5. Scope, Duration and Significance of Abuse

N-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene, similar to etonitazene, metonitazene and protonitazene (schedule I substances), have been described as potent synthetic opioids, and evidence suggests they are abused for their opioidergic effects (see Factor 6). The abuse of these benzimidazole-opioids, similar to other synthetic opioids, has resulted in serious adverse health effects. According to a public alert report[17] published in August 2023, *N*-pyrrolidino protonitazene has been positively confirmed in 20 medicolegal death investigation cases in the United States (n =16) and United Kingdom (n = 4). The cases that occurred in the United States originated from seven states including California, Illinois, Maine, Massachusetts, Minnesota, Wisconsin, and Wyoming. *N*-Pyrrolidino metonitazene has been identified in six toxicology cases as of June 2023 in the United States. The cases occurred in at least three states including Ohio, Illinois, and West Virginia.[18]

Data from law enforcement suggest that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are being abused in the United States as recreational drugs.[19] Since 2023, there have been 123 exhibits reported to the NFLIS-Drug (Federal, State and local laboratories) database pertaining to the trafficking, distribution, and abuse of these substances. There were 10 encounters of *N*-pyrrolidino metonitazene from four states in NFLIS-Drug: Florida (n = 1), Maine (n = 1), Missouri (n = 2) and Ohio (n = 6). *N*-Pyrrolidino protonitazene has been identified in 113 exhibits in NFLIS-Drug

[14] 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); Schedules of Controlled Substances: Temporary Placement of *N*-Desethyl Isotonitazene and *N*-Piperidinyl Etonitazene in Schedule I, 89 FR 60817 (Jul. 29, 2024).

[15] Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene (87 FR 21556, Apr. 12, 2022). *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene (89 FR 60817, Jul. 29 2024).

[16] NMS Labs, in collaboration with the Center for Forensic Science Research and Education at the Fredric Rieders Family Foundation and the Organized Crime Drug Enforcement Task Force at the United States Department of Justice, has received funding from the Centers for Disease Control and Prevention to develop systems for the early identification and notification of novel psychoactive substances in the drug supply within the United States.

[17] Krotulski, AJ; Walton, SE; Papsun, DM; DeBord, J; Fogarty, MF; Logan, BK. (2023) New Nitazene Analogue N-Pyrrolidino Protonitazene Impacting Drug Markets In North America and Europe, Center for Forensic Science Research and Education, United States. CSFRE Public Alert. August 2023.

[18] Krotulski, AJ; Horton, KB; Walton, SE; Papsun, DM; DeBord, J; Fogarty, MF; Logan, BK. (2023) N-Pyrrolidino Metonitazene—NPS Discovery New Drug Monograph, Center for Forensic Science Research and Education, United States.

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

from 16 states: California (n = 3), Colorado (n = 3), District of Columbia (n = 1), Florida (n = 47), Illinois (n = 1), Iowa (n = 10), Kentucky (n = 1), Mississippi (n = 1), Missouri (n = 1), New Jersey (n = 1), New York (n = 1), Ohio (n = 14), Pennsylvania (n = 2), Texas (n = 23), Virginia (n = 3), and Washington (n = 1).[20]

Because abusers of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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.[21] 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, an overdose event, or death, similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.). Law enforcement and toxicology reports demonstrate that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene exhibit pharmacological profiles similar to that of etonitazene, metonitazene, protonitazene, and other mu-opioid receptor agonists. These two benzimidazole-opioids bind to and act as agonists at the mu-opioid receptors.[22] 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.[23]

Consistent with any mu-opioid receptor agonist, the potential health and safety risks for users of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are high. *N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have been positively identified in forensic toxicology and postmortem cases. According to a public alert, *N*-pyrrolidino protonitazene has been positively identified in 20 medicolegal death investigations in the United States and United Kingdom as of August 2023. Of the cases, 16 occurred across seven states in the United States. Decedent ages ranged from mid-20s to mid-70s. *N*-Pyrrolidino protonitazene was co-identified with additional novel psychoactive substances (70 percent), quinine (60 percent), other benzimidazole-opioids (55 percent), methamphetamine/cocaine (55 percent), fentanyl (55 percent), xylazine (35 percent) and designer benzodiazepines (30 percent).[24] Also, *N*-pyrrolidino metonitazene has been identified in six toxicology cases in the United States as of June 2023. The introduction of potent synthetic opioids such as *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene into the illicit market may serve as a portal to problematic opioid use for those seeking these powerful opioids. As documented by toxicology reports, polysubstance abuse remains common in fatalities associated with the abuse of some of these benzimidazole-opioids.

The United States is currently experiencing an opioid epidemic, and the presence of synthetic opioids on the illicit drug market further exacerbates the problem. The trafficking and abuse of new synthetic opioids are deadly trends which pose imminent hazard to the public safety. Adverse health effects associated with the abuse of synthetic opioids and the continued evolution and increased popularity of these substances have been a serious concern in recent years. Because of the pharmacological similarities of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene to metonitazene and protonitazene, the use of these substances presents high risk of abuse and may negatively affect users and communities. The positive identification of these substances in toxicology cases is of serious concern to the public safety. Thus, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene pose imminent hazard to 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 uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene indicate that these substances meet the three statutory criteria. As required by 21 U.S.C. 811(h)(4), the then-Administrator transmitted to the then-Assistant Secretary, via letter dated December 7, 2023, notice of DEA's intent to place *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I on a temporary basis. By letter dated December 22, 2023, the then-Assistant Secretary had no objection to the temporary placement of these substances in schedule I. DEA subsequently published this NOI in the **Federal Register** on September 17, 2024. However, due to the time lapse between HHS's December 22, 2023, response, the then-Acting DEA Administrator by letter dated March 24, 2025, provided notification to the Acting Assistant Secretary per 21 U.S.C. 811(h)(4) of his intent to finalize the placement of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I on a temporary basis. HHS had no objection to the temporary placement of these substances in schedule I.

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 his determination that it is necessary to temporarily schedule *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I of the CSA, and finds that placement of

[20] NFLIS-Drug was queried on November 13, 2024.

[21] Jones CM, Logan J, Gladden RM, Bohm MK. Vital Signs: Demographic and Substance Use Trends Among Heroin Users—United States, 2002–2013. MMWR Morb Mortal Wkly Rep. 2015 Jul 10;64(26):719–25.

[22] 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.

[23] Fox LM, Hoffman RS, Vlahov D, Manini AF. Risk factors for severe respiratory depression from prescription opioid overdose. Addiction. 2018 Jan;113(1):59–66.

[24] Krotulski, AJ; Walton, SE; Papsun, DM; DeBord, J; Fogarty, MF; Logan, BK. (2023) New Nitazene Analogue N-Pyrrolidino Protonitazene Impacting Drug Markets in North America and Europe, Center for Forensic Science Research and Education, United States. CSFRE Public Alert. August 2023.

these substances in schedule I is necessary to avoid an imminent hazard to the public safety.

The temporary placement of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I of the CSA will take effect on the date the order is published in the **Federal Register** and will remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process.[25]

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.[26] 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.[27] Temporary scheduling orders are not subject to judicial review.[28]

Requirements for Handling

Upon the effective date of this temporary order, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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 but not limited to 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*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene 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 August 15, 2025. Any person who thereafter handles *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene and is not registered with DEA must submit an application for registration and may not continue to handle *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene as of August 15, 2025, 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 August 15, 2025 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*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene must surrender all currently held quantities of these substances.

3. *Security. N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.93, as of August 15, 2025.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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 August 15, 2025 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene) 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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 August 15, 2025. 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*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of August 15, 2025.

9. *Importation and Exportation.* All importation and exportation of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of August 15, 2025.

10. *Quota.* Only DEA-registered manufacturers may manufacture *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of August 15, 2025.

11. *Liability.* Any activity involving *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene not authorized by or in violation of the CSA, occurring as of August 15, 2025, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

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 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.[29]

[25] 21 U.S.C. 811(h)(1) and (2).

[26] 21 U.S.C. 811.

[27] 21 U.S.C. 877.

[28] 21 U.S.C. 811(h)(6).

[29] 21 U.S.C. 811(h)(1).

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, 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.*'' [30] (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 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 Acting Assistant Secretary in response to the notices that DEA transmitted to the Acting 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 (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, 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 RFA when issuing this temporary action.

In accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14192, 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), 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. DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

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)(77) and (78) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(77) 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: *N*-pyrrolidino metonitazene; metonitazepyne)	9762
(78) 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: *N*-pyrrolidino protonitazene; protonitazepyne)	9763

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Signing Authority

This document of the Drug Enforcement Administration was signed on August 12, 2025, by Administrator Terrance Cole. 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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[30] 5 U.S.C. 551(6).