in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E airspace extending upward from 700 feet above the surface at Atlanta Speedway Airport (formerly Clayton County-Tara Field), Hampton, GA by updating the airports name and updating the geographical coordinates of the airport to coincide with the FAA's database. This action would also increase the radius to 9.2 miles (formerly 6.8 miles) and eliminate excessive verbiage in the legal description.

Class E airspace designations are published in Paragraphs 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'', prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 feet or More Above the Surface of the Earth.

* * * * *

ASO GA E5 Hampton, GA [Amended]

Atlanta Speedway Airport, GA
(Lat. 33°23′24″ N. long. 84°19′52″ W)

That airspace extending upward from 700 feet above the surface within a 9.2-mile radius of Atlanta Speedway Airport.

Issued in College Park, Georgia, on December 1, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–26418 Filed 12–6–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–900]

Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-pyrrolidino etonitazene, and 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 seven synthetic benzimidazole-opioid substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act. When it is issued, the temporary scheduling order will impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess) or propose to handle these seven specified controlled substances.

DATES: December 7, 2021.

ADDRESSES: Drug Enforcement Administration, 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.

SUPPLEMENTARY INFORMATION: The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order [1] (in the form of a temporary amendment) to add the following seven 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-(2-(4-butoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)-*N,N*-diethylethan-1-amine (butonitazene),
- 2-(2-(4-ethoxybenzyl)-1*H*-benzimidazol-1-yl)-*N,N*-diethylethan-1-amine (etodesnitazene; etazene),
- *N,N*-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine) (flunitazene),
- *N,N*-diethyl-2-(2-(4-methoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine (metodesnitazene),
- *N,N*-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1*H*-

[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.

benzimidazol-1-yl)ethan-1-amine (metonitazene),

- 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (*N*-pyrrolidino etonitazene; etonitazepyne), and
- *N,N*-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine (protonitazene).

The temporary scheduling order will be published in the **Federal Register** on or after January 6, 2022.

Legal Authority

The CSA provides the Attorney General (as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100) with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 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. 21 U.S.C. 811(h)(1); 21 CFR part 1308.

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to place a substance in schedule I of the CSA temporarily (*i.e.,* to issue a temporary scheduling order). 21 U.S.C. 811(h)(4). The then-Acting Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[2] by letter dated June 16, 2021, regarding butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, and protonitazene. In a subsequent letter dated August 25, 2021, the Administrator transmitted the required notice to the Assistant Secretary for *N*-pyrrolidino etonitazene. The Assistant Secretary responded to these notices by letters dated July 7 and September 10, 2021, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (IND) or approved new drug applications (NDA) for butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. The Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I. Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and 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 seven benzimidazole-opioids.

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

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States, and no accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Seven Benzimidazole-Opioids: Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, *N*-Pyrrolidino Etonitazene, and Protonitazene

The United States currently is experiencing an opioid overdose epidemic, and the presence of synthetic opioids in the illicit drug market threatens to exacerbate this. The trafficking, continued evolution, and abuse of new synthetic opioids are deadly trends posing imminent hazards to public safety. Adverse health effects associated with abuse of synthetic opioids and increased popularity of these substances have been serious concerns in recent years. Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene are synthetic opioids recently identified on the illicit drug market in the United States.

Data obtained from preclinical pharmacology studies show that butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene have pharmacological profiles similar to those of the potent benzimidazole-opioids etonitazene and isotonitazene, both schedule I controlled substances. Because of their pharmacological similarities, use of these seven benzimidazole-opioid substances presents a high risk of abuse and may negatively affect users and communities. They have been identified in at least 44 toxicology and post-mortem cases in the United States between November 2020 and July 2021. Specifically, butonitazene has been identified in one case, etodesnitazene in five cases, flunitazene in four cases, metodesnitazene in one case, metonitazene in twenty cases, *N*-pyrrolidino etonitazene in eight cases, and protonitazene in five cases, which together create serious public safety concerns.

Available data and information for butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene, summarized below, indicate that these substances have high potential for abuse, no currently accepted medical use in treatment in the United States, and 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–900.

Factor 4. History and Current Pattern of Abuse

In the late 1950s, pharmaceutical research laboratories of the Swiss chemical company CIBA Aktiengesellschaft synthesized a group of benzimidazole derivatives with analgesic properties; however, the research did not lead to any medically approved analgesic products. These benzimidazole derivatives include schedule I substances such as synthetic opioids clonitazene, etonitazene, and isotonitazene. In 2019, isotonitazene emerged on the illicit drug market and was involved in numerous fatal overdose events. In August 2020, DEA temporarily controlled it as a schedule I substance under the CSA (85 FR 51342).

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

Subsequently, the benzimidazole-opioids at issue here have emerged on the illicit drug market. Law enforcement agencies have encountered etodesnitazene, flunitazene, metonitazene, and protonitazene in several solid (*e.g.,* powder and rock) and liquid forms. These substances are not approved for medical use anywhere in the world. The Assistant Secretary, by letters dated July 7 and September 10, 2021, informed DEA that there are no FDA-approved NDAs or INDs for them in the United States. Hence, there are no legitimate channels for these substances as marketed drug products. Their appearance on the illicit drug market is similar to other synthetic opioids trafficked for their psychoactive effects. These seven opioid substances are likely to be abused in the same manner as schedule I opioids such as etonitazene, isotonitazene, and heroin. They have been identified as white to beige powders or in liquid forms, typically of unknown purity or concentration.

In 2020 and 2021, butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, and protonitazene emerged on the illicit synthetic drug market as evidenced by their identification in forensic drug seizures or biological samples. In July 2020, metonitazene was first reported seized as a white powdery substance in a North Carolina case. Based on data from the National Forensic Laboratory Information System (NFLIS),[3] law enforcement often encounters etodesnitazene, flunitazene, metonitazene, and protonitazene in mixtures. Substances found in combination with some of these benzimidazole-opioids include cutting agents (caffeine, xylazine, etc.) or other substances of abuse such as heroin, fentanyl (schedule II), fentanyl analogs, and tramadol (schedule IV).

In the United States, butonitazene, etodesnitazene, flunitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene have been identified alone or in combination with other substances such as designer benzodiazepines and fentanyl (see Factors 5 and 6). Evidence suggests that individuals are using these substances as a replacement for other opioids, either knowingly or unknowingly. Information gathered from case histories and autopsy findings show that deaths involving metonitazene were similar to those of opioid-related deaths. Identified material or paraphernalia from death-scene investigations also were consistent with opioid use. The seven substances are likely to be abused in the same manner as schedule I opioids such as isotonitazene and heroin.

Factor 5. Scope, Duration, and Significance of Abuse

The subject substances have been described as synthetic opioids, and evidence suggests they are abused for their opioidergic effects (see Factor 6). Their abuse has resulted in their identification in toxicology and post-mortem cases. Between January and February of 2021, metonitazene has been positively identified in 20 forensic post-mortem cases from seven different states: Tennessee (10), Illinois (5), Florida (1), Iowa (1), Ohio (1), South Carolina (1), and Wisconsin (1). Most (18) of the decedents were male, with ages ranging from 19 to 63 years and an average age of 41 years. Metonitazene was identified as the sole drug detected in only three cases, and the only opioid in six cases.

Detection of *N*-pyrrolidino etonitazene in a toxicology case first was reported[4] in May 2021. It has been identified in a total of eight post-mortem cases from five different states (Colorado (1), Florida (1), New York (1), Pennsylvania (1), and West Virginia (4)) between January and April 2021. The decedents' ages spanned their 20s to 50s. *N*-Pyrrolidino etonitazene was the only drug of interest in one of these cases. In the other cases, it was co-identified with designer benzodiazepines (7), fentanyl (4), and methamphetamine (4). Data from law enforcement encounters suggests that etodesnitazene, flunitazene, metonitazene, and protonitazene are abused[5] in the United States as recreational drugs. Law enforcement encounters of etodesnitazene, flunitazene, metonitazene, and protonitazene as reported to NFLIS (Federal, State, and local laboratories) includes 270 exhibits since 2020 (queried 08/04/2021). NFLIS registered one encounter of etodesnitazene from one state, five encounters of flunitazene from four states, 262 encounters of metonitazene from eight states, and two encounters of protonitazene from two states. Data from NFLIS show that 561.55 grams of metonitazene has been encountered by law enforcement since 2020, and it was often suspected as heroin or fentanyl. This suggests that metonitazene might be presented as a substitute for heroin or fentanyl and likely abused in the same manner as either of these substances. The lack of identification of butonitazene, metodesnitazene, and *N*-pyrrolidino etonitazene in law enforcement reports might be due to the rapid appearance of these benzimidazole-opioids and under-reporting as forensic laboratories try to secure reference standards for these substances. However, butonitazene, metodesnitazene, and *N*-pyrrolidino etonitazene have been identified in toxicology cases.

The population likely to abuse these seven benzimidazole-opioids appears to be the same as those abusing other opioid substances such as heroin, tramadol, fentanyl, and other synthetic opioids. This is evidenced by the types of other drugs co-identified in biological samples and law enforcement encounters. Because abusers are likely to obtain these substances through unregulated sources, their identity, purity, and quantity are uncertain and likely to be inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well-characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[6] as of 2019, an estimated 10.1 million people aged 12 years or older misused opioids in the past year, including 9.7 million prescription pain reliever misusers and 745,000 heroin users. In 2019, an estimated 1.6 million people had an opioid use disorder, including 1.4 million people with a

[3] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1.0 million distinct annual state and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[4] Center for Forensic Science Research and Education. Public Alert: New High Potency Synthetic Opioid *N*-Pyrrolidino Etonitazene (Etonitazepyne) Linked to Overdoses across United States. June 17, 2021.

[5] While law enforcement data are not direct evidence of abuse, they can lead to an inference that drugs have been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[6] NSDUH, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of non-medical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.,* ever used), past year, and past month abuse or dependence. The 2019 NSDUH Annual Report. (Last accessed July 26, 2021).

prescription pain reliever use disorder and 438,000 people with heroin use disorder. This population likely is at risk of abusing butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. Individuals who initiate (*i.e.,* use a drug for the first time) use of these benzimidazole-opioids are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.). Law enforcement or toxicology reports demonstrate that the seven substances at issue are being distributed illicitly 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 in the illicit drug market. Data obtained from pre-clinical studies demonstrate that butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene exhibit pharmacological profiles similar to that of schedule I substances such as etonitazene, isotonitazene, and other mu-opioid receptor agonists. These seven benzimidazole-opioids bind to and act as agonists at the mu-opioid receptors. It is well established that substances that act as mu-opioid receptor agonists have a high potential for abuse and addiction and can induce dose-dependent respiratory depression.

As with any mu-opioid receptor agonist, the potential health and safety risks for users of butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene are high. Consistently, these substances have been identified in toxicology cases. The public health risks attendant to the abuse of mu-opioid receptor agonists are well established. These risks include large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. According to CDC data, synthetic opioid-related overdose deaths in the United States increased from 36,359 in 2019, to 56,688 in 2020 (CDC, 2021).[7] Of the drug overdose death data (70,630) for 2019, synthetic opioids were involved in about 51.4 percent (36,359) of all drug-involved overdose deaths.

According to a recent publication, since November 2020, there has been an increase in metonitazene-related adverse events, including deaths.[8] Metonitazene has been co-identified with other substances in biological samples from 20 post-mortem cases from seven different states: Florida (1), Illinois (5), Iowa (1), Ohio (1), South Carolina (1), Tennessee (10), and Wisconsin (1). Information gathered from case histories and autopsy findings show that deaths involving metonitazene were similar to those of opioid-related deaths. Identified material or paraphernalia from death-scene investigations were consistent with opioid use. Reports obtained from autopsy findings showed that deaths involving metonitazene presented pulmonary and cerebral edema, as well as distended bladder and signs of intravenous drug use. Of the cases for which death certificate data were available, metonitazene was reported as a cause of death in four cases, of which three cases listed metonitazene as the only cause.

According to recent reports, butonitazene (1 instance), etodesnitazene (5), flunitazene (4), metodesnitazene (1), metonitazene (20), protonitazene (5), and *N*-pyrrolidino etonitazene (10) have been identified in toxicology cases in the United States.[9] For cases involving *N*-pyrrolidino etonitazene, it was co-identified with fentanyl in four cases and with novel benzodiazepines (*e.g.,* flualprazolam, etizolam, and clonazolam) in six others.

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 butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and 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 butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene indicate that these substances meet the three statutory criteria. As required by 21 U.S.C. 811(h)(4), the then-Acting Administrator transmitted to the Assistant Secretary for Health, via letter dated June 16, 2021, notice of his intent to place butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, and protonitazene in schedule I on a temporary basis. In a letter to the Assistant Secretary for Health dated August 25, 2021, the Administrator transmitted notice of her intent to place *N*-pyrrolidino etonitazene in schedule I on a temporary basis.

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 butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and 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.

The temporary placement of butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before January 6, 2022. 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

[7] 12 Month-ending Provisional Number of Drug Overdose Deaths. Reported provisional data as of July 4, 2021. *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[8] Krotulski AJ, Papsun DM, Walton SE, Logan BK. Metonitazene in the United States-Forensic toxicology assessment of a potent new synthetic opioid using liquid chromatography mass spectrometry. Drug Test Anal. 2021 Jun 16. doi: 10.1002/dta.3115. Epub ahead of print.

[9] Center for Forensic Science Research and Education. NPS Opioids in the United States—Trend Report Q1 and Q2, 2021.

years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). The Administrator intends to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon the temporary order's publication, butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and 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. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties appropriate process and the government any additional relevant information needed to make determinations. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Analyses

The CSA provides for expedited temporary scheduling actions where necessary to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), 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 for Health of HHS, as delegated by the Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the **Federal Register** a Notice of Intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this Notice of Intent. The APA expressly differentiates between orders and rules, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*'' 5 U.S.C. 551(6) (emphasis added). 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), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

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

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

Further, DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

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 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. 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 (Federalism), 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)(50) through (56) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

Anne Milgram,

Administrator.

[FR Doc. 2021–26263 Filed 12–6–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–568]

Schedules of Controlled Substances: Placement of Methoxetamine (MXE) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would 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 with, or possess), or propose to handle, methoxetamine.

DATES: Comments must be submitted electronically or postmarked on or before February 7, 2022.

Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before January 6, 2022.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–568'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* DEA encourages commenters to submit all comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the on-line instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Submitted comments are not instantaneously available for public view on *regulations.gov.* If you have received a Comment Tracking Number, you have submitted your comment successfully and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available, unless reasonable cause is given, for public inspection online at *https://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also