2830, Email address: *OR.Reports.Clearance@ssa.gov*

You can submit comments until May 13, 2024, which is 30 days after the publication of this document. To receive a copy of the OMB clearance package, contact the SSA Reports Clearance Officer using any of the above contact methods. We prefer to receive comments by email or fax.

(Catalog of Federal Domestic Assistance Programs No 96.006 Supplemental Security Income)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

The Commissioner of Social Security, Martin O'Malley, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for SSA, for purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

For the reasons stated in the preamble, we amend 20 CFR part 416 as set forth below:

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart K—Income

■ 1. The authority citation for subpart K of part 416 is revised to read as follows:

Authority: 42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, 1383, and 1383b; sec. 211, Pub. L. 93–66, 87 Stat. 154 (42 U.S.C. 1382 note).

■ 2. In § 416.1130, revise paragraph (b)(1) to read as follows:

§ 416.1130 Introduction.

* * * * *

(b) * * *

(1) We calculate in-kind support and maintenance considering any shelter that is given to you or that you receive because someone else pays for it. Shelter includes room, rent, mortgage payments, real property taxes, heating fuel, gas, electricity, water, sewerage, and garbage collection services. You are not receiving in-kind support and maintenance in the form of room or rent if you are paying the amount charged under a business arrangement. A business arrangement exists when the amount of monthly required rent to be paid equals or exceeds the presumed maximum value described in § 416.1140(a)(1). If the required amount of rent is less than the presumed maximum value, we will impute as in-kind support and maintenance the difference between the required amount of rent and either the presumed maximum value or the current market rental value (see § 416.1101), whichever is less. In addition, cash payments to uniformed service members as allowances for on-base housing or privatized military housing are in-kind support and maintenance.

* * * * *

[FR Doc. 2024–07675 Filed 4–10–24; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–900]

Schedules of Controlled Substances: Placement of Etodesnitazene, N-Pyrrolidino Etonitazene, and Protonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing 2-(2-(4-ethoxybenzyl)-1*H*-benzimidazol-1-yl)-*N,N*-diethylethan-1-amine (other names: etodesnitazene; etazene), 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino etonitazene; etonitazepyne), and *N,N*-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine (other name: protonitazene), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action imposes permanent regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or handle etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene.

DATES: Effective April 11, 2024.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

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

Background

On April 12, 2022, DEA issued a temporary scheduling order, placing etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene, along with four other substances,[2] temporarily in schedule I of the Controlled Substances Act (CSA).[3] That order for etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene (codified at 21 CFR 1308.11(h)(51), (55), and (56)) was based on findings by the Administrator that the temporary

[1] 28 CFR 0.100.

[2] Those four other substances, [butonitazene, flunitazene, metodesnitazene, metonitazene], will not be discussed further in this final order.

[3] 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).

scheduling was necessary to avoid an imminent hazard to the public safety.[4]

On November 24, 2022, the Director-General of the World Health Organization recommended to the Secretary-General that etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene be placed in Schedule I of the Single Convention, as these substances have opioid-agonist mechanism of action similar to drugs that are controlled in Schedule I of the Single Convention (*i.e.,* etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene are similar to drugs such as isotonitazene and fentanyl) and has dependence and abuse potential. On May 17, 2023, the United States government was informed by the Secretariat of the United Nations, by letter, that during its 66th session in March 2023, the Commission voted to place etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene in Schedule I of the Single Convention (CND Mar/66/2, 66/3, and 66/4).

Etodesnitazene, *N*-Pyrrolidino Etonitazene, and Protonitazene

As discussed in the background section, etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene are temporarily controlled in schedule I of the CSA upon the Administrator's finding they pose imminent hazard to the public safety. Etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene share a pharmacological profile with etonitazene (schedule I), isotonitazene (schedule I), and other schedule I and II synthetic opioids that act as mu-opioid receptor agonists. The use of these substances presents a high risk of abuse and have negatively affected users and communities due to their pharmacological similarities with etonitazene and isotonitazene (potent mu-opioid agonists). The abuse of etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene has been associated with at least 46 toxicology cases in the United States between January 2021 and April 2023. The positive identification of these substances in toxicology cases is a serious concern to the public safety.

Law enforcement reports demonstrate that etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene are being illicitly distributed and abused. The illicit use and distribution of these substances are similar to that of isotonitazene (schedule I) and prescription opioid analgesics. According to the National Forensic Laboratory Information System (NFLIS-Drug) database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories, there has been 596 reports for etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene between January 2020 and May 2023[5] (query date: May 15, 2023).

DEA is not aware of any claims or of any medical or scientific literature suggesting that etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene have a currently accepted medical use in treatment in the United States. In addition, the Department of Health and Human Services (HHS) advised DEA, by letters dated July 7 and September 10, 2021, that there were no investigational new drug applications (IND) or approved new drug applications (NDA) for etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene in the United States. Since September 10, 2021, HHS has not advised DEA of any new IND or NDA for any of these substances. Because etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene are not formulated or available for clinical use as approved medicinal products, all current use of these substances by individuals is based on their own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs.

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

Conclusion

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

Requirements for Handling

Etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene have been controlled in schedule I of the CSA since April 12, 2022. Upon the effective date of this final order, etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene will be permanently subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture of, distribution of, importation of, exportation of, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, etodesnitazene, *N*-pyrrolidino etonitazene, or protonitazene must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, state, local, and tribal laws.

3. *Security.* Etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21

[4] *Id.*

[5] Reports to NFLIS-Drug are still pending for 2023.

[6] HHS and DEA both applied a five-part test for currently accepted medical use as part of this scheduling action. Under that test, with respect to a drug that has not been approved by the Food and Drug Administration, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: 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. 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).

CFR 1301.71 through 1301.76. Non-practitioners handling etodesnitazene, *N*-pyrrolidino etonitazene, or protonitazene must comply with the employee screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of etodesnitazene, *N*-pyrrolidino etonitazene, or protonitazene has been required to keep an inventory of all stocks of these substances on hand as of April 12, 2022, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and 1307.11 and 21 CFR parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute etodesnitazene, *N*-pyrrolidino etonitazene, or protonitazene must continue to comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

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

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

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), as amended by E.O. 14094, section 1(b), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB). This action makes no change in the status quo, as etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene are already listed as schedule I controlled substances.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, and ''without regard to'' the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b). *Id.*

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

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. Also, this action does not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this action does require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act of 1995

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

Congressional Review Act

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

List of Subjects in 21 CFR Part 1308

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

Signing Authority

This document of the Drug Enforcement Administration was signed on April 5, 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

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:

■ a. Redesignate paragraphs (b)(95) through (103) as paragraphs (b)(98) through (106);

■ b. Redesignate paragraphs (b)(69) through (94) as paragraphs (b)(71) through (96);

■ c. Redesignate paragraphs (b)(40) through (68) as paragraphs (b)(41) through (69);

■ d. Add new paragraph (b)(40), (70), and (97); and

■ e. Remove and reserve paragraphs (h)(51), (55), and (56).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *	
(40) 2-(2-(4-ethoxybenzyl)-1*H*-benzimidazol-1-yl)-*N,N*-diethylethan-1-amine (Other names: etodesnitazene; etazene)	9765
* * * * * * *	
(70) 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (Other names: *N*-pyrrolidino etonitazene; etonitazepyne)	9758
* * * * * * *	
(97) *N,N*-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine (Other name: protonitazene)	9759

* * * * *

[FR Doc. 2024–07684 Filed 4–10–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–900E]

Schedules of Controlled Substances: Extension of Temporary Placement of Butonitazene, Flunitazene, and Metodesnitazene in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary rule; temporary scheduling order; extension.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to extend the temporary schedule I status of butonitazene, flunitazene, and metodesnitazene, as identified in this order. The schedule I status of these three substances currently is in effect through April 12, 2024. This temporary order will extend the temporary scheduling of these three substances for one year, or until the permanent scheduling action for these substances is completed, whichever occurs first.

DATES: This temporary scheduling order, which extends schedule I control of three substances covered by an order (87 FR 21556, April 12, 2022), is effective April 12, 2024, and expires on April 12, 2025. If DEA publishes a final rule making this scheduling action permanent, this order will expire on the effective date of that rule, if the effective date is earlier than April 12, 2025.

FOR FURTHER INFORMATION CONTACT: Dr. 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: In this order, the Drug Enforcement Administration (DEA) extends the temporary scheduling of the following three controlled substances in schedule I of the Controlled Substances Act (CSA), 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 within the specific chemical designation:

- butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)-*N,N*-diethylethan-1-amine),
- flunitazene (*N,N*-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine),
- metodesnitazene (*N,N*-diethyl-2-(2-(4-methoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine).

Background and Legal Authority

On April 12, 2022, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the **Federal Register** (87 FR 21556) temporarily placing butonitazene, flunitazene, metodesnitazene, and four [1] additional benzimidazole-opioids in schedule I of the Controlled Substances Act (CSA) based upon a finding that these substances pose an imminent hazard to the public safety. That temporary order was effective upon the date of publication.

Under 21 U.S.C. 811(h)(2), the temporary scheduling of a substance expires at the end of two years from the

[1] The four additional benzimidazole-opioids were etodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. DEA pursued separate scheduling actions for metonitazene, *see* 88 FR 56466 (Aug. 18, 2023), and for etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene, to remain as a schedule I substances under the CSA in order to meet the United States' obligations under the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol.