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Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–631]

Schedules of Controlled Substances: Temporary Placement of Isotonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as isotonitazene), including its 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. This action is based on a finding by the Acting Administrator that the placement of isotonitazene in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed 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 isotonitazene.

DATES: This temporary scheduling order is effective August 20, 2020, until August 20, 2022. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) provides the Attorney General 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 permanently 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 [1] 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 (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of DEA (Administrator). 28 CFR 0.100.

Background

21 U.S.C. 811(h)(4) requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place isotonitazene in schedule I on a temporary basis to the Assistant Secretary for Health of HHS (Assistant Secretary) by letter dated March 2, 2020. The Assistant Secretary responded to this notice by letter dated March 31, 2020, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for isotonitazene. The Assistant Secretary also stated that HHS had no objection to the temporary placement of isotonitazene in schedule I of the CSA.

The Drug Enforcement Administration (DEA) has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). Isotonitazene is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for isotonitazene under section 505 of the FDCA, 21 U.S.C. 355. DEA has found that the control of isotonitazene in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent to temporarily schedule isotonitazene in the **Federal Register** on June 18, 2020. 85 FR 38619. That notice of intent discussed findings from DEA's three-factor analysis dated May 2020, which DEA made available on *www.regulations.gov* contemporaneously with the publication of the notice of intent. This temporary scheduling order discusses updated findings on isotonitazane for one of the three factors (Factor 5) in DEA's July 2020 analysis related to law enforcement seizures, overdoses, and regulatory status.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to 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). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance 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 are those that 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. 21 U.S.C. 812(b)(1).

Available data and information for isotonitazene summarized below indicate that it has 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. DEA's May and July 2020 three-factor analyses and the Assistant Secretary's March 31, 2020, letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov.*

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

[2] 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.

Isotonitazene

The availability of synthetic opioids in the illicit drug market continues to pose an 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. As the United States continues to experience an unprecedented epidemic of opioid misuse and abuse, the presence of new synthetic opioids with no approved medical use exacerbates the epidemic. The trafficking and abuse of new synthetic opioids are deadly new trends.

The identification of isotonitazene, chemically known as *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (other name: *N,N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine), in the illicit drug market has been reported in Canada, Estonia, Germany, Latvia, Sweden, and the United States (see Factor 4 below). Data obtained from preclinical pharmacology studies shows that isotonitazene has a pharmacological profile similar to that of the potent synthetic opioid etonitazene, a schedule I controlled substance. Because of the pharmacological similarities of isotonitazene to etonitazene, the use of isotonitazene presents a high risk of abuse and may negatively affect users and communities. The abuse of isotonitazene has been associated with at least 19 fatalities in the United States (see Factor 5 below). The positive identification of this substance in overdose and post-mortem cases is a serious concern for public safety. Thus, isotonitazene poses an imminent hazard to public safety.

Available data and information for isotonitazene, as summarized below, indicates that this substance has 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. 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–631.

Factor 4. History and Current Pattern of Abuse

The chemical syntheses of isotonitazene (a benzimidazole derivative) and other benzimidazole derivatives (including schedule I substances such as synthetic opioids etonitazene and clonitazene) were first reported in the scientific literature in 1957. Isotonitazene is not an approved pharmaceutical product and is not approved for medical use anywhere in the world. As discussed in the background section, the Assistant Secretary stated in a March 31, 2020, letter to DEA that there are no INDs or FDA-approved NDAs for isotonitazene in the United States. Hence, DEA notes there is no legitimate channel for isotonitazene as a marketed drug product.

Since 2014, numerous synthetic opioids structurally related to fentanyl and several opioids from other structural classes have begun to emerge in the illicit drug market, as evidenced by the identification of these drugs in forensic drug exhibits and toxicology samples. Beginning in April 2019, isotonitazene emerged on the illicit synthetic drug market in the United States, as evidenced by its identification in drug seizures and in biological samples collected and submitted to National Medical Services (NMS) Laboratory [3] in August 2019. In August 2019, isotonitazene was first reported in a drug case in Belgium and in toxicology casework in Canada (a toxicological sample was collected in March 2019). In the United States, the Center for Forensic Science Research and Education (under the novel psychoactive substances discovery program) first reported isotonitazene in November 2019.

According to a report by the European Monitoring Center for Drugs and Drug addiction and Europol,[4] between April 2019 and January 2020, four member-states (Estonia, Latvia, Germany, and Sweden) have reported 24 isotonitazene cases involving 109.6 grams of powder (22 cases) and 4.5 grams of liquid (two cases). Isotonitazene has been encountered by United States law enforcement primarily in powder form. In March 2020, Canada law enforcement also encountered isotonitazene in a tablet form, as a white triangular tablet with 'M' logo on one side and '8' logo on the other side, and as a blue tablet in Dilaudid counterfeit pills. Identification of isotonitazene in counterfeit pills is deeply concerning because the identity, purity, and quantity of isotonitazene in this formulation are uncertain, thus presenting additional safety concerns for unsuspecting users.

In the United States, isotonitazene has been identified as a single substance or in combination with other substances. In April 2019, the United States Customs and Border Protection (CBP) seized 1.6 grams of isotonitazene in California. In addition, Wisconsin State Crime Laboratories identified isotonitazene mixed with heroin and bromazolam, a nonscheduled benzodiazepine, in seized powder. Further, isotonitazene was identified in a substance obtained from the scene of a death investigation in Iowa. Evidence suggests that individuals are using isotonitazene as a replacement to heroin or other opioids, either knowingly or unknowingly.

Factor 5. Scope, Duration, and Significance of Abuse

Isotonitazene, similar to etonitazene (schedule I), has been described as a potent synthetic opioid and evidence suggests it is being abused for its opioidergic effects (see Factor 6). The abuse of isotonitazene, similar to other synthetic opioids, has resulted in adverse health effects. Isotonitazene has been positively identified in 18 death investigations between August 2019 and January 2020. These reports were from four states—Illinois (9), Indiana (7), Minnesota (1), and Wisconsin (1). Most (n = 12) of the decedents were male. The ages ranged from 24 to 66 years old with an average age of 41. Other substances identified in postmortem blood specimens obtained from these decedents include etizolam (6); flualprazolam, a nonscheduled benzodiazepine (7); fentanyl (6); heroin (3); tramadol, a schedule IV narcotic (2); and U–47700, a schedule I synthetic opioid (1). The average concentration of isotonitazene in these biological samples (blood) was 2.2 ± 2.1 nanogram/milliliter (ng/ml) (range 0.4 to 9.5 ng/ml). Isotonitazene was detected as the only opioid in 50 percent (n = 9) of the specimens for these decedents. DEA [5] is aware of another postmortem case that occurred in January 2020 in Pennsylvania where isotonitazene was identified in a biological sample. In total, isotonitazene has been positively identified in 19 postmortem cases.

[3] 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 U.S. 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.

[4] European Monitoring Centre for Drugs and Drug Addiction and Europol (2020), EMCDDA initial report on the new psychoactive substance *N,N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene). In accordance with Article 5b of Regulation (EC) No 1920/2006 (as amended), Publications Office of the European Union, Luxembourg.

[5] Email communication from DEA Philadelphia Field Division on March 4, 2020.

Recent communication from Minnesota Department of Health[6] reports the positive identification of isotonitazene in two overdose cases.

Law enforcement data indicate that isotonitazene has appeared in the United States' illicit drug market. According to the National Forensic Laboratory Information System (NFLIS)[7] database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State, and local forensic laboratories, there have been 48 encounters of isotonitazene in the United States (queried May 14, 2020). These 48 encounters occurred in 2019 and 2020 in five states: California (1), Iowa (5), Ohio (4), Tennessee (13), and Wisconsin (25). One of these encounters consisted of 1.6 grams of isotonitazene seized by the CBP in California in April 2019.

As of May 2020, Ohio and Wisconsin enacted emergency legislation to control isotonitazene as a schedule I controlled substance. Internationally, isotonitazene is controlled under Estonia, Latvia, Poland, and Sweden drug control legislation. In the United Kingdom, isotonitazene is controlled under the Psychoactive Substances Act 2016. Further, isotonitazene is controlled under the Norwegian Medicines Act and Lithuania medicine legislation.[8]

The population likely to abuse isotonitazene appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in isotonitazene fatal overdose cases. Because abusers of isotonitazene are likely to obtain it through unregulated sources, the identity, purity, and quantity 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. According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[9] as of 2018, an estimated 10.3 million people aged 12 years or older had misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. In 2018, an estimated 2.0 million people had an opioid use disorder which included 1.7 million people with a prescription pain reliever use disorder and 0.5 million people with heroin use disorder. This population abusing opioids is likely to be at risk of abusing isotonitazene. Individuals who initiate (*i.e.,* use a drug for the first time) use of isotonitazene are likely to be at risk of developing substance use disorders, overdoses, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.). Law enforcement and toxicology reports demonstrate that isotonitazene is 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 in the illicit drug market. Data obtained from pre-clinical studies demonstrate that isotonitazene exhibits a pharmacological profile similar to that of etonitazene and other mu-opioid receptor agonists. In an *in vivo* (in mice) study, isotonitazene was 500 times more potent than morphine as an analgesic in a tail-flick assay. The tail-flick assay is useful in evaluating antinociceptive effect. Data from *in vitro* studies showed that isotonitazene activated the mu-opioid receptor and acted as a mu-opioid receptor agonist. Isotonitazene, similar to hydromorphone and fentanyl, activated the mu-opioid receptor and acted as an agonist via interaction at the mu-opioid receptor with β-arrestin-2, a regulatory protein, in a live cell-based receptor assay. Naloxone, an opioid receptor antagonist, blocked isotonitazene's activation of the mu-opioid receptor. Substances that act as an agonist at the mu-opioid receptors have a high potential for addiction and can induce dose-dependent respiratory depression.

As with any mu-opioid receptor agonist, the potential health and safety risks for users are high. The public health risks attendant to the abuse of heroin and other mu-opioid receptor agonists are well established and have resulted in 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. A CDC report shows that from 2013 to 2018,[10] opioid-related overdose deaths in the United States increased from 25,052 to 46,802. Of the drug overdose death data for 2018, opioids were involved in about 69.5 percent of all drug-involved overdose deaths.

In the United States, isotonitazene has been co-identified with other substances in 18 postmortem cases, and DEA is aware of an additional death in January 2020, involving isotonitazene. These deaths associated with isotonitazene occurred in five states: Illinois (9), Indiana (7), Minnesota (1), Pennsylvania (1), and Wisconsin (1). Information gathered from case histories and autopsy findings shows that isotonitazene use is similar to that of classic opioid agonists. Evidence obtained from reported cases of death scenarios suggests that isotonitazene, similar to heroin, can be used intravenously.[11]

The introduction of potent synthetic opioids such as isotonitazene into the illicit market exacerbates problematic opioid use for those seeking these powerful opioids. As documented by a published toxicology report, poly-substance abuse remains common in fatalities associated with the abuse of isotonitazene.[12]

[6] Email communication from Minnesota Department of Health: Biomonitoring and Emerging Contaminants Unit; received May 26, 2020.

[7] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5 percent. 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. NFLIS data was queried on May 14, 2020.

[8] The Medicines Act, LOVDATA, *https://lovdata.no/dokument/NL/lov/1992-12-04-132,* 1992.

[9] The National Survey on Drug Use and Health (NSDUH), formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by HHS' Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical 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 twelve 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 2018 NSDUH annual report is available at *https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf* (last accessed June 18, 2020).

[10] CDC National Center for Health Statistics (NCHS), National Vital Statistics System, Mortality. NCHS Data Brief, Number 356, January 2020.

[11] Krotulski AJ, Papsun DM, Kacinko SL, and Logan BK (2020). Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. *Journal of Analytical Toxicology.* [Epub ahead of print].

[12] *Id.*

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 isotonitazene pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for isotonitazene 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 are those that 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 isotonitazene indicate that this substance has 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. As required by 21 U.S.C. 811(h)(4), by a letter dated March 2, 2020, the Acting Administrator notified the Assistant Secretary for Health of DEA's intention to temporarily place isotonitazene in schedule I. DEA subsequently published a Notice of Intent in the **Federal Register** on June 18, 2020. 85 FR 38619.

Conclusion

In accordance with the provisions of 21 U.S.C. 811(h), the Acting Administrator considered available data and information, and herein sets forth the grounds for his determination that it is necessary to temporarily schedule *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as: Isotonitazene) in schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Acting Administrator hereby finds it necessary to temporarily place isotonitazene in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling this substance is effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''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 with appropriate process and the government with 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. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this temporary order, isotonitazene will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis 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, isotonitazene must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of August 20, 2020. Any person who currently handles isotonitazene, and is not registered with DEA, must submit an application for registration and may not continue to handle isotonitazene as of August 20, 2020, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after August 20, 2020, is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle isotonitazene must surrender all currently held quantities of isotonitazene.

3. *Security.* Isotonitazene is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of August 20, 2020. Non-practitioners handling isotonitazene must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of isotonitazene must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from August 20, 2020, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of isotonitazene on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including isotonitazene) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to isotonitazene pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, 1317, and § 1307.11. Current DEA registrants authorized to handle isotonitazene shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute isotonitazene must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of August 20, 2020.

8. *Order Forms.* All DEA registrants who distribute isotonitazene must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of August 20, 2020.

9. *Importation and Exportation.* All importation and exportation of isotonitazene must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of August 20, 2020.

10. *Quota.* Only DEA registered manufacturers may manufacture isotonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of August 20, 2020.

11. *Liability.* Any activity involving isotonitazene not authorized by, or in violation of the CSA, occurring as of August 20, 2020, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

21 U.S.C. 811(h) provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intention 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 of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as 21 U.S.C. 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 of a publication in the **Federal Register** of 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 temporary scheduling order. The APA expressly differentiates between an order and a rule, 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 an intention for DEA to proceed through the issuance of an *order* instead of proceeding by rulemaking. Given that Congress specifically requires 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 21 U.S.C. 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even assuming that this action might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice-and-comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although DEA believes this temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Acting Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice 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 (OMB), 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. In addition, because this action is not considered an E.O. 12866 ''significant regulatory action,'' it does not meet the definition of an E.O. 13771 regulatory action. Therefore, the repeal and cost offset requirements of E.O. 13771 have not been triggered.

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 amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(48) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(48)	*N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: isotonitazene; *N,N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine)	9614

* * * * *

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9614]

RIN 1545–AM97

Certain Outbound Property Transfers by Domestic Corporations; Certain Stock Distributions by Domestic Corporations; Correcting Amendment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.