securities-offerings, and considered comments received at that time.

By the Commission.

Dated: January 7, 2026.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2026–00315 Filed 1–9–26; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1337]

Schedules of Controlled Substances: Placement of N-Pyrrolidino Metonitazene and N-Pyrrolidino Protonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino metonitazene or metonitazepyne) and 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino protonitazene or protonitazepyne), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, in schedule I under the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1961 Single Convention on Narcotic Drugs. This action imposes permanent regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with or possess), or handle *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene.

DATES: Effective February 11, 2026.

ADDRESSES: 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations, the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,'' the Attorney General must issue an order controlling such drug under the schedule she deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration.[1]

Background

On November 21, 2024, the Director-General of the World Health Organization recommended to the Secretary-General that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene be placed in Schedule I of the Single Convention, as these substances have pharmacological effects similar to other opioid drugs that are controlled in Schedule I of the Single Convention. On June 9, 2025, the Secretariat of the United Nations informed the United States government, by letter, that the Commission voted to place *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in Schedule I of the Single Convention during its 68th session on March 12, 2025 (CND Mar 68/2 and 68/1).

On August 15, 2025, DEA issued a temporary scheduling order, placing *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene temporarily in schedule I of the CSA.[2] That order for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene (codified at 21 CFR 1308.11(h)(77) and (78)) was based on the Administrator's finding that the temporary scheduling of these substances was necessary to avoid an imminent hazard to public safety.[3]

N-Pyrrolidino Metonitazene and N-Pyrrolidino Protonitazene

Benzimidazole-opioids, commonly referred to as ''nitazenes,'' emerged on the recreational drug market in 2019. This class of substances shares a similar pharmacological profile with fentanyl, morphine, and other mu-opioid receptor agonists. In 2023, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene emerged on the illicit opioid drug market. The abuse of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene has been associated with adverse events to include their identification in toxicology cases in the United States. Several substances belonging to the benzimidazole-opioid drug class have been controlled in the United States, and as a class of drug in China, Canada, and the United Kingdom.

Law enforcement reports demonstrate that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are being illicitly distributed and abused. According to the National Forensic Laboratory Information System (NFLIS-Drug)[4] database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories, there have been 284 reports for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene between January 2022 and August 2025 (query date: August 13, 2025). Specifically, there have been 253 encounters of *N*-pyrrolidino protonitazene from 22 States and 31 encounters of *N*-pyrrolidino metonitazene from 10 States. Benzimidazole-opioids have been identified in counterfeit prescription tablets in the United States. A report from the Expert Committee on Drug Dependence Critical Review on *N*-pyrrolidino protonitazene indicate this

[1] 28 CFR 0.100.

[2] *Schedules of Controlled Substances: Temporary Placement of N-pyrrolidino metonitazene and N-pyrrolidino protonitazene in Schedule I*, 90 FR 39314 (August 15, 2025).

[3] *Id.*

[4] 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 more than 96 percent of an estimated 1 million distinct annual federal, state, and local drug analysis cases. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data are not direct evidence of abuse, these 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).

substance has been sold online as ''China White'' heroin.[5]

N-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have no currently accepted medical use in treatment in the United States. The Department of Health and Human Services (HHS) advised DEA, by letter dated June 11, 2025, that based on a review by the Food and Drug Administration (FDA), there were no investigational new drug applications (IND) or approved new drug applications (NDA) for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in the United States. Since this letter, HHS has not advised DEA of any new IND or NDA for these substances. Because *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are not formulated or available for clinical use as approved medicinal products, all current use of these substances by individuals is based on their own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs.

Consistent with 21 U.S.C. 811(d)(1), DEA concludes that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have no currently accepted medical use in treatment in the United States[6] and are most appropriately placed permanently in schedule I of the CSA, the same schedule in which they temporarily reside. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to permanently schedule *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene pursuant to 21 U.S.C.811(a).

Conclusion

In order to meet the United States' obligation under the Single Convention and because *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have no currently accepted medical use in treatment in the United States, the Administrator has determined that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, and salts are possible within the specific existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, should be placed permanently in schedule I of the CSA.

Requirements for Handling

As discussed above, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have been temporarily controlled in schedule I of the CSA since August 15, 2025. Upon the effective date of this final order, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene will be permanently subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, *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. 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 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. N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security. N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71 through 1301.76. Non-practitioners handling *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must comply with the screening requirements of 21 CFR 1301.90 through 1301.93.

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 be in accordance with 21 CFR part 1302.

5. *Quota.* Generally, only registered manufacturers are permitted to 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.

6. *Inventory.* Any person registered with DEA to handle *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene) on hand every two years pursuant to 21 U.S.C. 827 and 958(e) and in accordance

[5] 47th Expert Committee on Drug Dependence Critical Review on *N*-pyrrolidino protonitazene and *N*-pyrrolidino metonitazene. 14–18 October 2024.

[6] 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: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) 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 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 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.

with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports 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 1301.74(b) and (c), 1301.76(b), and 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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.* Every DEA registrant who distributes *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene must continue to comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must continue to comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene not authorized by, or in violation of the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review) and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review). DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulations, or E.O. 14294, Fighting Overcriminalization in Federal Regulations. This action makes no change in the status quo, as *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are already listed as schedule I controlled substances.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols.[7] If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, and ''without regard to'' the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b). *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order, as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a). Therefore, DEA believes that the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[8] Also, this action does not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this action does require compliance with the following existing Office of Management and Budget (OMB) collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.)* that this final rule would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting reports under the CRA to both Houses of Congress and to the Comptroller General.

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 21 CFR 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:

[7] 21 U.S.C. 811(d)(1).

[8] 44 U.S.C. 3501–3521.

■ a. Redesignate paragraphs (b)(79) through (119) as paragraphs (b)(81) through (121);
■ b. Add new paragraphs (b)(79) and (80); and
■ c. Remove and reserve paragraphs (h)(77) and (78).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *	
(79) 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (Other names: *N*-pyrrolidino metonitazene; metonitazepyne)	9762
(80) 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino protonitazene; protonitazepyne)	9763
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Signing Authority

This document of the Drug Enforcement Administration was signed on January 5, 2025, by Administrator Terrance C. 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.

[FR Doc. 2026–00362 Filed 1–9–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2023–0590]

2023 Quarterly Listings; Fourth Quarter; Safety Zones, Security Zones, and Special Local Regulations

AGENCY: Coast Guard, DHS.

ACTION: Notification of expired temporary rules issued.

SUMMARY: This document provides notification of substantive rules issued by the Coast Guard that were made temporarily effective but expired before they could be published in the **Federal Register**. This document lists temporary safety zones, security zones, and special local regulations, all of limited duration and for which timely publication in the **Federal Register** was not possible. This document also announces notifications of enforcement for existing reoccurring regulations that we issued but were unable to be published before the enforcement period ended.

DATES: This document lists temporary Coast Guard rules and notifications of enforcement that became effective, primarily between October 2023 and December 2023, and expired before they could be published in the **Federal Register**.

ADDRESSES: Temporary rules listed in this document may be viewed online, under their respective docket numbers, at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this document contact Ambar Ali, Office of Regulations and Administrative Law, email *HQS-SMB-CG-LRA-Admin@uscg.mil,* telephone (202) 372–3862.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. *Safety zones* may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits, or it may be described as a zone around a vessel in motion. *Security zones* limit access to prevent injury or damage to vessels, ports, or waterfront facilities. *Special local regulations* are issued to enhance the safety of participants and spectators at regattas and other marine events.

Timely publication of these rules in the **Federal Register** may be precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, often informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels enforcing the restrictions imposed by the rule. Timely publication of notifications of enforcement of reoccurring regulations may be precluded when the event occurs with short notice or other agency procedural restraints.

Because **Federal Register** publication was not possible before the end of the effective period, mariners would have been notified of the contents of these safety zones, security zones, special local regulations, regulated navigation areas or drawbridge operation regulations by Coast Guard officials prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary safety zones, security zones, special local regulations, regulated navigation areas and drawbridge operation regulations. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if sufficient time is available to do so before they are placed in effect or terminated. In some of our reoccurring regulations, we say we will publish a notice of enforcement as one of the means of notifying the public. We use this notification to announce those notifications of enforcement that we issued and will post them to their dockets.

The following unpublished rules were placed in effect temporarily during the period between October 2023 and December 2023. To view copies of these rules, visit *www.regulations.gov* and search by the docket number indicated in the following table.