The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Embraer S.A. (Type Certificate Previously Held by Yaborã Indústria Aeronáutica S.A.; Embraer S.A.): Docket No. FAA–2024–2140; Project Identifier MCAI–2024–00242–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 1, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Embraer S.A. (Type Certificate previously held by Yaborã Indústria Aeronáutica S.A.; Embraer S.A.) Model EMB–120, –120ER, –120FC, –120QC, and –120RT airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a structural assessment that indicated the fuselage center I longitudinal skin splice and panel between frames 22 and 23 is susceptible to cracking. The FAA is issuing this AD to address undetected cracks in the fuselage center I longitudinal skin splice and panel between frames 22 and 23. The unsafe condition, if not addressed, could result in undetected fuselage crack propagation, and reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Agência Nacional de Aviação Civil (ANAC) AD 2024–04–02R01, effective May 31, 2024 (ANAC AD 2024–04–02R01).

(h) Exceptions to ANAC AD 2024–04–02R01

(1) Where ANAC AD 2024–04–02R01 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraphs (b)(1) and (2) of ANAC AD 2024–04–02R01 specify the initial compliance time for the high-frequency eddy current inspection of the fuselage center I longitudinal skin splice—frames 22 and 23, from the internal and external side of the fuselage, for this AD, the initial compliance time for doing the high-frequency eddy current inspection is prior to the accumulation of 50,000 total flight cycles, or within 800 flight cycles after the effective date of this AD, whichever occurs later.

(3) Where paragraphs (d)(1) and (2) of ANAC AD 2024–04–02R01 specify the initial compliance time for the high-frequency eddy current inspection of the fuselage center I skin panel—frames 22 and 23, from the external side of the fuselage, for this AD, the initial compliance time for doing the high-frequency eddy current inspection is prior to the accumulation of 50,000 total flight cycles, or within 800 flight cycles after the effective date of this AD, whichever occurs later.

(4) Where paragraphs (b)(3) and (d)(3) of ANAC AD 2024–04–02R01 specify corrective actions, for this AD, if any discrepancy including cracking is detected during any inspection required by this AD, the discrepancy must be repaired before further flight using a method approved by the Manager, International Validation Branch, FAA; or ANAC; or Embraer's ANAC Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(5) Paragraph (f) of ANAC AD 2024–04–02R01 specifies to report inspection results to ANAC and Embraer within a certain compliance time. For this AD, report inspection results at the applicable time specified in paragraph (h)(5)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(6) This AD does not adopt paragraph (g) of ANAC AD 2024–04–02R01.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(j) Additional Information

For more information about this AD, contact Hassan Ibrahim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3653; email: *Hassan.M.Ibrahim@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Agência Nacional de Aviação Civil (ANAC) AD 2024–04–02R01, effective May 31, 2024.

(ii) [Reserved]

(3) For ANAC material identified in this AD, contact ANAC, Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; phone 55 (12) 3203–6600; email *pac@anac.gov.br;* website *anac.gov.br/en/.* You may find this ANAC AD on the ANAC website *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on September 10, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–20991 Filed 9–16–24; 8:45 am]

BILLING CODE 4910–13–P

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: Proposed amendment; notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule two synthetic benzimidazole-opioid substances, *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, ethers, and salts is possible, in schedule I of the Controlled Substances Act. When it is issued, the temporary scheduling order will impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess) or propose to handle these two specified substances.

DATES: This notice of intent is effective September 17, 2024.

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

SUPPLEMENTARY INFORMATION: The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order [1] (in the form of a temporary amendment) to add the 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).

The temporary scheduling order will be published in the **Federal Register** on or after October 17, 2024.

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

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) 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 he 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 December 15, 2023, the Administrator transmitted the required notice to place *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I on a temporary basis to the Assistant Secretary for Health of HHS (Assistant Secretary).[6] On December 22, 2023, the 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 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.

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.[7] This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of *N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene.[8]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[9] Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States,[10] and a lack of accepted

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

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

[9] 21 U.S.C. 811(h)(1).

[10] 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 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 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 notice of intent, there is no evidence that health care providers have

safety for use under medical supervision.[11]

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.[12] *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[13] 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 Assistant Secretary in a letter to DEA dated December 22, 2023, stated that there are no FDA-approved NDAs or IND applications for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in the United States; hence, there are no legitimate channels for these substances as marketed drug products.

The appearance of benzimidazole-opioids on the illicit drug market is similar to other designer opioid drugs that are trafficked for their psychoactive effects. These substances are likely to be abused in the same manner as schedule I opioids, such as etonitazene, isotonitazene, and heroin. In 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.[14] 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[15] 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.[16]

Data from law enforcement suggest that *N*-pyrrolidino metonitazene and *N*-

widespread experience with medical use of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene or that the use of *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

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

[12] 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).

[13] 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).

[14] 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.

[15] 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.

[16] 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.

pyrrolidino protonitazene are being abused in the United States as recreational drugs.[17] Since 2023, there have been 37 exhibits reported to the NFLIS-Drug (Federal, State and local laboratories) database pertaining to the trafficking, distribution, and abuse of these substances. There were seven encounters of *N*-pyrrolidino metonitazene from two States in NFLIS-Drug: Missouri (n = 2) and Ohio (n = 5). *N*-Pyrrolidino protonitazene has been identified in 30 exhibits in NFLIS-Drug from five States: Florida (n = 4), Iowa (n = 10), Missouri (n = 1), Ohio (n = 13), and Texas (n = 2).[18]

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.[19] 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.[20] 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.[21]

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 post mortem 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).[22] 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 Administrator transmitted to the Assistant Secretary, via letter dated December 15, 2023, notice of her intent to place *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

This notice of intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily schedule *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene 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.

[17] 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).

[18] NFLIS-Drug was queried on July 17, 2024.

[19] 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.

[20] 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.

[21] 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.

[22] 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.

The temporary placement of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before October 17, 2024. Because the Administrator hereby finds this temporary scheduling order necessary to avoid an imminent hazard to the public safety, it will take effect on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process.[23] The Administrator intends to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon the temporary order's publication, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene will then be subject to the CSA's schedule I regulatory controls and to administrative, civil, and criminal sanctions applicable to their manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession.

The CSA sets forth specific criteria for scheduling drugs or other substances. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557.[24] 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.[25] Temporary scheduling orders are not subject to judicial review.[26]

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.[27]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the **Federal Register** a notice of intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. The APA expressly differentiates between orders and rules, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making*.'' [28] (Emphasis added). This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' and final decisions that conclude the scheduling process and are subject to judicial review. 21 U.S.C. 811(a) and 877. The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in section 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

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

Although DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Assistant Secretary in response to the notices that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (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. As discussed above, DEA is issuing this notice of intent pursuant to DEA's authority to issue a temporary scheduling order. 21 U.S.C. 811(h)(1). Therefore, in this instance, since DEA believes this temporary scheduling action is not a ''rule,'' it is not subject to the requirements of the RFA when issuing this temporary action.

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

This action will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132, it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

[23] 21 U.S.C. 811(h)(1) and (2).

[24] 21 U.S.C. 811.

[25] 21 U.S.C. 877.

[26] 21 U.S.C. 811(h)(6).

[27] 21 U.S.C. 811(h)(1).

[28] 5 U.S.C. 551(6).

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)(70) and (71) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

* * * * * * *

(70) 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
(71) 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

Signing Authority

This document of the Drug Enforcement Administration was signed on September 11, 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**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–21058 Filed 9–16–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–102161–23]

RIN 1545–BQ89

Identification of Basket Contract Transactions as Listed Transactions; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of a notice of public hearing on a proposed rulemaking and notice of public hearing.

SUMMARY: This document cancels a public hearing on proposed regulations that would identify transactions that are the same as, or substantially similar to, certain basket contract transactions as listed transactions, a type of reportable transaction.

DATES: The public hearing scheduled for September 26, 2024, at 10 a.m. ET is cancelled.

ADDRESSES: Public comments submitted for the proposed rule can be viewed electronically via the Federal eRulemaking Portal at *https://www.regulations.gov* by searching REG–102161–23. The public hearing scheduled to be held in the Auditorium at the Internal Revenue Building, 1111 Constitution Avenue NW, Washington, DC is cancelled.

FOR FURTHER INFORMATION CONTACT: Oluwafunmilayo Taylor, Section Chief, the Publications and Regulations Section at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and a notice of public hearing that appeared in the **Federal Register** on July 12, 2024 (89 FR 57111), announced that a public hearing being held in person and by teleconference was scheduled for September 26, 2024, at 10 a.m. ET. The subject of the public hearing is under 26 CFR part 1.

The public comment period for these regulations expired on September 10, 2024. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to testify and an outline of the topics to be addressed. We did not receive a request to testify at the Public Hearing. Therefore, the public hearing scheduled for September 26, 2024, at 10 a.m. ET is cancelled.

Kalle L. Wardlow,

Federal Register Liaison, Publications and Regulations, Associate Chief Counsel, (Procedure & Administration).

[FR Doc. 2024–21039 Filed 9–16–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–116787–23]

RIN 1545–BR31

Definition of the Term ''Coverage Month'' for Computing the Premium Tax Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and public hearing.

SUMMARY: This document contains proposed regulations that would amend the definition of ''coverage month'' and amend certain other rules in existing income tax regulations regarding the computation of an individual taxpayer's premium tax credit (PTC). The proposed coverage month amendment generally would provide that, in computing a PTC, a month may be a coverage month for an individual if the amount of the premium paid, including by advance payments of the PTC (APTC), for the month for the individual's coverage is sufficient to avoid termination of the individual's coverage for that month. The proposal also would amend the existing regulations relating to the amount of enrollment premiums used in computing the taxpayer's monthly PTC if a portion of the monthly enrollment premium for a coverage month is unpaid. Finally, the proposed regulations would clarify when an individual is considered to be ineligible for coverage under a State's Basic Health Program (BHP). The proposed regulations would affect taxpayers who enroll themselves, or enroll a family member, in individual health insurance coverage through a Health Insurance Exchange (Exchange) and may be allowed a PTC for the coverage. This document also provides a notice of a public hearing on these proposed regulations.