STATE OF NORTH DAKOTA
GOVERNOR DOUG BURGUM

NORTH DAKOTA STATE BOARD OF PHARMACY
OFFICE OF THE EXECUTIVE DIRECTOR

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Bill No 2064 – Controlled Substances Rescheduling
Senate Judiciary Committee – Peace Garden Room
11:00 AM - Wednesday – January 8th, 2025

Chair Larson, Members of the Senate Judiciary Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today.

Senate Bill 2093 is the biennial bill introduced by State Board of Pharmacy to bring the Controlled Substances Act up to date with what the Food and Drug Administration [FDA] and Drug Enforcement Administration [DEA] have done over the past two years. This bill also adds to the list of synthetic schedule I drugs.

The drafting of this bill, specifically Schedule I controlled substances was done in conjunction with the ND Attorney General's Office and their State Crime Lab. Our intension in drafting the Schedule I compounds is to be proactive to ensure we have future chemical modifications that could be made to the substances identified as controlled substances. In my testimony is the list of Scheduling Actions from the DEA in chronological order. In my testimony uploaded online, I have added the DEA published registrar citations for each of the substances added so it is available in the legislative record.

I would like to highlight each provision of the bill to ensure you have an understanding of the changes we have proposed for your consideration.

On Page 3, line 30, continuing to Page 4, line 4, represents three additional Opiate substances that have been identified by the DEA as novel compounds used in synthetic drugs.

On Page 7, lines 3-20, are additional fentanyl derivatives scheduled by the DEA. They represent more fentanyl compounds identified in illicit drugs. As you may recall, these Fentanyl compounds have been increasingly tied to numerous overdose deaths.

On Page 16, lines 1-3 and lines 7-8, we request removal of the current listing of two Indole Carboxamides which are synthetic cannabinoids. These are replaced by the compounds listed farther down on the page on lines 16-17 and 26-27. Last session, we were proactive in scheduling these compounds and when the DEA scheduled these their naming is a bit different than how we listed it, so the goal is to match it for consistency, even though they are the same substance. The other compounds on lines 18-25 represent other Indole Carboxamide compounds scheduled by the DEA.

On Page 20, lines 1-2, is an additional Cyclohexylphenols, another chemical variation of a synthetic cannabinoid, which has been identified and scheduled by the DEA.

On Page 27, lines 4-9, are three additional substituted cathinones compounds which are being proposed to be added based on the DEA's scheduling actions. These are stimulant drugs.

Lastly for Schedule I changes, on page 27 line 28 is an additional stimulant compound scheduled by the DEA.

Moving into page 30, line 20, and continuing into page 34, line 3, are proposed changes to the Schedule III anabolic steroids. These are drugs that have a medical purpose. The DEA did a significant rewrite of this section based on their authority granted under a 2014 law called the Designer Anabolic Steroid Control Act. This Act was in response to the increasing misuse of these steroids. The changes are meant to mirror those changes with many additional compounds being added.

On Page 37 line 19, is a new drug, Zuranolone, a schedule IV depressant marketed under the name Zurzuvae which is approved for the treatment of postpartum depression.

On Page 38, lines 15-17, we are proposing the addition of a hallucinogenic substance comprised of a pharmaceutical composition of psilocybin as a Schedule IV controlled substance. This drug currently known as COMP360 is going through FDA clinical trials for use in treatment resistant depression. The reason for the language offered in the amendments is due to psilocybin as it currently stands would now fall as a Schedule I compound without this specific addition. This will allow the drug to be available to patients in North Dakota if it is ultimately approved by the FDA.

As is customary with previous years, on Page 38, line 25, we respectfully ask for an emergency measure be attached to this bill that if enacted would make these changes occur as quickly as possible.

I do appreciate your attention to this lengthy and complicated bill draft and testimony. I will be happy to answer any questions you may have regarding this important legislation.

*Scheduled under 21 USC 811(h)
**Extension of temporary control
NC = Not Controlled

SUBSTANCE	PROPOSAL PUBLICATION DATE	FINAL ORDER			CSA SCHEDULE
		PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	
N,N-DIISOPROPYLTRYPTAMINE (DiPT)	01-14-22	07-27-22	87 FR 45076		I Withdrew 2022 proposed rule
2,5-DIMETHOXY-4-CHLOROAMPHETAMINE (DOC)	04-11-22	08-29-22	87 FR 52712		I Withdrew 2022 proposed rule
2,5-DIMETHOXY-4-IODOAMPHETAMINE (DOI)	04-11-22	08-29-22	87 FR 52712		I Withdrew 2022 proposed rule
AMINEPTINE (7-[(10,11-DIHYDRO-5H-DIBENZO[A,D]CYCLOHEPTEN-5-YL)AMINO]HEPTANOIC ACID)	07-22-22	11-17-22	87 FR 68895	12/19/2022	I
[18F]FP-CIT	11-04-21	11-21-22	87 FR 70715	12/21/2022	II --> NC
ZIPEPROL (1-METHOXY-3-[4-(2-METHOXY-2-PHENYLETHYL)PIPERAZIN-1-YL]-1-PHENYLPROPAN-2-OL)	05-14-20	11-21-22	87 FR 70717	12/21/2022	I
MESOCARB (N-PHENYL-N'-(3-(1-PHENYLPROPAN-2-YL)-1,2,3-OXADIAZOL-3-IUM-5-YL)CARBAMIMIDATE)	08-11-21	11-22-22	87 FR 71247	12/22/2022	I
FENFLURAMINE	07-19-22	12-23-22	87 FR 78857	12/23/2022	IV --> NC
METHIOPROPAMINE (N-METHYL-1-(THIOPHEN-2-YL)PROPANE-2-AMINE	09-02-21	12-09-22	87 FR 75470	1/9/2023	I
1-(1-(1-(4-BROMOPHENYL)ETHYL)PIPERIDIN-4-YL)-1,3-DIHYDRO-2H-BENZO[D]IMIDAZOL-2-ONE (BRORPHINE)		03-06-23	88 FR 13692	4/5/2023	I
EUTYLONE (1-(1,3-BENZODIOXOL-5-YL)-2-(ETHYLAMINO)BUTAN-1-ONE)		04-10-23	88 FR 21101	4/10/2023	I
4-(2-CHLOROPHENYL)-2-ETHYL-9-METHYL-6H-THIENO[3,2-F][1,2,4]TRIAZOLO[4,3-A][1,4]DIAZEPINE (ETIZOLAM) *		07-26-23	88 FR 48112	7/26/2023	I
6-(2-CHLOROPHENYL)-1-METHYL-8-NITRO-4H-BENZO[F][1,2,4]TRIAZOLO[4,3-A][1,4]DIAZEPINE (CLONAZOLAM) *		07-26-23	88 FR 48112	7/26/2023	I
7-CHLORO-5-(2-CHLOROPHENYL)-1-METHYL-1,3-DIHYDRO-2H-BENZO[E][1,4]DIAZEPIN-2-ONE (DICLAZEPAM) *		07-26-23	88 FR 48112	7/26/2023	I
8-BROMO-6-(2-FLUOROPHENYL)-1-METHYL-4H-BENZO[F][1,2,4]TRAZOLO[4,3-A][1,4]DIAZEPINE (FLUBROMAZOLAM) *		07-26-23	88 FR 48112	7/26/2023	I
8-CHLORO-6-(2-FLUOROPHENYL)-1-METHYL-4H-BENZO[F][1,2,4]TRIAZOLO[4,3-A][1,4]DIAZEPINE (FLUALPRAZOLAM) *		07-26-23	88 FR 48112	7/26/2023	I
ANABOLIC STEROIDS (amended regulations consistent with DASCA; updated and moved specific listing to 21 CFR 1308.13(f))		08-01-23	88 FR 50036	8/1/2023	III
N,N-DIETHYL-2-(2-(4-METHOXYBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (METONITAZENE)		08-18-23	88 FR 56466	9/18/2023	I
ZURANOLONE		10-31-23	88 FR 74347	10/31/2023	IV
2',5'-DIMETHOXYFENTANYL (N-(1-(2,5-DIMETHOXYPHENETHYL)PIPERIDINE-4-YL)-N-PHENYLPROPIONAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
3-FURANYL FENTANYL (N-(1-PHENTHYLPIPERIDIN-4-YL)-N-PHENYLFURAN-3-CARBOXAMIDE)		12-07-23	88 FR 85104	12/7/2023	I

*Scheduled under 21 USC 811(h)
**Extension of temporary control
NC = Not Controlled

SUBSTANCE	PROPOSAL PUBLICATION DATE	FINAL ORDER			CSA SCHEDULE
		PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	
ALPHA'-METHYL BUTYRYL FENTANYL (2-METHYL-N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLBUTANAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
ISOVALERY FENTANYL (3-METHYL-N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLBUTANAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
META-FLUOROFENTANYL (N-(3-FLUORPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
META-FLUOROISOBUTYRYL FENTANYL (N-(3-FLUOROPHENYL)-N-(1-PHENYLPIPERIDIN-4-YL)ISOBUTYRAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
ORTHO-FLUOROFURANYL FENTANYL (N-(2-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)FURAN-2-CARBOXAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
PARA-METHOXYFURANYL FENTANYL (N-(4-METHOXYPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)FURAN-2-CARBOXAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
PARA-METHYLCYCLOPROPYL FENTANYL (N-(4-METHYLPHENYL)-N-(1-PHENYLPIPERIDIN-4-YL)CYCLOPROPANECARBOXAMIDE)		12-07-23	88 FR 85104	12/7/2023	I
4F-MDMB-BUTICA (METHYL 2-[[1-(4-FLUOROBUTYL)INDOLE-3-CARBONYL]AMINO]-3,3-DIMETHYL-BUTANOATE) *		12-12-23	88 FR 86040	12/12/2023	I
5F-EDMB-PICA (ETHYL 2-[[1-5-FLUOROPENTYL)INDOLE-3-CARBONYL]AMINO-3,3-DIMETHYL-BUTANOATE *		12-12-23	88 FR 86040	12/12/2023	I
ADB-4EN-PINACA (N-(1-AMINO-3,3-DIMETHYL-1-OXOBUTAN-2-YL)-1-(PENT-4-EN-1-YL)-1H-INDAZOLE-3-CARBOXAMIDE *		12-12-23	88 FR 86040	12/12/2023	I
CUMYL-PEGACLONE (5-PENTYL-2-(2-PHENYLPROPAN-2-YL)PYRIDO[4,3-B]INDOLE-1-ONE *		12-12-23	88 FR 86040	12/12/2023	I
MDMB-4EN-PINACA (METHYL 3,3-DIMETHYL-2-(1-(PENT-4-EN-1-YL)-1H-INDAZOLE-3-CARBOXAMIDO)BUTANOATE) *		12-12-23	88 FR 86040	12/12/2023	I
MMB-FUBICA (METHYL 2-(1-(4-FLUOROBENZYL)-1H-INDOLE-3-CARBOXAMIDO)-3-METHYL BUTANOATE *		12-12-23	88 FR 86040	12/12/2023	I
3-MMC (2-(METHYLAMINO)-1-(3-METHYLPHENYL)PROPAN-1-ONE)		12-13-23	88 FR 86266	12/13/2023	I
ADB-BUTINACA (N-(1-AMINO-3,3-DIMETHYL-1-OXOBUTAN-2-YL)-1-BUTYL-1H-INDAZOLE-3-CARBOXAMIDE)		12-13-23	88 FR 86266	12/13/2023	I
ALPHA-PIHP (4-METHYL-1-PHENYL-2-(PYRROLIDIN-1-YL)PENTAN-1-ONE)		12-13-23	88 FR 86266	12/13/2023	I
2-(2-(4-ETHOXYBENZYL)-1H-BENZIMIDAZOL-1-YL)-N,N-DIETHYLETHAN-1-AMINE (ETODESNITAZENE; ETAZENE)		04-11-24	89 FR 25514	4/11/2024	I
2-(4-ETHOXYBENZYL)-5-NITRO-1-(2-(PYRROLIDIN-1-YL)ETHYL)-1H-BENZIMIDAZOLE (N-PYRROLIDINO ETONITAZENE)		04-11-24	89 FR 25514	4/11/2024	I
N,N-DIETHYL-2-(5-NITRO-2-(4-PROPOXYBENZYL)-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (PROTONITAZENE)		04-11-24	89 FR 25514	4/11/2024	I
2-(2-(4-BUTOXYBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)-N,N-DIETHYLETHAN-1-AMINE (BUTONITAZENE) **		04-11-24	89 FR 25517	4/12/2024	I
N,N-DIETHYL-2-(2-(4-FLUOROBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (FLUNITAZENE) **		04-11-24	89 FR 25517	4/12/2024	I
N,N-DIETHYL-2-(2-(4-METHOXYBENZYL)-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (METODESNITAZENE) **		04-11-24	89 FR 25517	4/12/2024	I

*Scheduled under 21 USC 811(h)
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SUBSTANCE	PROPOSAL PUBLICATION DATE	FINAL ORDER			CSA SCHEDULE
		PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	
2-METHYL AP-237 (1-(2-METHYL-4-(3-PHENYLPROP-2-EN-1-YL)PIPERAZIN-1-YL)BUTAN-1-ONE)		03-15-24	89 FR 18793	4/15/2024	I
2-(4-ETHOXYBENZYL)-5-NITRO-1-(2-(PIPERIDIN-1-YL)ETHYL)-1H-BENZIMIDAZOLE (N-PIPERIDINYL ETONITAZENE; ETONITAZEPIPNE) *		07-29-24	89 FR 60817	7/29/2024	I
N-ETHYL-2-(2-(4-ISOPROPOXYBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (N-DESETHYL ISOTONITAZENE) *		07-29-24	89 FR 60817	7/29/2024	I
2-(2-(4-BUTOXYBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)-N,N-DIETHYLETHAN-1-AMINE (BUTONITAZENE)		10-25-24	89 FR 85047	10/25/2024	I
N,N-DIETHYL-2-(2-(4-FLUOROBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (FLUNITAZENE)		10-25-24	89 FR 85047	10/25/2024	I
N,N-DIETHYL-2-(2-(4-METHOXYBENZYL)-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (METODESNITAZENE)		10-25-24	89 FR 85047	10/25/2024	I
ETHYLPHENIDATE (ETHYL 2-PHENYL-2-(PIPERIDIN-2-YL)ACETATE)	09-22-23	10-22-24	89 FR 84281	11/21/2024	I

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Issued in Washington, DC, on April 3, 2023.

Brian Konie,

Acting Manager, Airspace Rules and Regulations.

[FR Doc. 2023–07297 Filed 4–7–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1003]

Specific Listing for Eutylone, a Currently Controlled Schedule I Substance

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Controlled Substances Code Number (drug code) for 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one (also known as eutylone or bk-EBDB) in schedule I of the Controlled Substances Act (CSA). Although eutylone is not specifically listed in schedule I of the CSA with its own unique drug code, it has been controlled in the United States since March 7, 2014, as a positional isomer of pentylone, a schedule I hallucinogen. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include eutylone.

DATES: Effective April 10, 2023.

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

SUPPLEMENTARY INFORMATION:

Eutylone Control

Eutylone (also known as 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one or bk-EBDB) is a chemical substance which is structurally related to pentylone (also known as 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one or bk-MBDP). Pentylone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(64). The introductory text to paragraph (d) provides: (1) A listed substance includes "any of 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," and (2) the term "isomer" includes the optical, position[al], and geometric isomers.

When compared to the chemical structure of pentylone, eutylone meets the definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term "positional isomer" in 21 CFR 1308.11(d). Both pentylone and eutylone possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety between functional groups. Accordingly, under 21 CFR 1308.11(d), eutylone, as a positional isomer of pentylone, has been and continues to be a schedule I controlled substance.[1]

The Drug Enforcement Administration (DEA)'s Authority To Control Eutylone

This rule is prompted by a letter dated May 27, 2022, in which the United States government was informed by the Secretariat of the United Nations that eutylone has been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention). This letter was prompted by a decision at the 65th Session of the Commission on Narcotic Drugs (CND) in March 2022 to schedule eutylone under Schedule II of the 1971 Convention (CND Dec/65/3). Preceding this decision, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the **Federal Register** with an opportunity to submit domestic information and opportunity to comment on this action, July 23, 2021, 86 FR 39038 and February 15, 2022, 87 FR 8586. In every instance, FDA noted that eutylone was already controlled in schedule I of the Controlled Substances Act (CSA) as a positional isomer of pentylone, and the February 2022 notice stated that no additional permanent controls for eutylone under the CSA would be necessary to fulfill United States' obligations as a party to the 1971 Convention.

As discussed above in this final rule, eutylone—by virtue of being a positional isomer of pentylone—has been controlled in schedule I of the CSA temporarily since March 7, 2014 (79 FR 12938), and permanently since March 1, 2017 (82 FR 12171). Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to eutylone. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of eutylone as a schedule I controlled substance in any way. This action, as an administrative matter, merely establishes a separate, specific listing for eutylone in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for the substance. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of eutylone, who had previously been granted individual quotas for such purposes under the drug code for pentylone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. Eutylone is currently controlled in schedule I as a positional isomer of pentylone, and eutylone has no currently accepted medical use in treatment to qualify for placement in a schedule other than schedule I (*see* 21 U.S.C. 812(b)(2)–(5)).

Pursuant to 5 U.S.C. 553(b)(3)(B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures. The addition of a separate listing for eutylone and its DEA controlled substances code number in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of this drug as a schedule I controlled substance, but instead is "a minor or merely technical amendment in which the public is not particularly interested." *National Nutritional Foods Ass'n* v. *Kennedy,* 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79–752, at 200 (1945)). *See also Utility Solid Waste Activities Group* v. *E.P.A.,* 236 F.3d 749, 755 (D.C. Cir. 2001) (the "unnecessary" prong "is confined to those situations in which the administrative rule is a routine determination, insignificant in nature

[1] Pentylone (and its isomers) has been subject to temporary schedule I controls since March 7, 2014, first pursuant to a final order (March 7, 2014, 79 FR 12938) and the subsequent one-year extension of that order (March 4, 2016, 81 FR 11429), and then permanently pursuant to a final rule which continued the imposition of those controls (March 1, 2017, 82 FR 12171).

and impact, and inconsequential to the industry and public") (internal quotations and citation omitted). This rule is a "technical amendment" to 21 CFR 1308.11(d) as it is "insignificant in nature and impact, and inconsequential to the industry and public." Therefore, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary.

In addition, because eutylone is already subject to domestic control under schedule I as a positional isomer of pentylone and no additional requirements are being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3). DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of eutylone. Eutylone is currently controlled as a schedule I controlled substance, and this level of control does not change with this rulemaking.

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

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. This rule is not a significant regulatory action under E.O. 12866. Eutylone already is a controlled substance in the United States under schedule I, as it is a positional isomer of a schedule I hallucinogen, pentylone. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list eutylone in schedule I and to assign the DEA controlled substances code number 7549 to the substance. A separate listing for eutylone and its DEA controlled substances code number will not alter the status of eutylone as a schedule I controlled substance. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule 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 rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

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 other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

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. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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. 1532, DEA has determined 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 rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. Amend § 1308.11 by adding new paragraph (d)(101) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(101) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one (other names: eutylone; bk-EBDB)	7549

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on April 3, 2023, 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.

[FR Doc. 2023–07335 Filed 4–7–23; 8:45 am]

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needed to completely close the lavatory door.

(9) The on-board wheelchair must prominently display instructions for proper use.

(f) You are not required to expand the existing FAA-certificated on-board wheelchair stowage space of the aircraft, or modify the interior arrangement of the lavatory or the aircraft, in order to comply with this section. However, if the on-board wheelchair that you obtain does not fit within the original stowage space, and another space exists (*e.g.*, an overhead compartment) where the on-board wheelchair could fit consistent with FAA safety standards, then you must stow the on-board wheelchair in that space and must request any necessary FAA approval to do so. You are not required to make the on-board wheelchair available if the pilot-in-command determines that safety or security considerations preclude its use.

(g) You must acquire an OBW that complies with as many requirements set forth in paragraph (e) of this section as are available. You are not responsible for the failure of third parties to develop and deliver an on-board wheelchair that complies with a requirement set forth in paragraph (e) of this section so long as you make reasonable efforts to purchase such an OBW and inform the Department at the address cited in § 382.159 that an on-board wheelchair meeting that requirement is unavailable despite your reasonable efforts. If you cannot provide a wheelchair meeting requirement (e)(8) of this section despite your reasonable efforts, then you must provide, on request, the use of the visual barrier (*e.g.*, a curtain) described in § 382.63(f)(7) to enable the passenger to perform lavatory functions in privacy.

(h) If you replace an on-board wheelchair on aircraft with an FAA-certificated maximum seating capacity of 125 or more after October 2, 2026, then you must replace it with an on-board wheelchair that meets the standards set forth in paragraph (e) of this section.

Issued this 25th day of July, 2023, in Washington, DC.

Peter Paul Montgomery Buttigieg,

Secretary.

[FR Doc. 2023–16178 Filed 7–31–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1300, 1302, and 1308

[Docket No. DEA–481]

RIN 1117–AB81

Implementation of the Designer Anabolic Steroid Control Act of 2014

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: On December 18, 2014, the Designer Anabolic Steroid Control Act of 2014 (DASCA) became law. The Act amended the Controlled Substances Act to revise and add specified substances to the definition of "anabolic steroid." The Act provided a new mechanism for temporary and permanent scheduling of anabolic steroids, and added specific labeling requirements for products containing anabolic steroids. The Drug Enforcement Administration (DEA) is publishing this rule to amend and reorganize its regulations to make them consistent with DASCA regarding the updated definition, specific substances, criteria and timeframes applicable to temporary and permanent scheduling of anabolic steroids, and labeling requirements.

DATES: This final rule is effective August 1, 2023.

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

SUPPLEMENTARY INFORMATION: On December 18, 2014, the Designer Anabolic Steroid Control Act of 2014, Public Law 113–260 (128 Stat. 2929) (DASCA), became law. The purpose of this final rule is to codify in Drug Enforcement Administration (DEA) regulations the statutory amendments to the Controlled Substances Act (CSA) made by DASCA. This final rule merely conforms the DEA's regulations to the statutory amendments to the CSA that have already taken effect, and does not add additional requirements to the regulations. Thus, because this rule does no more than incorporate statutory amendments into DEA's regulations, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary; and the rule is instead being issued as a final rule effective immediately.

DASCA's Changes to the CSA

A House Report for DASCA stated that the purpose of the Act is "to more effectively regulate anabolic steroids." H.R. Rep. No. 113–587, Part 2, at 4 (2014). DASCA makes four changes to the CSA: DASCA (1) revises and adds additional substances to the existing definition of "anabolic steroid" in 21 U.S.C. 802(41); (2) provides a new mechanism for temporary and permanent scheduling of anabolic steroids in 21 U.S.C. 811(i); (3) adds labeling requirements for anabolic steroids under 21 U.S.C. 825(e); and (4) provides new penalties for violating the labeling requirements under 21 U.S.C. 842(a)(16) and 842(c)(1)(C) and (D).

It is evident from the enactment of DASCA that Congress believed the prior two public laws addressing steroids under the CSA (the Anabolic Steroids Control Act of 1990, Pub. L. 101–647, and the Anabolic Steroid Control Act of 2004, Pub. L. 108–358) had not sufficiently stemmed the misuse of anabolic steroids by athletes, students, and others. Among other things, Congress found that the prior statutory definition of an anabolic steroid was too narrow and that this narrowness was being exploited by some manufacturers and distributors. DASCA was designed to remedy this situation by: (1) expressly controlling under the CSA additional anabolic steroids that have emerged in the United States in recent years; and (2) expanding the definition of an anabolic steroid to allow other such steroids to be controlled as they emerged in the future. Indeed, the word "designer" in DASCA's title reflects that Congress was targeting those who sought to circumvent the CSA by producing anabolic steroids that were slightly different in chemical structure from those substances specifically listed in the CSA but which were intended to cause the same effects—and thus were potentially harmful to users. The following statement by one of the sponsors of the legislation, Senator Whitehouse, illustrates these considerations:

> [A] loophole in current law allows for designer anabolic steroids to easily be found on the internet, in gyms, and even in retail stores.
>
> Designer steroids are produced by reverse engineering existing illegal steroids and then slightly modifying the chemical composition, so that the resulting product is not on [DEA's] list of controlled substances. When taken by consumers, designer steroids can cause serious medical consequences, including liver injury and increased risk of heart attack and stroke. They may also lead to psychological effects such as aggression, hostility, and addiction.

160 Cong. Rec. S891–892 (daily ed. Feb. 11, 2014) (statement of Sen. Whitehouse); *accord* 160 Cong. Rec. H7460 (daily ed. Sept. 15, 2014) (statement of Rep. Pitts); *id.* at H7461 (statement of Rep. Christensen); *id.* (statement of Rep. Waxman).

Changes to the Definition of an Anabolic Steroid

To curtail the foregoing activity, DASCA amended the CSA definition of "anabolic steroid" by adding 22 new substances to the prior statutory list of anabolic steroids. *See* 21 U.S.C. 802(41)(A)(i)–(lxxiv). While the statute lists 25 substances, two of these substances are duplicates of substances previously listed in the regulatory definition of anabolic steroid, and one substance is included twice on the statutory list, bringing the actual number to 22 new specific substances. In particular, methasterone and prostanozol were included in the statute but were already listed, albeit under alternative chemical names, in the regulatory definition of anabolic steroid.[1] 4-Chloro-17α-methyl-androsta-1,4-diene-3,17β-diol is listed twice in the statute. *See id.* 802(41)(A)(liii), (lvii).

This rule revises the existing regulatory definition of "anabolic steroid" in 21 CFR 1300.01(b) to incorporate the revised statutory standard, moves the list of specifically named anabolic steroids from 21 CFR 1300.01(b) to 21 CFR 1308.13(f), and adds the 22 new substances included in DASCA to the relocated list at 21 CFR 1308.13(f).[2] In addition to incorporating the language of the statutory amendments of DASCA into DEA's regulations, this rule relocates and makes a number of organizational and typographical changes to the regulatory list of anabolic steroids to improve the list's clarity. These changes, however, do not add or remove any substances from this list beyond the 22 new substances added by DASCA or otherwise alter DASCA's language. DASCA expanded the definition of "anabolic steroid" to include a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed and is derived from, or has a chemical structure substantially similar to a listed anabolic steroid or steroids, if it: (1) has been created or manufactured with the intent of producing a substance that either promotes muscle growth or otherwise causes a pharmacological effect similar to that of testosterone; or (2) has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any pharmacological effect similar to that of testosterone. 21 U.S.C. 802(41)(C)(i). Unless otherwise excepted or listed in another schedule, all substances meeting the definition of "anabolic steroid" are controlled under schedule III of the CSA. *See id.* 812(c), Schedule III, (e); 21 CFR 1300.01(b), 1308.13(f). Thus, other substances that meet DASCA's revised definition of an anabolic steroid are also considered schedule III substances, even if they are not specifically listed in § 1308.13(f).

Under this modified definition, a substance shall not be considered to be a drug or hormonal substance if it: (1) is an herb or other botanical, a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical, or a combination of two or more such substances; (2) is a dietary ingredient for purposes of the Federal Food, Drug and Cosmetic Act (FD&C Act); and (3) is not anabolic or androgenic. 21 U.S.C. 802(41)(C)(ii). Any person claiming the benefit of exemption or exception under this definition shall bear the burden in administrative or judicial proceedings of going forward with evidence with respect to such exemption or exception in accordance with 21 U.S.C. 885(a). 21 U.S.C. 802(41)(C)(iii).

Changes to the Provisions Governing the Administrative Scheduling of Anabolic Steroids

To further diminish the ability of illicit manufacturers of anabolic steroids to circumvent the law by producing new designer substances with similar effects, DASCA also made it easier for DEA to add such substances to the list of anabolic steroids on a temporary and permanent basis. Specifically, DASCA added a new subsection to the CSA (21 U.S.C. 811(i)), which gives the Attorney General (and thus the Administrator of DEA by delegation) the authority to issue a temporary order adding a drug or substance to the definition of "anabolic steroid" upon the finding that: (A) the substance satisfies the criteria for being considered an anabolic steroid but is not already listed in 21 U.S.C. 802(41) or in the regulations of the Attorney General (in practice, the regulatory definition of "anabolic steroid" in 21 CFR 1300.01); and (B) such addition will assist in preventing abuse or misuse of the substance. 21 U.S.C. 811(i)(1). Such a temporary control order may last up to 24 months after the effective date, with a possible extension of 6 months, and may not take effect until 30 days after the date of the publication by the Attorney General of a notice in the **Federal Register** of the intention to issue such an order and the grounds upon which such an order is to be issued. 21 U.S.C. 811(i)(2). The Attorney General shall also transmit notice of a proposed order to the Secretary of Health and Human Services and take into consideration any comments submitted by the Secretary in response to that notice. 21 U.S.C. 811(i)(3). DASCA also gives the DEA the authority to issue, by rule, a permanent order adding a drug or other substance to the definition of an anabolic steroid if that drug or other substance satisfies the criteria for being considered an anabolic steroid under 21 U.S.C. 802(41). 21 U.S.C. 811(i)(6).

Unlike scheduling under 21 U.S.C. 811(a), nothing in DASCA requires this rulemaking to take place on the record after opportunity for a hearing, and thus these permanent orders may be issued pursuant to the informal rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5 of the United States Code. *See* 5 U.S.C. 553(c).

New Labeling Requirements for Anabolic Steroids

To protect potential consumers from unknowingly ingesting anabolic steroids, and to ensure that all persons in the distribution chain identify those items that contain anabolic steroids, DASCA also added a labeling requirement to the CSA. This labeling provision states that it is unlawful to import, export, manufacture, distribute, or dispense—or possess with intent to manufacture, distribute, or dispense—an anabolic steroid or product containing an anabolic steroid, unless the product bears a label clearly identifying the anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC). 21 U.S.C. 825(e)(1). DASCA makes an exception to the IUPAC labeling requirement where the product is labeled in the manner required under the CSA and the FD&C Act; that is, the product is the subject of an approved application as described in 21 U.S.C. 355(b) or (j), or the product is

[1] Methasterone is currently identified as 2α,17α-dimethyl-5α-androstan-17β-ol-3-one in 21 CFR 1300.01(b)("anabolic steroid")(32), but as 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one in 21 U.S.C. 802(41)(A)(lviii). Prostanozol is currently identified as 17β-hydroxy-5α-androstano[3,2-c]pyrazole in 21 CFR 1300.01(b)("anabolic steroid")(58), but as [3,2-c]pyrazole-5α-androstan-17β-ol in 21 U.S.C. 802(41)(A)(lxxiv). This rule revises the regulatory list of anabolic steroids to include all these variations of the chemical names of methasterone and prostanozol.

[2] Although the list is being relocated from 21 CFR 1300.01(b) to 21 CFR 1308.13(f), all listed or defined anabolic steroids will maintain the same Controlled Substance Code Number, 4000.

exempt from the provisions of 21 U.S.C. 355 because it is intended solely for investigational use as described in 21 U.S.C. 355(i) and it is being used exclusively for the purposes of a clinical trial that is the subject of an effective investigational new drug application. *Id.* 825(e)(2).

DASCA also added new civil fine provisions for failure to comply with the labeling requirements:

- For a violation by an importer, exporter, manufacturer, or distributor (except as provided in the subsequent paragraph), up to $500,000 per instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute. 21 U.S.C. 842(c)(1)(C).
- In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of the labeling requirements at the retail level, up to $1,000 per violation. "At the retail level" refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container, or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level is a separate violation. 21 U.S.C. 842(c)(1)(D). Failure to comply with labeling requirements may be taken into account by DEA when issuing or revoking a registration.[3]

These penalty provisions are discussed here for the sake of completeness and given their close connection with other DASCA provisions. DEA is not amending its regulations to incorporate these civil fine provisions, as DEA's regulations do not address civil fines in general, making such amendment unnecessary.

Impact of Statutory Changes on Regulatory Requirements

In enacting DASCA and expanding the scope of substances that fall within the CSA definition of an anabolic steroid, Congress increased the number of substances that are schedule III controlled substances and subject to the corresponding provisions of the CSA. This law added 22 new substances to the list of schedule III controlled substances, which are included in 21 CFR 1308.13(f).

Since December 18, 2014, the manufacture, import, export, distribution, or sale of a newly listed anabolic steroid or a substance meeting the revised definition of an anabolic steroid, except by DEA registrants, has been a violation of the CSA that may result in imprisonment and fines. 21 U.S.C. 841, 960. Possession of the steroids unless legally obtained is also subject to criminal penalties. 21 U.S.C. 844. Importation of these schedule III steroids is illegal unless the person importing the steroids is registered with DEA as an importer or researcher and files the required declaration for each shipment. Illegal importation of a schedule III anabolic steroid is a violation of the CSA that may result in imprisonment and fines. 21 U.S.C. 960(a)(1).

Disposal of Anabolic Steroids

Persons who possess substances defined as anabolic steroids and who wish to dispose of them rather than becoming registered to handle them should contact their local DEA Diversion field office for assistance in disposing of these substances legally. The DEA Diversion field office will provide the person with instructions regarding the disposal. A list of local DEA Diversion field offices may be found at *https://apps2.deadiversion.usdoj.gov/contactDea/spring/fullSearch.*

Good Cause for Issuing This Rule as a Final Rule Without Notice and Comment

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA), 5 U.S.C. 553, including notice of proposed rulemaking and the opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest. DEA finds there is good cause within the meaning of the APA to issue these amendments as a final rule without notice and comment, because these amendments, as explained above, merely conform the implementing regulations with recent amendments to the CSA that have already taken effect (*see* 5 U.S.C. 553(b)(B), relating to notice and comment procedures). "[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary." *Gray Panthers Advocacy Comm.* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991); *see also United States* v. *Cain,* 583 F.3d 408, 420 (6th Cir. 2009) (contrasting legislative rules, which require notice-and-comment procedures, "with regulations that merely restate or interpret statutory obligations," which do not); *Komjathy* v. *Nat'l Transp. Safety Bd.,* 832 F.2d 1294, 1296–97 (D.C. Cir. 1987) (per curiam) (when a rule "does no more than repeat, virtually verbatim, the statutory grant of authority," notice-and-comment procedures are not required).

As DEA is simply incorporating the terms of DASCA into its regulations and making organizational and technical changes, publishing a notice of proposed rulemaking and soliciting public comment is unnecessary. The revised definition of "anabolic steroid," the identification of 22 new specific substances as anabolic steroids, the new mechanism for temporary and permanent scheduling of anabolic steroids, and the revised labeling requirements for anabolic steroids have already been in effect since December 18, 2014. Moreover, while the list of anabolic steroids has been moved to § 1308.13(f), this change is a technical one; it imposes no new or substantive requirement on the public or DEA registrants. For the reasons discussed above, DEA also finds good cause exists to make this rule effective immediately upon publication. Therefore, we are issuing these amendments as a final rule, effective upon publication in the **Federal Register**. This rule constitutes final action on these changes under the APA, 5 U.S.C. 553.

Regulatory Analysis

As explained above, DEA is issuing this final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the DASCA. In issuing this final rule, DEA has not gone beyond the statutory text enacted by Congress. DEA's regulatory analysis is discussed below.

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

This final rule was developed in accordance with the principles of Executive Orders 12866 and 13563. Executive Order 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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 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

[3] See 21 U.S.C. 823(a), 824(a).

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 Executive order. This rule is not a "significant regulatory action" under Executive Order 12866.

On December 18, 2014, the Designer Anabolic Steroid Control Act of 2014 (DASCA) became law. The Act amended the Controlled Substances Act (CSA) to expand the general definition of "anabolic steroid" to include a broader range of substances, and to add 22 new specific substances to the list of named substances in the definition. The Act further provided a new mechanism for temporary and permanent scheduling of anabolic steroids as schedule III controlled substances, and added new labeling requirements for anabolic steroids, with penalties for violation of such requirements. These provisions of DASCA were self-implementing, and did not require any amendments to the Code of Federal Regulations in order to be effective. The 22 new specific substances that were not previously controlled and the other unnamed substances that meet DASCA's revised definition of anabolic steroid became schedule III substances with the passage of DASCA.

As stated above, the DEA is simply updating its regulations to be consistent with the exact terms of DASCA; this final rule does not change the legal status of these substances. Because the placement of these substances in schedule III, the revised general definition of "anabolic steroid," the criteria and timeframes applicable to temporary and permanent scheduling of anabolic steroids, and the labeling requirements for anabolic steroids (with penalties for violation) have already been in effect since December 18, 2014, any economic impact of DASCA has already been absorbed by the economy.

Therefore, this final rule will have no economic impact. Accordingly, the DEA does not anticipate that this rulemaking will 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.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

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. As explained above, the DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply to this final rule.

Paperwork Reduction Act of 1995

This rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Unfunded Mandates Reform Act of 1995

This rule will not 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 one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. 2 U.S.C. 1532.

Congressional Review Act

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

Signing Authority

This document of the Drug Enforcement Administration was signed on July 18, 2023, 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**.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1302

Drug traffic control, Exports, Imports, Labeling, Packaging and containers.

21 CFR Part 1308

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

For the reasons set forth above, 21 CFR parts 1300, 1302, and 1308 are amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

■ 2. Section 1300.01 is amended in paragraph (b) by revising the definition of "Anabolic steroid" as follows:

§ 1300.01 Definition relating to controlled substances.

* * * * *

(b) * * *

Anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes (but is not limited to) those substances listed in § 1308.13(f) of this chapter.

(1)(i) Except as provided in paragraph (1)(ii) of this definition, such term does not include an anabolic steroid that is expressly intended for administration

through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this definition.

(2)(i) Subject to paragraph (2)(ii) of this definition, a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in § 1308.13(f) of this chapter and is derived from, or has a chemical structure substantially similar to, one or more anabolic steroids listed in § 1308.13(f) of this chapter shall be considered to be an anabolic steroid for purposes of this chapter if—

(A) The drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—

(*1*) Promotes muscle growth; or

(*2*) Otherwise causes a pharmacological effect similar to that of testosterone; or

(B) The drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this definition if it—

(A) Is—

(*1*) An herb or other botanical;

(*2*) A concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(*3*) A combination of 2 or more substances described in paragraph (2)(ii)(A)(*1*) or (*2*) of this definition;

(B) Is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); and

(C) Is not anabolic or androgenic.

(iii) In accordance with 21 U.S.C. 885(a), any person claiming the benefit of an exemption or exception under paragraph (2)(ii) of this definition shall bear the burden of going forward with the evidence with respect to such exemption or exception.

* * * * *

PART 1302—LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1302 continues to read as follows:

Authority: 21 U.S.C. 821, 825, 871(b), 958(e).

■ 4. Section 1302.08 is added to read as follows:

§ 1302.08 False labeling of anabolic steroids.

(a) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

(b)(1) A product described in paragraph (b)(2) of this section is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this section if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(2) A product is described in this paragraph (b)(2) if the product—

(i) Is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)); or

(ii) Is exempt from the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act relating to new drugs because—

(A) It is intended solely for investigational use as described in section 505(i) of the Federal Food, Drug, and Cosmetic Act; and

(B) Such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 5. 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.

■ 6. Section 1308.13 is amended by revising paragraph (f) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(f) *Anabolic steroids.* Unless specifically excepted or unless listed in another schedule, any substance meeting the definition of anabolic steroid as set forth in § 1300.01 of this chapter, including any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers (4000):

(1) 5α-androstan-3,17-dione;

(2) 5α-androstan-3,6,17-trione;

(3) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);

(4) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);

(5) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene);

(6) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);

(7) 1-androstenedione (5α-androst-1-en-3,17-dione);

(8) 4-androstenedione (androst-4-en-3,17-dione);

(9) 5-androstenedione (androst-5-en-3,17-dione);

(10) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(11) boldenone (17β-hydroxyandrost-1,4-diene-3-one);

(12) boldione (androsta-1,4-diene-3,17-dione);

(13) 6-bromo-androsta-1,4-diene-3,17-dione;

(14) 6-bromo-androstan-3,17-dione;

(15) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(16) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;

(17) 4-chloro-17α-methyl-androst-4-ene-3β,17β-diol;

(18) 4-chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one;

(19) 4-chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione;

(20) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one);

(21) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one);

(22) desoxymethyltestosterone (17α-methyl-5α-androst-2-en-17β-ol) (a.k.a. "madol");

(23) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);

(24) Δ1-dihydrotestosterone (a.k.a. "1-testosterone") (17β-hydroxy-5α-androst-1-en-3-one);

(25) 3β,17β-dihydroxy-5α-androstane;

(26) 3α,17β-dihydroxy-5α-androstane;

(27) 2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one;

(28) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one);

(29) 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol;

(30) estra-4,9,11-triene-3,17-dione;

(31) 13β-ethyl-17β-hydroxygon-4-en-3-one;

(32) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);

(33) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one);

(34) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one);

(35) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]furazan);
(36) [3,2-c]furazan-5α-androstan-17β-ol;
(37) 18a-homo-3-hydroxy-estra-2,5(10)-dien-17-one;
(38) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);
(39) 4-hydroxy-androst-4-ene-3,17-dione;
(40) 17β-hydroxy-androstano[2,3-d]isoxazole;
(41) 17β-hydroxy-androstano[3,2-c]isoxazole;
(42) 3β-hydroxy-estra-4,9,11-trien-17-one;
(43) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);
(44) mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one);
(45) mesterolone (1α-methyl-17β-hydroxy-5α-androstan-3-one);
(46) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);
(47) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene);
(48) methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one or 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one);
(49) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);
(50) 17α-methyl-androsta-1,4-diene-3,17β-diol;
(51) 17α-methyl-5α-androstan-17β-ol;
(52) 17α-methyl-androstan-3-hydroxyimine-17β-ol;
(53) 6α-methyl-androst-4-ene-3,17-dione;
(54) 17α-methyl-androst-2-ene-3,17β-diol;
(55) 17α-methyl-3β,17β-dihydroxy-5α-androstane;
(56) 17α-methyl-3α,17β-dihydroxy-5α-androstane;
(57) 17α-methyl-3β,17β-dihydroxyandrost-4-ene;
(58) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);
(59) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);
(60) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. "17-α-methyl-1-testosterone");
(61) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);
(62) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9,11-trien-3-one);
(63) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);
(64) nandrolone (17β-hydroxyestr-4-en-3-one);
(65) 19-nor-4-androstenediol (3β,17β-dihydroxyestr-4-ene);
(66) 19-nor-4-androstenediol (3α,17β-dihydroxyestr-4-ene);
(67) 19-nor-5-androstenediol (3β,17β-dihydroxyestr-5-ene);
(68) 19-nor-5-androstenediol (3α,17β-dihydroxyestr-5-ene);
(69) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);
(70) 19-nor-4-androstenedione (estr-4-en-3,17-dione);
(71) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
(72) norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);
(73) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);
(74) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);
(75) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);
(76) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-5α-androstan-3-one);
(77) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);
(78) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-5α-androstan-3-one);
(79) prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole or [3,2-c]pyrazole-5α-androstan-17β-ol);
(80) [3,2-c]pyrazole-androst-4-en-17β-ol;
(81) stanozolol (17α-methyl-17β-hydroxy-5α-androst-2-eno[3,2-c]-pyrazole);
(82) stenbolone (17β-hydroxy-2-methyl-5α-androst-1-en-3-one);
(83) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
(84) testosterone (17β-hydroxyandrost-4-en-3-one);
(85) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one); and
(86) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one).

* * * * *

■ 7. Section 1308.50 is added to read as follows:

§ 1308.50 Temporary and permanent scheduling of recently emerged anabolic steroids.

(a) The Administrator may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Administrator finds that—

(1) The drug or other substance satisfies the criteria for being considered an anabolic steroid under 21 U.S.C. 802(41) but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(2) Adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(b) An order issued under paragraph (a) of this section shall not take effect until 30 days after the date of the publication by the Administrator 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. The order shall expire not later than 24 months after the date it becomes effective, except that the Administrator may, during the pendency of proceedings under paragraph (f) of this section, extend the temporary scheduling order for up to 6 months.

(c) The Administrator shall transmit notice of an order proposed to be issued under paragraph (a) of this section to the Secretary of Health and Human Services. In issuing an order under paragraph (a), the Administrator shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph (c).

(d) A temporary scheduling order issued under paragraph (a) of this section shall be vacated upon the issuance of a permanent scheduling order under paragraph (f) of this section.

(e) An order issued under paragraph (a) of this section is not subject to judicial review.

(f) The Administrator may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid under 21 U.S.C. 802(41). Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (a) of this section.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–15747 Filed 7–31–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9515]

RIN 1545–BH20

Guidance Under Section 1502; Amendment of Matching Rule for Certain Gains on Member Stock; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to Treasury Decision 9515, which was published in the **Federal Register** for Friday, March 4, 2011.

responsible agency or the USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

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List of Subjects in 7 CFR Part 622

Flood control, Grant programs—natural resources, Loan programs—natural resources, Soil conservation, Technical assistance, Watersheds.

For the reasons discussed above, NRCS amends 7 CFR part 622 as follows:

PART 622—WATERSHED PROJECTS

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1001–1012a, and 33 U.S.C. 701b–1.

Subpart B—Qualifications

■ 2. In § 622.10, revise paragraph (a) to read as follows.

§ 622.10 Sponsors.

(a) Watershed projects are sponsored by one or more local organizations qualifying as sponsors. All watershed plans must be sponsored by entities legally organized under State law or by any Indian Tribe or Tribal organization having the authority to carry out, operate, and maintain works of improvement.

(1) *In General.* Those plans that incorporate the use of nonstructural or structural measures must be sponsored by organizations that, individually or collectively, have:

(i) The power of eminent domain, except as provided in paragraph (a)(2) of this section; and

(ii) The authority to levy taxes or use other adequate funding sources, to finance their share of the watershed project cost and all operation and maintenance costs.

(2) *Exception.* Paragraph (a)(1)(i) of this section does not apply to Indian Tribes or Tribal organizations.

* * * * *

Terry Cosby,

Chief, Natural Resources Conservation Service.

[FR Doc. 2024–17819 Filed 8–13–24; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA1258]

Schedules of Controlled Substances: Placement of Zuranolone in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the **Federal Register** on October 31, 2023, placing zuranolone (chemically known as 1-[2-[(3*R*,5*R*,8*R*,9*R*,10*S*,13*S*,14*S*,17*S*)-3-hydroxy-3,13-dimethyl-2,4,5,6,7,8,9,10,11,12,14,15,16,17-tetradecahydro-1*H*-cyclopenta[*a*]phenanthren-17-yl]-2-oxoethyl]pyrazole-4-carbonitrile) and its salts in schedule IV of the Controlled Substances Act. With the issuance of this final rule, the Drug Enforcement Administration maintains zuranolone, including its salts, in schedule IV of the Controlled Substances Act.

DATES: Effective September 13, 2024.

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

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II–V, DEA is required to issue an interim final rule (IFR), with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and subsequently to issue a final rule.[1] When controlling a drug pursuant to subsection 811(j), DEA must apply the scheduling criteria of 21 U.S.C. 811(b) through (d), and 812(b).[2]

On August 4, 2023, the U.S. Food and Drug Administration (FDA) approved the New Drug Application (commonly referred to as NDA) for zuranolone to be marketed as a prescription drug (ZURZUVAE, capsule) for the treatment of post-partum depression. DEA received notification that FDA approved the NDA on the same date. Pursuant to its FDA-approved prescription drug labeling, ZURZUVAE, 50 mg, is to be administered orally once in the evening with fat-consuming food for 14 days. The dose may be reduced for patients who cannot tolerate 50 mg. In addition, on July 12, 2023, HHS recommended that DEA place zuranolone and its salts in schedule IV of the CSA.

On October 31, 2023, DEA, pursuant to 21 U.S.C. 811(j), published an IFR in the **Federal Register** to make zuranolone (including its salts) a schedule IV controlled substance.[3] The IFR provided an opportunity for interested persons to submit comments, as well as file a request for a hearing or waiver of a hearing, on or before November 30, 2023. DEA did not receive any requests for a hearing or waiver of a hearing.

Comment Received

DEA received one comment on the IFR to control zuranolone in schedule IV of the CSA. The commenter briefly expressed that schedule IV was the appropriate schedule for zuranolone based on the similarity of this substance to substances in schedule IV and requested information on what surveillance and reporting systems exist to ensure proper use of zuranolone due to its documented abuse potential.

DEA Response: DEA determined in the IFR, and re-affirms in this final rule, that zuranolone meets the criteria under 21 U.S.C. 812(b)(4) for schedule IV control. As described by HHS, and in DEA's September 2023 eight-factor analysis, zuranolone demonstrated abuse potential similar to schedule IV

[1] 21 U.S.C. 811(j).

[2] 21 U.S.C. 811(j)(3).

[3] *Schedules of Controlled Substances: Placement of Zuranolone in Schedule IV,* 88 FR 74347 (Oct. 31, 2023).

depressants. DEA appreciates the support for this rulemaking.

In response to the request of information regarding surveillance and reporting systems in place, DEA notes that diversion and illicit trafficking of zuranolone will be monitored by DEA's National Forensic Laboratory Information System (NFLIS)-Drug.[4] NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

DEA also notes that the monitoring of adverse effects for any new drug products, including abuse potential, largely falls under the purview of HHS, including FDA. FDA monitors the adverse events for all drugs through a postmarketing pharmacovigilance program.[5]

DEA is aware that in the publicly available NDA letter,[6] FDA noted reporting information under sections "Reporting Requirements" and "Requested Pharmacovigilance." Specifically, the sponsor of the zuranolone drug product ZURZUVAE must follow standard reporting guidance as described in 21 CFR 314.80(c)(1) (*e.g.*, 15-day alert reports), submit standard periodic (including quarterly) adverse drug experience reports as described in 21 CFR 314.80(c)(2), and submit standard annual reports as described in 21 CFR 314.81(b)(2). Further, the sponsor must submit additional reports as described in the letter, including "all serious and nonserious domestic and foreign adverse drug experience reports of Central Nervous System (CNS) depressant effects including adverse sequelae of the CNS depressant effects, such as motor vehicle accidents, falls, loss of consciousness, respiratory depression, or impairment of the ability to care for a child as a 15-day 'Alert report' (described under 21 CFR 314.80(c)(1)), from any source, including information derived from reports in the scientific literature and postmarketing studies (whether or not conducted under an investigational new drug application), through the 5th year following initial U.S. approval." DEA notes that additional information about published alerts, as well as the drug labeling and approval process, can be found at "Drugs@FDA: FDA-Approved Drugs" on FDA's website.[7] Importantly, drug labeling is used to communicate to both healthcare providers and patients any potential risks associated with the product, including abuse-related risks, if any, and is updated over time.

Additionally, adverse effects can be reported to FDA's Adverse Event Reporting System (FAERS). FDA has a publicly available FAERS dashboard,[8] which states "[t]he intention of this tool is to expand access of FAERS data to the general public to search for information related to human adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers."

Based on the rationale set forth in the IFR, DEA adopts the IFR, without change.

Requirements for Handling Zuranolone

As indicated above, zuranolone has been a schedule IV controlled substance by virtue of an IFR issued by DEA in October 2023. Thus, this final rule does not alter the regulatory requirements applicable to handlers of zuranolone that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Zuranolone is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distributing, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) zuranolone 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. These registration requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

2. *Disposal of Stocks.* Any person unwilling or unable to obtain a schedule IV registration must surrender all quantities of currently held zuranolone, or may transfer all quantities of currently held zuranolone to a person registered with DEA. Zuranolone is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Zuranolone is subject to schedule III–V security requirements for DEA registrants and must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling zuranolone must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels and packaging for commercial containers of zuranolone must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Since October 31, 2023, every DEA registrant who possesses any quantity of zuranolone must have an initial inventory of all stocks of controlled substances (including zuranolone) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who registers with DEA to handle zuranolone must take an initial inventory of all stocks of controlled substances (including zuranolone) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take inventory of all controlled substances (including zuranolone) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for zuranolone, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and in accordance with 21 CFR 1301.74(b) and

[4] NFLIS-Drug 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 percent of an estimated 1 million distinct annual state and local drug analysis cases. NFLIS includes drug chemistry results only from completed analyses. Although NFLIS-Drug data are not direct evidence of abuse, they can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV*, 76 FR 77330, 77332 (Dec. 12, 2011).

[5] *https://www.fda.gov/drugs/surveillance/postmarketing-adverse-event-reporting-compliance-program.*

[6] *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/217369Orig2s000Corrected_ltr.pdf.*

[7] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.*

[8] *https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.*

(c), and 1301.76(b), and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for zuranolone, or products containing zuranolone, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of zuranolone may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act (FDCA), as applicable, and the CSA.

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

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

Regulatory Analyses

Administrative Procedure Act

This final rule, without change, affirms the IFR that is already in effect. Section 553 of the APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA, and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. Additionally, subsection 811(j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause. DEA issued an IFR on October 31, 2023, and solicited public comments on that rule. Subsection (j) further provides that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). As stated above, DEA received one comment and no requests for a hearing or waiver of a hearing. DEA is now issuing the final rule in accordance with subsection (j).

Executive Orders 12866, 13563, and 14094, Regulatory Review

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule 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 rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521.

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. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this final rule.

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 proposed 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 rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 6, 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**.

List of Subjects in 21 CFR Part 1308

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ Accordingly, the interim rule amending 21 CFR part 1308, published October 31, 2023, at 88 FR 74347, is adopted as a final rule without change.

Heather Achbach,

Federal Register Liaison Officer Drug Enforcement Administration.

[FR Doc. 2024–18087 Filed 8–13–24; 8:45 am]

BILLING CODE 4410–09–P

Country	Entity	License requirement	License review policy	Federal Register citation
	R2, Sharjah Airport Free Zone Street, Office 806, Sharjah, United Arab Emirates; *and* PO Box 120683, Saif-Zone, Sharjah, United Arab Emirates; *and* . SM-Office E1–1414D, Ajman Free Zone, Ajman, United Arab Emirates.			

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2023–26935 Filed 12–5–23; 11:15 am]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

Federal Old-Age, Survivors and Disability Insurance (1950–)

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 20 of the Code of Federal Regulations, Parts 400 to 499, revised as of April 1, 2023, in Appendix I to Subpart P of Part 404, in Part B, section 101.00, revise the first sentence of paragraph C.7.c. to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part B

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101.00 Musculoskeletal Disorders.

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C. * * *

7. * * *

c. For 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. * * *

[FR Doc. 2023–26983 Filed 12–6–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1036]

Schedules of Controlled Substances: Placement of Nine Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places nine fentanyl-related substances, as identified in this final rule, 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. These nine fentanyl-related substances are currently listed in schedule I pursuant to a temporary scheduling order. This action makes permanent the imposition of the 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, conduct instructional activities or chemical analysis with, or possess), or propose to handle these nine specific fentanyl-related controlled substances.

DATES: *Effective date:* December 7, 2023.

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: In this rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following nine controlled 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 (CSA):

- *meta*-fluorofentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide),
- *meta*-fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide),
- *para*-methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),
- 3-furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide),
- 2′,5′-dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide),
- isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide),
- *ortho*-fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),
- *alpha*′-methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide), and
- *para*-methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide).

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);[1] or (3) on the petition of any interested party.[2] This action was initiated on the Attorney General's own motion, as delegated to the Administrator of the DEA (Administrator), and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of HHS

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. 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.

[2] 21 U.S.C. 811(a).

(Assistant Secretary) and an evaluation of all relevant data by DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl.

Background

On February 6, 2018, DEA published an order in the **Federal Register** (FR) (83 FR 5188) amending 21 CFR 1308.11(h), temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety and pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The nine substances named in this final rule meet the existing definition of fentanyl-related substances, as they are not otherwise controlled in any other schedule (i.e., not included under another DEA Controlled Substance Code Number) and are structurally related to fentanyl by one or more of the five modifications listed under the definition. That temporary scheduling order was effective on the date of publication and was based on findings by the former Acting Administrator that the temporary scheduling of these substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as these nine specific substances already covered by that order, was set to expire on February 6, 2020. However, on February 6, 2020, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103). This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024.

Comment: One commenter stated that fentanyl and the list of related substances is a hazard due to the overdose deaths that have been occurring. This commenter also referenced the National Institute on Drug Abuse, stating that fentanyl-related overdoses have been increasing in the United States. Lastly, this commenter stated that permanently placing fentanyl and the list of related substances in schedule I would improve public health and allow for regulation of these substances.

DEA Response: DEA appreciates the comments in support of this rulemaking. One clarification to note is that fentanyl remains a schedule II substance. This final rule only applies to the fentanyl-related substances that are listed in this final order.

Comment: One commenter stated the proposed rule would make it more difficult to produce and distribute these dangerous fentanyl-related substances, which would help combat the opioid epidemic in the United States. This commenter also referenced a news article by National Public Radio, stating that these nine fentanyl-related substances are not currently classified as controlled substances, making it easy to produce and distribute these substances without legal consequences. Lastly, this commenter recognized that this proposal could have significant impacts on the healthcare industry, such as increased oversight and regulation of fentanyl-related substances, which could prevent their misuse and abuse.

DEA Response: DEA appreciates the comments in support of this rulemaking. One clarification to note based on the comment above is that, by temporary order on February 6, 2018, DEA placed these nine fentanyl-related substances under schedule I. 83 FR 5188. That temporary order defined a fentanyl-related substance to mean any substance not otherwise controlled in any schedule (*i.e.*, not listed under another DEA Controlled Substance Code Number), and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), that is structurally related to fentanyl by one or more of five specified structural modifications. Therefore, these nine fentanyl-related substances are in fact already schedule I controlled substances.

The final rule being issued today applies to nine fentanyl-related substances that were the subject of a February 6, 2018, temporary scheduling order. These nine substances will now be listed in 21 CFR 1308.11(b), as specified in the text of the rule that appears below. This final rule should not have a significant impact on the healthcare industry because these nine fentanyl-related substances have no medical use and they have already been added as schedule I controlled substances since 2018.

Comment: One commenter discussed the direct and indirect effects on federal and state healthcare from this regulation. The commenter suggested that this regulation will boost federal oversight of manufacturing and disseminating harmful chemicals. In addition, this regulation would limit availability and expected use, ensure protection of residents, and increases confidence in the medical field. In addition, the commenter stated that is critical to restrict the use of "fentanyl replicates" to those who may need them for medical conditions. Lastly, the commenter stated that raising awareness of the risks of abusing these drugs benefits their prevention.

DEA Response: DEA appreciates the comments in support of this rulemaking. As mentioned previously, FDA has not approved a marketing application for a drug product containing any of these nine substances for any therapeutic indication. These substances have no medical use in the United States.

Comment: One commenter stated that this rule will affect federal healthcare because many federal agencies are trying to tackle the opioid crisis. The commenter discussed the rising number of pediatric deaths from fentanyl in 2021 and the surge in 2018 of fentanyl overdoses among older adolescents as well as in children younger than five. The commenter agrees with this final rule to schedule these fentanyl-related substances. The commenter also stated that fentanyl is highly addictive and that while fentanyl is prescribed for chronic pain or major surgery, it should be a last resort.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Comment: One commenter agreed with this final rule to make permanent these nine specific fentanyl-related substances rather than continuing multiple temporary extensions. Once finalized, the commenter stated that the federal government could act against anyone handling these substances since over 150 people die each day from a fentanyl-related drug overdose.

DEA Response: DEA appreciates the comments in support of this rulemaking. Again, DEA notes that fentanyl is a schedule II controlled substance that can be prescribed for approved medical uses. However, the nine fentanyl-related substances addressed in this rule are already

schedule I controlled substances and none of them have any medical use in the United States.

Comment: One commenter stated that fentanyl should be placed in schedule I. The commenter compared this substance to marijuana, which is a schedule I drug and thought it was mind-blowing that fentanyl was not a schedule I substance. It was suggested that the rising number of deaths, the risk to public health, abuse potential, and dependency should classify fentanyl as a schedule I.

DEA Response: DEA appreciates this comment. As stated previously, fentanyl remains a schedule II substance. Fentanyl has approved medical uses in the United States. This final rule only applies to the fentanyl-related substances that are listed in this final order.

Scheduling Conclusion

After consideration of the relevant matter presented through public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl. DEA is permanently scheduling these nine fentanyl-related substances as schedule I controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also specifies the findings required to place a drug or other substance in any particular schedule.[3] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds the following:

(1) The abuse potential of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl is associated with each substance's pharmacological similarity to other schedule I and II mu-opioid receptor agonist substances which have a high potential for abuse. Similar to morphine (schedule II), fentanyl (schedule II), and several schedule I opioid substances that are structurally related to fentanyl, these nine fentanyl-related substances have been shown to bind and act as mu-opioid receptor agonists;

(2) *meta*-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, have no currently accepted medical use in treatment in the United States;[4] and

(3) There is a lack of accepted safety for use of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl under medical supervision.

Based on these findings, the Administrator concludes that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, 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, warrant control in schedule I of the CSA.[5]

This final rule does not affect the scheduling of fentanyl itself, which remains a schedule II controlled substance.

Requirements for Handling Meta-Fluorofentanyl, Meta-Fluoroisobutyryl Fentanyl, Para-Methoxyfuranyl Fentanyl, 3-Furanyl Fentanyl, 2′,5′-Dimethoxyfentanyl, Isovaleryl Fentanyl, Ortho-Fluorofuranyl Fentanyl, Alpha′-Methyl Butyryl Fentanyl, and Para-Methylcyclopropyl Fentanyl

Meta-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl will continue, on a permanent basis,[6] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, or who desires to handle these nine substances, is required to 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.* *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-

[3] 21 U.S.C. 812(b).

[4] Although there is no evidence suggesting that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, 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.

57 FR 10499 (1992).

[5] 21 U.S.C. 812(b)(1).

[6] *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and/or *para*-methylcyclopropyl fentanyl have been subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h), by virtue of the February 6, 2018 temporary scheduling order (83 FR 5188) and the subsequent statutory extension of that order through December 31, 2024 (Pub. L. 117–328, Division O, Title VI, Sec. 601).

dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl 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.* *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl 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 CFR 1301.71–1301.76. Non-practitioners handling these nine substances must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels and labeling for commercial containers of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, must be in compliance with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1301.74(b) and (c), 1301.76(b), 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding these substances to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must continue to comply with the 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 *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders (E.O.) 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), 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 *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2',5'-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha'*-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are already listed as a 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the states, on the relationship between the National Government and the states, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this final rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small

entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have already established and implemented the systems and processes required to handle these substances.

As discussed in the NPRM, there are 108 registrations authorized to handle one or more of the following substances: *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 108 registrations represent a maximum of 95 small entities. Therefore, DEA conservatively estimates as many as 95 small entities are affected by this rule.

A review of the 108 registrations indicates that all entities that currently handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, also handle other schedule I controlled substances and have established and implemented (or maintain) the systems and processes required to handle these substances. Therefore, DEA anticipates that this final rule will impose minimal or no economic impact on any affected entities, and, thus, will not have a significant economic impact on any of the small entities. Therefore, DEA has concluded that this final rule will not have a significant economic impact on a substantial number of small entities.

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 million 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.

Paperwork Reduction Act of 1995

This final rule does not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. Also, this final rule does not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this final rule 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.

Congressional Review Act

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

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of nine substances that has already been in effect. These nine substances all fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order (83 FR 5188). Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024.[7] The February 2018 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of the fentanyl-related substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Because this rule finalizes the control status of nine substances that has already been in effect, it does not alter the legal obligations of any person who handles these substances. Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, since this rule does not change the current scheduling status and corresponding legal obligations, DEA is making the rule effective on the date of publication in the **Federal Register**, as any delay in the effective date is unnecessary and would be contrary to the public interest.

[7] Public Law 117–328, Division O, Title VI, Sec. 601.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 29, 2023, 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.

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, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(10) through (94) to read as follows:

Old paragraph	New paragraph
(b)(10) through (33)	(b)(11) through (34).
(b)(34) through (43)	(b)(36) through (45).
(b)(44) through (47)	(b)(47) through (50).
(b)(48) through (50)	(b)(52) through (54).
(b)(51) through (66)	(b)(57) through (72).
(b)(67) through (74)	(b)(74) through (81).
(b)(75) through (94)	(b)(84) through (103).

■ b. Add new paragraphs (b)(10), (35), (46), (51), (55), (56), (73), (82), and (83); The additions to read as follows:

§ 1308.11 Schedule I. (b) * * *

* * * * *

(10) *alpha'*-Methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide)	9864
(35) 2',5'-Dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide)	9861
(46) 3-Furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide)	9860
(51) Isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide)	9862
(55) *meta*-Fluorofentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide)	9857
(56) *meta*-Fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide)	9858
(73) *ortho*-Fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)	9863
(82) *para*-Methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide	9859
(83) *para*-Methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide)	9865

* * * * *

[FR Doc. 2023–26694 Filed 12–6–23; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 42

[Public Notice: 12224]

RIN 1400–AE83

Immigrant Visas

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State ("Department") is amending its regulation governing immigrant visas by removing the section which allows a consular officer to conduct an informal evaluation of the family members of an immigrant visa applicant to identify potential grounds of ineligibility. The existing regulation was promulgated in 1952, at a time when a consular officer could more readily assess a family member's potential qualification for a visa without a formal visa application. Assessing eligibility for an immigrant visa is now a more complex task and not one which can be accomplished accurately with an informal evaluation.

DATES: This final rule is effective on January 8, 2024.

FOR FURTHER INFORMATION CONTACT: Claire Kelly, Office of Visa Services, Bureau of Consular Affairs, Department of State; telephone (202) 485–7586, *VisaRegs@state.gov.*

SUPPLEMENTARY INFORMATION: The Department published a notice of proposed rulemaking, Public Notice 11604 at 88 FR 16384 (Mar. 17, 2023) (hereafter "proposed rule"), with a request for comments, proposing to amend Part 42 of Title 22 of the Code of Federal Regulations. The rule will eliminate 22 CFR 42.68 in its entirety. The regulatory amendment was discussed in detail in the proposed rule, and that discussion is adopted by reference in this final rule. The Department received two responsive comments, both in support of eliminating 22 CFR 42.68. The Department is now promulgating a final rule with no changes from the proposed rule. This rule results in no change for applicants, as the authority granted by 22 CFR 42.68 was no longer used by consular officers.[1]

Analysis of Comments

The proposed rule was published in the **Federal Register** on March 17, 2023. The comment period closed May 16, 2023. The Department received two responsive comments, both in favor of the proposed elimination of 22 CFR 42.68, and one non-responsive comment.

One of the two responsive comments advocated for replacing 22 CFR 42.68 with "supportive and accessible eligibility screenings for noncitizens seeking visas," while the other comment only expressed its support for the proposed elimination. The Department has considered these comments. Considering the complexity required to evaluate a noncitizen's eligibility for a visa, and limited resources to reliably assess eligibility absent a visa application, the Department is unable to offer any eligibility screenings. Noncitizens who wish to receive a nonimmigrant or immigrant visa must formally apply for a visa to allow a consular officer to assess their eligibility for the visa.

[1] *See* the proposed rule for further discussion.

Regulatory Findings

A. Administrative Procedure Act

As this rule involves amending visa policy, which is a foreign affairs function of the United States, it is exempt from both the delayed effective date and notice and comment requirements of 5 U.S.C. 553 per subsection (a)(1). Notwithstanding the applicability of the foreign affairs exception to this rule, the Department, for its own benefit, sought public comment on the proposed elimination of 22 CFR 42.68. *See, e.g., Hoctor* v. *U.S. Dep't of Agric.*, 82 F.3d 165, 171–72 (7th Cir. 1996) (observing that there is nothing in the APA that forbids an agency's use of notice-and-comment procedures even if not required under the APA, and that courts should attach no weight to an agency's varied approaches involving similar rules). Though this rule is not subject to 5 U.S.C. 553(d), the Department is also choosing to delay the effective date of this rule for 30 days.

B. Regulatory Flexibility Act

As this rulemaking is not required to be published for notice and comment under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory

ASO AL D Fort Novosel (Ozark), AL [Amended]

Cairns Army Air Field (Fort Novosel), AL
(Lat. 31°16'33" N, long. 85°42'48" W)

That airspace extending upward from the surface to and including 2,800 feet MSL within a 5-mile radius of lat. 31°18'30" N, long. 85°42'20" W. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

ASO GA D Columbus, GA [Amended]

Columbus Airport, GA
(Lat. 32°30'59" N, long. 84°56'20" W)
Lawson AAF (Fort Moore)
(Lat. 32°19'54" N, long. 84°59'14" W)

That airspace extending upward from the surface to and including 2,900 feet MSL within a 4.4-mile radius of the Columbus Airport, and that airspace extending upward from the surface to and including 2,700 feet MSL within a 5.2-mile radius of Lawson Army Airfield (Ft. Moore) and that airspace within 1 mile each side of the 145° bearing from the AAF extending from the 5.2-mile radius to 6.8 miles southeast of the AAF. This Class D airspace is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6002 Class E Surface Airspace.

* * * * *

ASO AL E2 Fort Novosel (Ozark), AL [Amended]

Columbus Airport, GA
(Lat. 32°30'59" N, long. 84°56'20" W)
Lawson AAF (Fort Moore)
(Lat. 32°19'54" N, long. 84°59'14" W)

That airspace extending upward from the surface to and including 2,900 feet MSL within a 4.4-mile radius of the Columbus Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

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

* * * * *

ASO MS E5 Columbus, MS [Amended]

Columbus AFB, MS
(Lat. 33°38'43" N, long. 88°26'45" W)
Monroe County Airport
(Lat. 33°52'26" N, long. 88°29'23" W)
Columbus-Lowndes County Airport
(Lat. 33°27'55" N, long. 88°22'51" W)
Golden Triangle Regional Airport
(Lat. 33°26'54" N, long. 88°35'29" W)
Oktibbeha Airport
(Lat. 33°29'52" N, long. 88°4'53" W)
McCharen Field
(Lat. 33°35'03" N, long. 88°40'00" W)

That airspace extending upward from 700 feet above the surface within a 10-mile radius of Columbus AFB, a 16-mile radius of Monroe County Airport, and within a 6.4-mile radius of Columbus-Lowndes County Airport, and within a 6.6-mile radius of Golden Triangle Regional Airport, and within a 6.2-mile radius of Oktibbeha Airport, and a 6.3-mile radius of McCharen Field.

* * * * *

Issued in College Park, Georgia, on December 6, 2023.

Andreese C. Davis,

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

[FR Doc. 2023–27195 Filed 12–11–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1006]

Schedules of Controlled Substances: Temporary Placement of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule six synthetic cannabinoids and their optical and geometric isomers, salts, and salts of isomers, whenever the existence of such isomers and salts is possible, in schedule I under the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these six substances in schedule I is necessary to avoid 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 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 these six specified controlled substances.

DATES: This temporary scheduling order is effective December 12, 2023, until December 12, 2025. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., 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 Drug Enforcement Administration (DEA) issues a temporary scheduling order [1] (in the form of a temporary amendment) to add the following six substances, including their optical and geometric isomers, salts, and salts of isomers, whenever the existence of such isomers and salts is possible, to schedule I under the Controlled Substances Act (CSA):

- Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate (Other name: MDMB–4en–PINACA),
- Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (Other names: 4F–MDMB–BUTICA; 4F–MDMB–BICA),
- *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide (Other name: ADB–4en–PINACA),
- 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (Other name: CUMYL–PEGACLONE; SGT–151),
- Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (Other names: 5F–EDMB–PICA; 5F–EDMB–2201), and
- Methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate (Other name: MMB–FUBICA).

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 the Administrator finds that such action is necessary to avoid an imminent hazard to the public safety.[2] In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Administrator may extend the temporary scheduling for up to one year.[3]

[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this order 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] 21 U.S.C. 811(h)(1).

[3] 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 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355.[4]

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to place a substance in schedule I of the CSA temporarily (*i.e.*, to issue a temporary scheduling order).[5] The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[6] by letter dated January 24, 2022, regarding MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA. The Assistant Secretary responded to this notice by letter dated March 7, 2022, and advised that, based on a review by the Food and Drug Administration (FDA), there are currently no approved new drug applications or investigational new drug applications for MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA. The Assistant Secretary also stated that HHS has no objection to the temporary placement of these substances in schedule I of the CSA.

DEA has taken into consideration the Assistant Secretary's comments as required by subsection 811(h)(4). DEA has found that the control of these six synthetic cannabinoids (SCs) in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety. MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA 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 six substances.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent (NOI) to temporarily schedule MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA on April 4, 2023.[7] That NOI discussed findings from DEA's three-factor analysis dated April 2023, which DEA made available on *www.regulations.gov*.

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. Consideration of these factors includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances.[8]

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

The DEA's three-factor analysis and the Assistant Secretary's March 7, 2022, letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at *www.regulations.gov*.

Synthetic Cannabinoids

Synthetic cannabinoids (SCs) are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC, schedule I), the main psychoactive ingredient in marijuana (schedule I). SCs were introduced to the designer drug market in several European countries as "herbal incense" before the initial encounter in the United States by the U.S. Customs and Border Protection (CBP) in November 2008. From 2009, abuse of SCs has escalated in the United States as evidenced by large numbers of law enforcement encounters of SCs applied onto plant material and in other designer drug products intended for human consumption.[11] Recent hospital reports, scientific publications, and/or law enforcement reports demonstrate that MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA, and their associated designer drug products, are being abused for their psychoactive properties (see Factors 5 and 6 in DEA's three-factor analysis). As with many generations of SCs encountered since 2009, the abuse of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA is negatively impacting communities in the United States.

As noted by DEA and CBP, SCs originate from foreign sources, such as China. Substances in bulk powder form are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. According to online discussion boards and law enforcement encounters, spraying or mixing the SCs with plant material provides a vehicle for the most common route of administration—smoking (using a pipe, a water pipe, or rolling the drug-laced plant material in cigarette papers).

MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA have no accepted medical use in treatment in the United States.[12] Emergency department presentations involving MDMB–4en–PINACA or CUMYL–PEGACLONE have included seizures, sudden collapse, involuntary muscle spasms, jerking movements, catatonia, and increased violence. Multiple deaths have been reported involving MDMB–4en–PINACA, 4F–MDMB–BUTICA, and CUMYL–PEGACLONE. In addition, all six SCs have been seized by law enforcement in the United States. Use of other schedule I SCs (*e.g.*, JWH–018, AB–FUBINACA) has resulted in signs of addiction and withdrawal. Based on the pharmacological similarities between MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA and other schedule I SCs (*e.g.*, JWH–018, AB–FUBINACA), these six SCs are likely to produce signs of addiction and withdrawal similar to

[4] 21 U.S.C. 811(h)(1); 21 CFR part 1308.

[5] 21 U.S.C. 811(h)(4).

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

[7] 88 FR 19896.

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

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

[10] 21 U.S.C. 812(b)(1).

[11] 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.

[12] Although there is no evidence suggesting that MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, 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. 57 FR 10499, Mar. 26, 1992, pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

those produced by other schedule I SCs (*e.g.*, JWH–018, AB–FUBINACA).

MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA are SCs that have pharmacological effects similar to the schedule I hallucinogen THC and other temporarily and permanently controlled schedule I SCs. With no approved medical use and limited safety or toxicological information, MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA have emerged in the designer drug market, and the abuse of these substances for their psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

SCs have been developed by researchers over the last 30 years as tools for investigating the endocannabinoid system (*e.g.*, determining CB1 and CB2 receptor activity). The first encounter of SCs intended for illicit use within the United States occurred in November 2008 by CBP. Since then, the popularity of SCs as product adulterants and objects of abuse has increased as evidenced by law enforcement seizures, public health information, and media reports.

Research and clinical reports have demonstrated that SCs are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and psychoactive "high," believed to be similar to marijuana. The adulterated products are marketed as "legal" alternatives to marijuana.

The designer drug products laced with SCs, including MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA, are often sold under the guise of "herbal incense" or "potpourri," using various product names, and are routinely labeled "not for human consumption." Additionally, these products are marketed as a "legal high" or "legal alternative to marijuana" and are readily available over the internet, in head shops, or sold in convenience stores. There are incorrect assumptions that these products are safe, that these are synthetic forms of marijuana, and that labeling these products as "not for human consumption" is a legal defense to criminal prosecution under the Controlled Substances Analogue Enforcement Act.

The powder form of SCs is typically dissolved in solvents (*e.g.*, acetone) before being applied to plant material, or dissolved in a propellant intended for use in electronic cigarette devices. Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more SCs are mixed together, or in large areas where the plant material is spread out so that a dissolved SC mixture can be applied directly. Once mixed, the SC plant material is then allowed to dry before manufacturers package the product for distribution, ignoring any quality control mechanisms to prevent contamination or to ensure a uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the drug during the manufacturing process. The failure to adhere to any manufacturing standards with regard to amounts, the substance(s) included, purity, or contamination may further increase the risk of adverse events. However, it is important to note that adherence to manufacturing standards would not eliminate their potential to produce adverse effects because the toxicity and safety profiles of these SCs have not been studied. MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA, similar to other schedule I SCs (*e.g.*, JWH–018, AB–FUBINACA), have been found in powder form or mixed with dried leaves or herbal blends that were marketed for human use.

Following their manufacture in China, SCs are often encountered in countries, including New Zealand, Australia, and Russia, before appearing throughout Europe and, eventually, in the United States. Law enforcement in the United States has encountered MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA, and has documented the abuse of these substances. SCs and their associated products are available over the internet and sold in gas stations, convenience stores, and tobacco and head shops. MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA, similar to the previously scheduled SCs, have been seized alone and/or laced on products that are marketed under the guise of "herbal incense" and promoted as a "legal" alternative to marijuana.

CUMYL–PEGACLONE was detailed in a patent published in 2014, was first reported as an adulterated plant material in Germany in December 2016, and appeared in the United States in September 2018. These data further support the trend that SCs often appear in the illicit drug markets of other countries, including those in Europe, before being reported in the United States. Law enforcement has seized CUMYL–PEGACLONE, and the substance's abuse has been associated with overdoses requiring emergency medical intervention. Adverse effects reported following the abuse of CUMYL–PEGACLONE have included seizures followed by collapse and deaths. CUMYL–PEGACLONE has also been encountered laced onto paper in attempts to be smuggled inside of prison facilities.

Users abuse SCs by smoking for the purpose of achieving intoxication, which has resulted in numerous emergency department visits and calls to poison centers. As reported by the American Association of Poison Control Centers (AAPCC), severe, life-threatening health effects, including severe agitation and anxiety, nausea, vomiting, seizures, and hallucinations, can occur following ingestion of SCs. The AAPCC has specifically noted that SCs are made specifically to be abused.[13] Emergency department presentations involving MDMB–4en–PINACA or CUMYL–PEGACLONE have included seizures, sudden collapse, involuntary muscle spasms, jerking movements, catatonia, or increased violence. Multiple deaths have been reported involving MDMB–4en–PINACA, 4F–MDMB–BUTICA, and CUMYL–PEGACLONE (see Factor 6 in DEA's three-factor analysis).

Factor 5. Scope, Duration, and Significance of Abuse

Novel SCs substances, differing only by small chemical structural modifications intended to avoid prosecution while maintaining the pharmacological effects, continue to be sold on the illicit drug market as evidence by law enforcement encounters of these substances. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products. The threat of serious injury to the individual and the imminent threat to public safety following the ingestion of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, MMB–FUBICA, and other SCs persist.

Additional information obtained through the National Forensic Laboratory Information System

[13] *https://aapcc.org/track/synthetic-cannabinoids.*

(NFLIS),[14] along with additional data, may be found in DEA's three-factor analysis. According to NFLIS data,[15] state and local forensic laboratories have detected the following information about the SCs in question:

- MDMB–4en–PINACA was identified in 9,566 NFLIS reports since 2019. In addition, MDMB–4en–PINACA was identified in five exhibits mixed with heroin and/or fentanyl and packaged for sale as suspected heroin.
- 4F–MDMB–BUTICA was identified in 385 NFLIS reports since 2020. 4F–MDMB–BUTICA was also identified in one exhibit in a pill form, mixed with methamphetamine and a synthetic cathinone known as eutylone.
- CUMYL–PEGACLONE was identified in two CBP drug seizures in 2018 and 2021, respectively.
- 5F–EDMB–PICA was identified in 106 NFLIS reports since 2020.
- MMB–FUBICA was identified in 397 NFLIS reports since 2016.

Factor 6. What, if Any, Risk There Is to the Public Health

Since first being identified in the United States in 2008, the ingestion of SCs continues to result in serious adverse effects. Details of these events involving MDMB–4en–PINACA and CUMYL–PEGACLONE are summarized below (for additional information and citations, see Factors 5 and 6 in DEA's three-factor analysis).

1. In October 2017 in France, two 16-year-old juveniles were given a cigarette laced with white powder by an unknown individual. Upon arrest of the dealer, he stated the powder was SGT–151. Both juveniles developed seizures followed by collapse. Toxicological analysis of both victim's blood and blood collected from the arrested dealer (who claimed to be a user of the same powder) confirmed the presence of CUMYL–PEGACLONE (SGT–151) and its metabolite, *N*-dealkyl CUMYL–PEGACLONE.

2. Between January and December 2017 in Germany, CUMYL–PEGACLONE was detected in 34 forensic serum/blood samples from fatal and non-fatal cases. Of these cases, six deaths were reported by the Institute of Forensic Medicine in Munich and the Institute of Forensic Medicine in Mainz, respectively. Details of the deaths demonstrated multiple factors in addition to SCs as possible causes of death.

3. Between July 1, 2018, and December 31, 2020, in Northern Australia, CUMYL–PEGACLONE was detected in five deaths. Concurrent alcohol use and underlying cardiovascular disease were considered relevant factors in most cases.

4. In September 2019, the Center for Forensic Science Research and Education released a report detailing the identification of MDMB–4en–PINACA in biological fluids per their toxicology department.

5. In February 2020, local law enforcement in Holyoke, Massachusetts, reported serious adverse effects following the abuse of the contents in glassine bags with suspected heroin. Analysis of contents in the bags confirmed the presence of MDMB–4en–PINACA. Per law enforcement witnesses to the overdoses, individuals were experiencing involuntary body/muscle spasms and movements that appeared similar to a seizure, although more violent. Victims were alert and conscious, and they appeared to be under the influence of some unknown narcotics at the time, with officers noting that what was observed was nothing like a typical heroin overdose. Victims described it like being under the influence of phencyclidine (schedule II substance) or something similar. In some cases, people were violent and emergency personnel were having a difficult time providing medical attention to these individuals. Emergency personnel also described very high heart rates and blood pressure. Some individuals were acting erratic and running in and out of traffic.

6. In March 2021, a forensic toxicology report from the Defense Health Agency reported the presence of ADB–BUTINACA, ADB–BUTINACA N-butanoic acid (a metabolite of ADB–BUTINACA), and MDMB–4en–PINACA 3,3-dimethylbutanoic acid (a metabolite of MDMB–4en–PINCA) in a submitted urine specimen.

7. MDMB–4en–PINACA and/or its metabolite were detected in 25 forensic investigation cases between August 2019 and March 2020. The first positive sample was collected in May 2019. The majority of cases (n = 16, 64%) were submitted from postmortem investigations, followed by eight cases from suspected clinical toxicology investigations, and one case from an impaired driving investigation.

Because they share pharmacological similarities with schedule I substances (Δ^9-THC, JWH–018, and other temporarily and permanently controlled schedule I SCs), MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA pose serious risks to an abuser. Tolerance to SCs may develop fairly rapidly with larger doses being required to achieve the desired effect. Acute and chronic abuse of SCs in general have been linked to adverse health effects including signs of addiction and withdrawal, numerous reports of emergency department admissions, and overall toxicity and deaths. Psychiatric case reports have been reported in the scientific literature detailing the SC abuse and associated psychoses (see Factor 6 in DEA's three-factor analysis). As abusers obtain these drugs through unknown sources, the identity and purity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users.

MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA are being encountered on the illicit drug market and have no accepted medical use in the United States. Regardless, these products continue to be easily available and abused by diverse populations.

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 with, possession, and/or abuse of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA pose an imminent hazard to the 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 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 MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA indicate that these substances 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.

[14] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories in the United States.

[15] At the time of query (March 16, 2022), 2021 and 2022 data were still reporting.

As required by 21 U.S.C. 811(h)(4), the Administrator transmitted to the Assistant Secretary for Health, via a letter dated January 24, 2022, notice of her intent to place MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA in schedule I on a temporary basis. HHS had no objection to the temporary placement of these substances in schedule I.

DEA subsequently published a NOI in the **Federal Register** on April 4, 2023.[16]

Conclusion

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 place MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA in schedule I of the CSA, and finds that placement of these substances in schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

This temporary order scheduling these substances will be effective on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process.[17]

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent 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.[18] The permanent 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.[19] Temporary scheduling orders are not subject to judicial review.[20]

Requirements for Handling

Upon the effective date of this temporary order, MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA 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 (possesses, manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with), or desires to handle, MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, or MMB–FUBICA must be registered with the 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 December 12, 2023. Any person who currently handles MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, or MMB–FUBICA, and is not registered with the DEA, must submit an application for registration and may not continue to handle MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA as of December 12, 2023, unless the 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 December 12, 2023 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 MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, or MMB–FUBICA must surrender all currently held quantities of these six substances.

3. *Security.* MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.93, as of December 12, 2023.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA must comply with 21 U.S.C. 825 and 958(e), and 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from December 12, 2023 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA 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 will 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 MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA) 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 MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, 1317 and section 1307.11. Current DEA registrants authorized to handle these six substances 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 must submit reports with respect to MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304, 1312, and 1317, and sections 1301.74(c) and 1301.76(b), as of December 12, 2023. Manufacturers and distributors must also submit reports regarding these six substances to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA must

[16] 88 FR 19896.

[17] 21 U.S.C. 811(h)(1) and (2).

[18] 21 U.S.C. 811.

[19] 21 U.S.C. 877.

[20] 21 U.S.C. 811(h)(6).

comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of December 12, 2023.

9. *Importation and Exportation.* All importation and exportation of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of December 12, 2023.

10. *Quota.* Only DEA registered manufacturers may manufacture MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303, as of December 12, 2023.

11. *Liability.* Any activity involving MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA not authorized by, or in violation of the CSA, occurring as of December 12, 2023, is unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

The CSA provides for expedited temporary scheduling actions where necessary to avoid imminent hazards to the public safety. Under 21 U.S.C. 811(h), the Administrator, as delegated by the Attorney General, may, by order, temporarily schedule 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]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order (as distinct from a rule) 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, which are applicable to rulemaking, do not apply to this temporary scheduling order. 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.*" [22] 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.

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

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

Signing Authority

This document of the Drug Enforcement Administration was signed on December 7, 2023, 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.

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, the 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 paragraphs (h)(62) to (h)(67) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

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

[22] 5 U.S.C. 551(6) (emphasis added).

[FR Doc. 2023–27243 Filed 12–11–23; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0949]

RIN 1625–AA00

Safety Zone; Kaneohe Bay, Oahu, HI—Navy P8 Aircraft Salvage Operations

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a 0.5 nautical mile radius temporary safety zone for navigable waters in Kaneohe Bay, HI encompassing the partially submerged Navy P8 aircraft. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by salvage operations of the Navy P8 aircraft. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Honolulu.

DATES: This rule is effective without actual notice from December 12, 2023 through December 10, 2023. For the purposes of enforcement, actual notice will be used from December 2, 2023. This rule will be enforced each day it is in effect from 7 a.m. to 6 p.m. December 12, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov*, type USCG–2023–0949 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Chief Petty Officer Bradley Lindsey, Waterways Management Division, U.S. Coast Guard Sector Honolulu; telephone 808–541–4363, *bradley.w.lindsey@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it would be impracticable and contrary to the public interest. The Coast Guard was unable to publish an NPRM and hold a reasonable comment period for this rulemaking due to the emergent nature and logistical coordination of salvage operations. It is impracticable to publish an NPRM because we must establish this safety zone by December 2, 2023.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to remove the existing threat to the environment and safeguard against future potential threat to the environment as well as safety hazards associated with emergency salvage operations of the Navy P8 aircraft.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Honolulu (COTP) has determined that potential hazards associated with emergency salvage operations starting December 2, 2023, will be a safety concern for anyone within a 0.5 nautical mile radius of the Navy P8 aircraft. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while salvage operations take place.

IV. Discussion of the Rule

This rule establishes a safety zone from 7 a.m. until 6 p.m. on December 2, 2023, through December 10, 2023. The Coast Guard is establishing a 0.5 nautical mile radius temporary safety zone for navigable waters in Kaneohe Bay, HI encompassing the partially submerged Navy P8 aircraft. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the aircraft is being salvaged. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a "significant regulatory action," under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review).

main deck except with regard to special condition (j) for smoke detection.

(r) When a crew rest compartment is installed or enclosed as a removable module in part of a cargo compartment or is located directly adjacent to a cargo compartment without an intervening cargo compartment wall, the following applies:

(1) Any wall of the module (container) forming part of the boundary of the reduced cargo compartment, subject to direct flame impingement from a fire in the cargo compartment and including any interface item between the module (container), and the airplane structure or systems, must meet the applicable requirements of § 25.855 at Amendment 25–60.

(2) Means must be provided so that the fire protection level of the cargo compartment meets the applicable requirements of §§ 25.855 at amendment 25–60, 25.857 at amendment 25–60 and 25.858 at amendment 25–54 when the module (container) is not installed.

(3) Use of each emergency evacuation route must not require occupants of the crew rest compartment to enter the cargo compartment in order to return to the passenger compartment.

(4) The aural warning in special condition (g) must sound in the crew rest compartment in the event of a fire in the cargo compartment.

(s) Means must be provided to prevent access into the Class C cargo compartment during all airplane operations and to ensure that the maintenance door is closed during all airplane flight operations.

(t) All enclosed stowage compartments within the crew rest that are not limited to stowage of emergency equipment or airplane-supplied equipment (*e.g.*, bedding) must meet the design criteria given in the table below. As indicated by the table below, this special condition does not address enclosed stowage compartments greater than 200 ft³ in interior volume. The in-flight accessibility of very large, enclosed stowage compartments and the subsequent impact on the crewmember's ability to effectively reach any part of the compartment with the contents of a hand fire extinguisher will require additional fire protection considerations similar to those required for inaccessible compartments such as Class C cargo compartments.

STOWAGE COMPARTMENT INTERIOR VOLUMES

Fire protection features	Less than 25 ft³	25 ft³ to 57 ft³	57 ft³ to 200 ft³
Materials of Construction [1]	Yes	Yes	Yes.
Detectors [2]	No	Yes	Yes.
Liner [3]	No	No	Yes.
Locating Device [4]	No	Yes	Yes.

[1] *Materials of Construction:* The material used to construct each enclosed stowage compartment must at least be fire resistant and must meet the flammability standards established for interior components per the requirements of § 25.853. For compartments less than 25 ft³ in interior volume, the design must ensure the ability to contain a fire likely to occur within the compartment under normal use.

[2] *Detectors:* Enclosed stowage compartments equal to or exceeding 25 ft³ in interior volume must be provided with a smoke or fire detection system to ensure that a fire can be detected within a one-minute detection time. Flight tests must be conducted to show compliance with this requirement. Each system (or systems) must provide:

(a) A visual indication in the flight deck within one minute after the start of a fire;

(b) An aural warning in the crew rest compartment; and

(c) A warning in the main passenger cabin. This warning must be readily detectable by a flight attendant, taking into consideration the positioning of flight attendants throughout the main passenger compartment during various phases of flight.

[3] *Liner:* If it can be shown that the material used to construct the stowage compartment meets the flammability requirements of a liner for a Class B cargo compartment, then no liner would be required for enclosed stowage compartments equal to or greater than 25 ft³ in interior volume but less than 57 ft³ in interior volume. For all enclosed stowage compartments equal to or greater than 57 ft³ in interior volume but less than or equal to 200 ft³, a liner must be provided that meets the requirements of § 25.855 at Amendment 25–60 for a class B cargo compartment.

[4] *Location Detector:* Crew rest areas which contain enclosed stowage compartments exceeding 25 ft³ interior volume and which are located away from one central location such as the entry to the crew rest area or a common area within the crew rest area would require additional fire protection features and/or devices to assist the firefighter in determining the location of a fire.

Issued in in Kansas City, Missouri, on December 8, 2023.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2023–27396 Filed 12–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA1156]

Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing two phenethylamine hallucinogens, as identified in this proposed rule, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances for one of these substances 2,5-dimethoxy-4-chloroamphetamine. 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 these two specific controlled substances.

DATES: Comments must be submitted electronically or postmarked on or before January 12, 2024.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.47 and/or 1316.49, as applicable. Requests for a

hearing, and waivers of an opportunity for a hearing or to participate in a hearing, must be received or postmarked on or before January 12, 2024.

To be considered by DEA as part of this rulemaking, comments and requests for a hearing must be submitted in response to this proposed rule within the timeframe specified above, regardless of whether the person previously submitted a comment or hearing request in response to the notice of proposed rulemaking that DEA published in the **Federal Register** on April 11, 2022 (87 FR 21069), and subsequently withdrew on August 29, 2022 (87 FR 52712), under docket number DEA824.

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. DEA1156" 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, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that 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.
- *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 FR 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 filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 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 and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: In this proposed rule, the Drug Enforcement Administration (DEA) proposes to schedule the following two controlled substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- 2,5-dimethoxy-4-iodoamphetamine (DOI) and
- 2,5-dimethoxy-4-chloroamphetamine (DOC).

This proposed rule supersedes the April 11, 2022 notice of proposed rulemaking (NPRM) that DEA published in the **Federal Register** (87 FR 21069), to place DOI and DOC in schedule I of the CSA, which DEA withdrew on August 29, 2022 (87 FR 52712) in order to provide additional clarity on the process for submitting hearing requests. The scientific, medical, and other bases for the proposed placement of DOI and DOC in schedule I remain the same in this proposed rule as they were described in the April 2022 proposed rule, except for minor updates to certain data.

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. 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 it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

DEA will generally make available in publicly redacted form comments containing personal identifying information and confidential business information identified, as directed above. If a comment has so much confidential business information that DEA cannot effectively redact it, DEA may not make available publicly all or part of that comment. Comments posted to *https://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as confidential as directed above.

An electronic copy of this document and supplemental information to this proposed rule are available at *https://www.regulations.gov* for easy reference.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person with regarding to the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing. 21 CFR 1316.49.

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**. 21 CFR 1308.44(b), 1316.53. Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, she will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether DOI and/or DOC meet the statutory criteria for placement in schedule I, as proposed in this rule.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on his own motion. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the then-Assistant Secretary for Health of the Department of Health and Human Services (HHS).

In addition, regarding the placement of DOC in the Controlled Substances Act (CSA), the United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of HHS (Secretary),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the CSA and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary did not consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of DEA), by rule, and upon the recommendation of the Secretary, may add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

DOI and DOC belong to the phenethylamine class of drugs with hallucinogenic properties, similar to 2,5-dimethoxy-4-methamphetamine (DOM), a schedule I hallucinogen. DOI and DOC have no approved medical use in the United States.

On September 26, 2018, DEA, in accordance with the provisions of 21 U.S.C. 811(b), requested HHS provide a scientific and medical evaluation as well as a scheduling recommendation for DOI and DOC. Additionally, on May 7, 2020, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 63rd Session in March 2020, voted to place DOC in Schedule I of the 1971 Convention (CND Dec/63/4). As a signatory to this international treaty, the United States is required, by scheduling under the CSA, to place appropriate controls on DOC to meet the minimum requirements of the treaty.

Article 2, paragraph 7(a), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule I of the 1971 Convention. The United States must adhere to specific export and import provisions that are provided in the 1971 Convention. This requirement is accomplished by the CSA with the export and import provisions established in 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312. Under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) In regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured, exported to and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule III and IV of the 1971 Convention, quantities manufactured, as well as quantities exported and imported; (3) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (4) in regard to each substance in Schedule II–IV of the 1971 Convention, quantities used for the manufacture of non-psychotropic substances or products. Lastly, under Article 2, paragraph 7(a)(vi) of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. The United States complies with this provision as persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action.

Proposed Determination To Schedule DOI and DOC

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on DOI and DOC and on September 26, 2018, submitted it to the then-Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for DOI and DOC. On September 28, 2020, HHS provided to DEA a scientific and medical evaluation entitled "Basis for the Recommendation to Control 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) and their Salts in Schedule I of the Controlled Substances Act (CSA)" and a scheduling recommendation. Following consideration of the eight factors and findings related to these substances' abuse potential, legitimate medical use,

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

and dependence liability, HHS recommended that DOI and DOC and their salts be controlled in schedule I of the CSA under 21 U.S.C. 812(b). In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS and all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c).

After a review of the available data, including the scientific and medical evaluation and scheduling recommendation provided by HHS, the Administrator published an NPRM in the **Federal Register** on April 11, 2022 (87 FR 21069), to place DOI and DOC in schedule I of the CSA. DEA withdrew that proposed rule on August 29, 2022 (87 FR 52712). This proposed rule supersedes the April 2022 proposed rule, to provide additional clarity on the process for submitting hearing requests. The bases for the proposed placement of DOI and DOC in schedule I remain the same in this proposed rule as they were described in the April 2022 proposed rule.

Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in the April 2022 proposed rule and in this proposed scheduling determination. Please note that both DEA and HHS analyses are available in their entirety under "Supporting Documents" of the public docket for this proposed rule at *https://www.regulations.gov* under docket number "DEA1156."

1. The Drug's Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation document for DOI and DOC, DEA also considered all other relevant data regarding actual or relative potential for abuse of DOI and DOC. The term "abuse" is not defined in the CSA; however, the legislative history of the CSA suggests the following four prongs in determining whether a particular drug or substance has a potential for abuse: [3]

a. Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

b. There is a significant diversion of the drug or other substance from legitimate drug channels; or

c. Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or

d. The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

DEA reviewed the scientific and medical evaluation provided by HHS and all other data relevant to the abuse potential of DOI and DOC. These data as presented below demonstrate that DOI and DOC have a high potential for abuse.

a. There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

Data show that DOI and DOC have been encountered by law enforcement in the United States (see Factor 5), indicating DOI and DOC availability for abuse. According to HHS, individuals are using DOI and DOC for their hallucinogenic effects and taking them in amounts sufficient to create a hazard to their health.

b. There is significant diversion of the drug or substance from legitimate drug channels.

HHS states that DOI and DOC are not Food and Drug Administration (FDA)-approved drugs for treatment in the United States and is unaware of any country in which their use is legal. DOI and DOC are available for purchase from legitimate chemical synthesis companies because they are used in scientific research. There is no evidence of diversion from these companies.

c. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substance.

DOI and DOC are not found in FDA-approved drug products and practitioners may neither legally prescribe nor dispense these substances. Therefore, individuals are taking DOI and DOC on their own initiative, rather than based on medical advice from practitioners licensed by law to administer drugs. This is consistent with the data from law enforcement seizures and case reports indicating that individuals are taking DOI and DOC on their own initiative rather than on the medical advice of licensed practitioners.

d. The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Chemically, DOI and DOC are analogs of the schedule I hallucinogen DOM. The effects and pharmacological action of DOI and DOC are similar to those of other schedule I hallucinogens, such as DOM and lysergic acid diethylamide (LSD), which have no accepted medical use and a high abuse potential.

In drug discrimination studies (an *in vivo* test to assess drug abuse liability of test drugs in comparison to known drugs of abuse), DOI and DOC produce full substitution for the discriminative stimulus effects of DOM, LSD, and *N,N*-dimethyltryptamine (DMT, schedule I). In humans, anecdotal reports suggest that DOI and DOC produce classic hallucinogenic effects that are similar to DOM, including visual and auditory hallucinations, fatigue, headache, gastrointestinal distress, insomnia and anxiety. HHS notes that use of DOC in combination with other drugs is associated with emergency department admissions and one death.

Due to the psychological and cognitive disturbances associated with DOI and DOC, as with other schedule I hallucinogens, it is reasonable to assume that DOI and DOC have substantial capability to be a hazard to the health of the user and to the safety of the community.

2. Scientific Evidence of the Drug's Pharmacological Effects, If Known

In vitro testing shows that DOI and DOC bind to and act as agonists at serotonin (5–HT) 2A (5–HT_{2A}) receptors. In rats, DOI administration induced an increase in wet dog shakes and back muscle contractions. These effects were attributed to 5–HT_{2A} receptor activation, since pretreatment with a 5–HT_{2A} receptor inverse agonist blocked the effect. Agonism of the 5–HT_{2A} receptor is the primary mechanism of action of typical hallucinogenic responses, suggesting that DOI and DOC have hallucinogenic effects. Additionally, animal testing data in rats show that DOI and DOC fully substitute for DOM, LSD, and DMT discriminative stimulus effects in drug discrimination tests.

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., 2nd Sess. (1970) reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

In humans, HHS reported that anecdotal reports of hallucinogenic experiences with DOI and DOC are available on online drug forums such as *www.erowid.org,* in which recreational drug users report on their experiences with all classes of substances. In these reports, DOI and DOC are reported to induce hallucinogenic effects, including prominent visual effects.

Additionally, a World Health Organization (WHO) critical review of DOC[4] mentions its hallucinogenic effects reported by those that self-experimented with DOC and notes the duration of action may last 12 to 24 hours. WHO notes that the long duration of effects is shared by other structurally related schedule I hallucinogens including DOI, 2,5-dimethoxy-4-bromoamphetamine (DOB), and DOM. DOI and DOC are commonly administered orally and/or sublingually when encountered in the form of blotters.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

DOI and DOC are centrally-acting hallucinogens and part of the phenethylamine hallucinogen family and share structural similarities with schedule I phenethylamine hallucinogens such as DOM. DOI (CAS 42203–78–1) has a molecular formula of $C_{11}H_{16}INO_2$ and a molecular weight of 321.16 g/mol. The hydrochloride salt of DOI has a melting point of 201 °C. DOC (CAS 123431–31–2) has a molecular formula of $C_{11}H_{16}ClNO_2$ and a molecular weight of 229.70 g/mol. The hydrochloride salt of DOC has a melting point of 193–194.5 °C. DOI and DOC are white, odorless, and crystalline solids.

4. Its History and Current Pattern of Abuse

The history and current pattern of abuse of DOI and DOC are described in law enforcement reports and anecdotal reports by drug abusers. In the United States, law enforcement entities initially encountered DOI and DOC in 2005, according to the National Forensic Laboratory Information System (NFLIS)-Drug[5] database. See Factor 5 for additional information. DOI and DOC are encountered in various forms (*e.g.,* powder, tablets, capsules, liquid, or on blotter paper).

Anecdotal reports on the internet indicate that individuals are using substances they identified as DOI and DOC for their hallucinogenic effects. Importantly, it is impossible to know if the street drugs sold to an individual as DOI or DOC are actually the substances they are marketed as in the absence of chemical analysis or evaluation of biological fluids following ingestion. However, in animal drug discrimination studies, DOI and DOC produced effects that are similar to the effects elicited by schedule I hallucinogens such as DOM, LSD, and DMT.

Regarding DOC, a July 2019 report from the European Monitoring Centre for Drugs and Drug Addiction included data from their toxicology portal, and indicated that 16 non-fatal intoxications associated with DOC had been reported internationally between 2008 and 2017. In 2019, the United Nations Office on Drugs and Crime reported three deaths associated with DOC (one each in 2015 and 2018; information about the third is unknown).

5. The Scope, Duration, and Significance of Abuse

Data from NFLIS-Drug indicate that DOI and DOC were found in samples starting in 2005, in the United States. Specifically, there were 40 NFLIS-Drug reports for DOI from 2005 through December 2022, and 790 NFLIS-Drug reports for DOC during the same period. DOI has been encountered in 15 states, whereas DOC has been encountered in 39 states. In response to abuse and safety concerns, DOI has been controlled in Florida.

Abuse of DOI and DOC has been characterized as causing acute public health and safety issues worldwide. In particular, WHO reports that DOC has been available in Europe since 2001. Based on available abuse data, public health risk, and drug trafficking data, the WHO recommended to the United Nations (UN) that DOC be controlled internationally. In March 2020, the UN Commission on Narcotic Drugs voted to place DOC into Schedule I of the 1971 Convention.

6. What, if Any, Risk There Is to the Public Health

DOI and DOC share similar mechanisms of action with and produce similar physiological and subjective effects (see Factor 2 for more information) as other schedule I hallucinogens, such as DOM, DMT, and LSD. Thus, DOI and DOC pose the same risks to public health as similar hallucinogens. Predominantly, the risks to public health are borne by users (*i.e.,* hallucinogenic effects, sensory distortion, impaired judgment, strange or dangerous behaviors), but they can affect the general public, as with driving under the influence. To date, there are no reports of distressing responses or death associated with DOI in medical literature. There have been three published reports, in 2008, 2014, and 2015, of adverse events associated with DOC including, but not limited to, seizures, agitation, tachycardia, hypertension, and death of one individual. Since DOI is structurally similar to DOC and produces similar effects to DOC, it is likely to produce serious adverse effects similar to DOC. Thus, serious adverse events that may include death represent a risk to the individual drug users and to public health.

7. Its Psychic or Physiological Dependence Liability

According to HHS, the physiological dependence liability of DOI and DOC in animals and humans is not reported in scientific and medical literature. Thus, it is not possible to determine whether DOI and DOC produce physiological dependence following acute or chronic administration.

According to HHS, DOI, DOC, and other related phenethylamine hallucinogens (such as the schedule I substance DOM) are highly abusable substances. Drug discrimination studies in animals indicate that DOI and DOC fully substitute to the discriminative stimulus effects of schedule I hallucinogens DOM, LSD, and DMT. HHS notes that hallucinogens are not usually associated with physical dependence, likely due to the rapid development of tolerance precluding daily administration. Hallucinogen abusers may develop psychological dependence as evidenced by the continued use of these substances despite knowledge of their potential toxic and adverse effects.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

DOI and DOC are not immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and on DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of DOI

[4] World Health Organization (WHO). 2019a. Critical Review Report: DOC (4-Chloro-2,5-dimethoxyamfetamine) Expert Committee on Drug Dependence, Forty-second Meeting. Geneva.

[5] NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. NFLIS-Drug data were queried on October 27, 2023.

and DOC. As such, DEA proposes to schedule DOI and DOC as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule, per 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the then-Assistant Secretary for Health of HHS to place DOI and DOC in schedule I and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) DOI and DOC have a high potential for abuse that is comparable to other schedule I substances, such as the phenethylamine hallucinogen DOM;

(2) DOI and DOC have no currently accepted medical use in treatment in the United States. FDA has not approved a marketing application for a drug product containing DOI or DOC for any therapeutic indication, and DEA and HHS know of no clinical studies or petitioners claiming an accepted medical use in the United States.[6]

(3) There is a lack of accepted safety for use of DOI and DOC under medical supervision. The use of DOC is associated with serious adverse consequences including deaths. Since DOI is structurally similar to DOC and produces effects similar to DOC, it is likely that DOI may produce serious adverse events similar to DOC. Because DOI and DOC have no approved medical use and have not been investigated as new drugs, their safety for use under medical supervision has not been determined.

Based on these findings, the Administrator of DEA concludes that DOI and DOC warrant control in schedule I of the CSA. More precisely, because of their hallucinogenic effects, and because they may produce hallucinogenic-like tolerance and dependence in humans, DEA proposes to place DOI and DOC, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical description, in 21 CFR 1308.11(d) (the hallucinogenic substances category of schedule I).

Requirements for Handling DOI and DOC

If this rule is finalized as proposed, DOI and DOC would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distributing, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) would need to 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.

2. Security. DOI and DOC would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling DOI and DOC also would need to comply with the screening requirements of 21 CFR 1301.90–1301.93.

3. Labeling and Packaging. All labels and packaging for commercial containers of DOI and DOC would need to comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

4. Quota. Only registered manufacturers would be permitted to manufacture DOI and DOC in accordance with quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. Inventory. Every DEA registrant who possesses any quantity of DOI and DOC would need to have an initial inventory of all stocks of controlled substances (including DOI and DOC) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant would need to take inventory of all controlled substances (including DOI and DOC) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. Records and Reports. Every DEA registrant would need to maintain records and submit reports for DOI and DOC, pursuant to 21 U.S.C. 827 and 832(a), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317

7. Order Forms. Every DEA registrant who distributes DOI and DOC would need to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of DOI and DOC would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. Liability. Any activity involving DOI and DOC not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review, and Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This proposed regulation 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 proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule 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.

[6] Although there is no evidence suggesting that DOI and DOC have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, 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. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Paperwork Reduction Act

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521.

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA proposes placing the substances DOI and DOC (chemical names: 2,5-dimethoxy-4-iodoamphetamine [DOI] and 2,5-dimethoxy-4-chloroamphetamine [DOC]), including their 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 CSA. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention for DOC. 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 DOI and DOC.

According to HHS, and also by DEA's findings in this proposed rule, DOI and DOC have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. There appear to be no legitimate sources for DOI and DOC as marketed drugs in the United States, but DEA notes that these substances are available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of DOI and DOC from legitimate suppliers. As such, the proposed rule, if finalized, is not expected to result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this proposed 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.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 7, 2023, 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.

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, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.11, as proposed to be amended at 88 FR 22388 (April 13, 2023), add paragraphs (d)(104) and (d)(105) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

* * * * * * *

(104) 2,5-dimethoxy-4-iodoamphetamine (Other name: DOI) 7447

(105) 2,5-dimethoxy-4-chloroamphetamine (Other name: DOC) 7448

* * * * * * *

* * * * *

[FR Doc. 2023–27289 Filed 12–12–23; 8:45 am]

BILLING CODE 4410–09–P

section 513(f)(2) of the act, is pending before the Food and Drug Administration, or

(ii) There is a predetermined change control plan (PCCP) cleared under section 515C of the act, provided that the change is consistent with the PCCP.

* * * * *

§ 807.87 [Amended]

■ 3. Amend § 807.87 by removing the phrase "(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0281)" that appears after paragraph (m).

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 4. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 379k–1, 381.

■ 5. In § 814.39, revise paragraph (b) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(b) An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post approval periodic reports required as a condition to approval of the device, *e.g.,* an editorial change in labeling which does not affect the safety or effectiveness of the device, or if the change is consistent with a predetermined change control plan (PCCP) approved under section 515C of the act.

* * * * *

Dated: March 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05473 Filed 3–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1245]

Schedules of Controlled Substances: Placement of 2-Methyl AP–237 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 1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one (commonly known as 2-methyl AP–237), including its optical and geometric 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, 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 the 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 propose to handle 2-methyl AP–237.

DATES: Effective April 15, 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 1961 United Nations Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, 570 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 (Administrator of DEA or Administrator). 28 CFR 0.100.

Background

In a letter dated November 24, 2022, the Director-General of the World Health Organization recommended to the Secretary-General of the United Nations that 2-methyl AP–237 be placed in Schedule I of the Single Convention, as this substance has an opioid mechanism of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.,* 2-methyl AP–237 is similar to drugs such as isotonitazene) 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 2-methyl AP–237 in Schedule I of the Single Convention (CND Mar/66/1).

2-Methyl AP–237

2-Methyl AP–237 has a pharmacological profile similar to other classical opioids such as fentanyl (schedule II), morphine (schedule II) and heroin (schedule I), which act as mu-opioid receptor agonists. Because of the pharmacological similarities of 2-methyl AP–237 to the aforementioned opioids, 2-methyl AP–237 presents a high risk of abuse and has negatively affected users and communities. According to the DEA Toxicology Testing Program (DEA TOX) [1] and a recent publication,[2] the abuse of 2-methyl AP–237 has been associated with at least seven fatalities in the United States between February 2020 and July 2023. The identification of this substance in post-mortem cases is a serious concern to public safety.

In June 2019, 2-methyl AP–237 emerged on the United States illicit drug market as evidenced by its identification in drug seizures.[3] Law enforcement

[1] The DEA Toxicology Testing Program (DEA TOX) was initiated in response to the ongoing novel synthetic drug abuse epidemic. This program provides toxicology data on synthetic drugs from biological samples that may not be routinely identified, which are generated from drug overdose victims. Data queried on 8/7/2023.

[2] Fogarty, MF, Vandeputte, MM, Krotulski, AJ, Walton, SE, Stove, CP, and Logan, BK (2022). Toxicological and pharmacological characterization of novel cinnamylpiperazine synthetic opioids in humans and in vitro including 2-methyl AP–237 and AP–238. Archives of Toxicology 96:1701–1710.

[3] 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

Continued

reports demonstrate that 2-methyl AP–237 is being illicitly distributed and abused. The illicit use and distribution of this substance is similar to that of heroin (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 have been 92 reports of 2-methyl AP–237 in the United States since 2019 (data queried July 17, 2023).

DEA is not aware of any claims or any medical or scientific literature suggesting that 2-methyl AP–237 has a currently accepted medical use in treatment in the United States. In addition, the Assistant Secretary for Health of the U.S. Department of Health and Human Services, by a letter to DEA dated December 22, 2022, stated that there are no investigational new drug applications or approved new drug applications for 2-methyl AP–237 in the United States; hence, there are no legitimate channels for this substance as a marketed drug product in the United States. Because 2-methyl AP–237 is not formulated or available for clinical use as an approved medicinal product, all current use of this substance 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 a drug.

Therefore, consistent with 21 U.S.C. 811(d)(1), DEA concludes that 2-methyl AP–237 has no currently accepted medical use in treatment in the United States [4] and is most appropriately placed in schedule I of the CSA. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to permanently schedule 2-methyl AP–237 pursuant to 21 U.S.C. 811(a).

Conclusion

In order to meet the United States' obligations under the Single Convention and because 2-methyl AP–237 has no currently accepted medical use in treatment in the United States, the Administrator has determined that 2-methyl AP–237, including its optical and geometric 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, should be placed in schedule I of the CSA.

Requirements for Handling

Upon the effective date of the final order contained in this document, 2-methyl AP–237 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, 2-methyl AP–237 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 this substance in a manner not authorized by the CSA is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* 2-Methyl AP–237 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.* 2-Methyl AP–237 is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling 2-methyl AP–237 must 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 2-methyl AP–237 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 2-methyl AP–237 in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle 2-methyl AP–237 must have an initial inventory of all stocks of controlled substances (including this substance) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including 2-methyl AP–237) on hand every two years 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 2-methyl AP–237 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 parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding 2-methyl AP–237 to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute 2-methyl AP–237 must comply with the 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 2-methyl AP–237 must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving 2-methyl AP–237 not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

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* Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV; 76 FR 77330, 77332, December 12, 2011. NFLIS data was queried on July 17, 2023. Reports to NFLIS-Drug are still pending for 2023.

[4] Although, as discussed above, there is no evidence suggesting that 2-methyl AP–237 has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, 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. 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).

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 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).

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 order would modify an existing collection of information requirement under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521. Pursuant to section 3507(d) of the PRA of 1995 (44 U.S.C. 3507(d)), DEA is adding new reporting and recordkeeping requirements for 1117–0003. This order also involves existing collection 1117–0004, but would not modify the existing collection of information requirement under the PRA. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

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.

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)(59) through (b)(103) as follows:

Old paragraph	New paragraph
(b)(59) through (103)	(b)(60) through (104).

■ b. Add new paragraph (b)(59).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *

(59) 2-Methyl AP–237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one) 9664

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Signing Authority

This document of the Drug Enforcement Administration was signed on March 8, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for

publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–05543 Filed 3–14–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice: 12306]

RIN 1400–AF80

International Traffic in Arms Regulations: Addition to List of Proscribed Countries

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to add Nicaragua in the list of countries for which it is the policy of the United States to deny licenses or other approvals for exports and imports of defense services and defense articles, except as otherwise provided.

DATES: The rule is effective on March 15, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Maria Tatarska, Foreign Affairs Officer, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (771) 205–7671; email *DDTCCustomerService@state.gov* ATTN: Regulatory Change, ITAR Section 126.1: Nicaragua.

SUPPLEMENTARY INFORMATION: Due to growing concerns regarding Nicaragua's continuing dismantling of democratic institutions, attacks on civil society, and increased security cooperation with Russia, to include support of Russia's full-scale invasion of Ukraine, the Under Secretary of State for Arms Control and International Security has determined that it is in the best interests of U.S. national security and foreign policy to restrict, with certain exceptions, the export and import of defense articles and defense services destined for or originating in Nicaragua. This policy reflects the U.S. government's opposition to the trade of arms with Nicaragua and its authoritarian government dominated by President Daniel Ortega Saavedra and his wife, Vice President Rosario Murillo Zambrana. Pursuant to this determination, the Department is adding Nicaragua to ITAR § 126.1 in paragraph (p). The policy of denial toward Nicaragua applies to licenses or other approvals for exports and imports of defense articles or defense services, except that a license or other approval may be issued on a case-by-case basis for non-lethal military equipment intended solely for humanitarian assistance, to include natural disaster relief. Further, in accordance with ITAR § 129.7, no broker, as described in ITAR § 129.2, may engage in or make a proposal to engage in brokering activities subject to the ITAR that involve Nicaragua without obtaining the approval of the Directorate of Defense Trade Controls. Consistent with ITAR § 129.7(d), the Department of State will apply the same policy of denial to such requests.

Regulatory Analysis and Notices

Administrative Procedure Act

This rulemaking is exempt from the rulemaking requirements of section 553 of the Administrative Procedure Act (APA) pursuant to 5 U.S.C. 553(a)(1) as a military or foreign affairs function of the United States.

Regulatory Flexibility Act

Since this rule is exempt from the notice-and-comment provisions of 5 U.S.C. 553, the rule does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

The Department does not believe this rulemaking is a major rule within the definition of 5 U.S.C. 804.

Executive Orders 12372 and 13132

This rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866, 13563, and 14094

Executive Order 12866, as amended by Executive Orders 13563 and 14094, 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, distributed impacts, and equity). As a result of this change, certain exemptions to licensing requirements will not be available for exports, reexports, retransfers, and temporary imports destined for or originating in Nicaragua. However, a license or other approval may be issued on a case-by-case basis for non-lethal military equipment intended solely for humanitarian assistance, to include natural disaster relief. Because the scope of this rule does not impose significant additional regulatory requirements or obligations, the Department believes costs associated with this rule will be minimal. This rule has been designated a "significant regulatory action" by the Office and Information and Regulatory Affairs under Executive Order 12866.

Executive Order 12988

The Department of State has reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State determined that this rulemaking will not have Tribal implications, will not impose substantial direct compliance costs on Indian Tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

For the reasons set forth above, title 22, chapter I, subchapter M, part 126 is amended as follows:

PART 126—GENERAL POLICIES AND PROVISIONS

■ 1. The authority citation for part 126 continues to read as follows:

Authority: 22 U.S.C. 287c, 2651a, 2752, 2753, 2776, 2778, 2779, 2779a, 2780, 2791, 2797; Sec. 1225, Pub. L. 108–375, 118 Stat. 2091; Sec. 7045, Pub. L. 112–74, 125 Stat.

in which it is approved. Once approved, a TEM IPA is effective until December 31 of the first year in which it is effective or until December 31 of the year in which the TEM IPA representative notifies NMFS in writing that the TEM IPA is no longer in effect, whichever is later. A TEM IPA may not expire mid-year. No party may leave a TEM IPA once it is approved, except as allowed under paragraph (d)(3) of this section.

(d) *NMFS review of a proposed TEM IPA.*—(1) *Approval.* A TEM IPA will be approved by NMFS if the TEM IPA meets the following requirements:

(i) Complies with the submission requirements of paragraphs (b) and (c) of this section; and

(ii) Contains the information required in paragraph (b) of this section.

(2) *Amendments to a TEM IPA.* Amendments in writing to an approved TEM IPA may be submitted to NMFS at any time and will be reviewed under the requirements of paragraph (b) of this section. An amendment to an approved TEM IPA is effective when NMFS notifies the TEM IPA representative in writing of NMFS approval.

(3) *Disapproval.* (i) NMFS will disapprove a proposed TEM IPA or a proposed amendment to a TEM IPA:

(A) If the proposed TEM IPA fails to meet any of the requirements of paragraph (b) of this section; or

(B) If a proposed amendment to a TEM IPA would cause the TEM IPA to no longer comply with the requirements of paragraph (b) of this section.

(ii) [Reserved]

(4) *Initial Administrative Determination (IAD).* If NMFS identifies deficiencies in the proposed TEM IPA, NMFS will notify the applicant in writing that the proposed TEM IPA will not be approved. The TEM IPA representative will be provided one 30-day period to address, in writing, all deficiencies identified by NMFS. Additional information or a revised TEM IPA received by NMFS after the expiration of the 30-day period specified by NMFS will not be considered. NMFS will evaluate any additional information submitted by the TEM IPA representative within the 30-day period. If the Regional Administrator determines that the additional information addresses the deficiencies in the proposed TEM IPA, the Regional Administrator will approve the proposed TEM IPA under paragraph (d) of this section. However, if NMFS determines that the proposed TEM IPA does not comply with the requirements of paragraph (b) of this section, NMFS will issue an IAD providing the reasons for disapproving the proposed TEM IPA.

(5) *Appeal.* A TEM IPA representative who receives an IAD disapproving a proposed TEM IPA may appeal under the procedures set forth at 15 CFR part 906. If the TEM IPA representative fails to timely file an appeal of the IAD pursuant to 15 CFR part 906, the IAD will become the final agency action. If the IAD is appealed and the final agency action approves the proposed TEM IPA, the TEM IPA will be effective as described in paragraph (c) of this section.

(6) *Pending approval.* While appeal of an IAD disapproving a proposed TEM IPA is pending, proposed parties to the TEM IPA subject to the IAD, which are not currently parties to an approved TEM IPA, are not authorized to participate in trawl EM category.

(e) *Public release of a TEM IPA and performance metrics.* Each fishing year NMFS will release to the public and publish on the NMFS Alaska Region website:

(1) *Approvals.* Approved TEM IPAs and Approval Memos;

(2) *Parties.* List of parties to each approved TEM IPA; and

(3) *Names.* Names of vessels covered by each approved TEM IPA that:

(i) On average, harvesting pollock catch in excess of 300,000 pounds (136 mt) per fishing trip in the GOA;

(ii) Harvest bycatch in quantities that exceed MRAs; and

(iii) Vessels' performance under the TEM IPA and any restrictions, penalties, or performance criteria imposed under the TEM IPA by vessel name.

(f) *TEM IPA Annual Report.* The representative of each approved TEM IPA must submit a written annual report to the Council at the address specified in § 679.61(f). The Council will make the annual report available to the public.

(1) *Submission deadline.* The TEM IPA Annual Report must be received by the Council no later than May 15 of the following fishing year.

(2) *Information requirements.* The TEM IPA Annual Report must contain the following information:

(i) A comprehensive description of the incentive measures in effect in the previous year;

(ii) A description of how these incentive measures affected individual vessels;

(iii) An evaluation of whether incentive measures were effective in limiting changes in vessel behavior including the effectiveness of:

(A) Measures to discourage participating vessels, on average, from harvesting pollock catch in excess of 300,000 pounds (136 mt) per fishing trip in the GOA;

(B) Measures that incentivize participating vessels to avoid exceeding MRAs established in § 679.20(e) applicable to non-EM vessels;

(C) Restrictions, penalties, or performance criteria that were imposed to prevent vessels from consistently exceeding catcher vessel harvest limit for pollock in the GOA or MRAs relative to non-EM vessels by vessel name (see §§ 679.7(b)(2) and 679.20(e));

(D) The frequency of vessels exceeding the catcher vessel harvest limit for pollock in the GOA and MRA limits relative to non-EM vessels (see §§ 679.7(b)(2) and 679.20(e)); and

(E) Identification of, and the TEM IPA's response to, vessels directed fishing in conflict with harvest specifications or directed fishing for Steller Sea Lion forage species within closed Steller Sea Lion protection areas.

(iv) A description of any amendments to the TEM IPA that were approved by NMFS since the last annual report and the reasons that the amendments to the TEM IPA were requested.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1143]

Schedules of Controlled Substances: Temporary Placement of N-Desethyl Isotonitazene and N-Piperidinyl Etonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule two synthetic benzimidazole-opioid substances, as identified in this order, in schedule I of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these two substances in schedule I is necessary to avoid imminent hazard to the public safety. This order imposes 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 these two specified controlled substances.

DATES: This temporary scheduling order is effective July 29, 2024, until July 29, 2026. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., 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 Drug Enforcement Administration (DEA) issues a temporary scheduling order [1] (in the form of a temporary amendment) to add the following two 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):

- *N*-ethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as *N*-desethyl isotonitazene), and
- 2-(4-ethoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1*H*-benzimidazole (commonly known as either *N*-piperidinyl etonitazene or etonitazepipne).

Legal Authority

Under 21 U.S.C. 811(h)(1), the Attorney General, as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100, has the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the evaluation requirements of 21 U.S.C. 811(b), if the Administrator finds that such action is necessary to avoid an imminent hazard to the public safety.[2] In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year.[3]

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355.[4]

[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this action 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] 21 U.S.C. 811(h)(1).

[3] 21 U.S.C. 811(h)(2).

[4] 21 U.S.C. 811(h)(1); 21 CFR part 1308.

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).[5] The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[6] by letter dated April 3, 2023, regarding *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene. The Assistant Secretary responded to this notice by letter dated May 11, 2023, 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 *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene. The Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene currently are not listed in any schedule under the CSA, and no exemptions or approvals under 21 U.S.C. 355 are in effect for these substances.

DEA has taken into consideration the Assistant Secretary's comments as required by subsection 811(h)(4). DEA has found the control of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene 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 (NOI) to temporarily schedule *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene on October 25, 2023.[7] That NOI discussed findings from DEA's three-factor analysis dated January 2023, which DEA made available on *www.regulations.gov*.

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.[8] Consideration of these factors includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances.[9]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[10] Substances in schedule I have 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.[11]

Two Benzimidazole-Opioids: N-desethyl isotonitazene and N-piperidinyl etonitazene

The continued encounter of novel psychoactive substances (NPS) on the recreational drug market poses a threat to public safety. Following the class-wide scheduling of fentanyl-related substances,[12] there has been an increase in the emergence of synthetic opioids that are not structurally related to fentanyl. Beginning in 2019, a new class of synthetic opioids known as benzimidazole-opioids, commonly referred to as "nitazenes," emerged on the recreational drug market. This class of substances was first synthesized in the 1950s by CIBA Aktiengesellschaft in Switzerland, and it has a similar pharmacological profile to fentanyl, morphine, and other mu-opioid receptor agonists. Between August 2020 and April 2022, DEA temporarily controlled eight benzimidazole-opioids because they posed a threat to public safety.[13]

Recently, additional benzimidazole-opioids have been identified within the rapidly expanding class of "nitazene" compounds on the recreational drug market. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene are some of the recently encountered "nitazene"

[5] 21 U.S.C. 811(h)(4).

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

[7] 88 FR 73293 (Oct. 25, 2023).

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

[9] *Id.*

[10] 21 U.S.C. 811(h)(1).

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

[12] On February 6, 2018, pursuant to 21 U.S.C. 811(h), the then Acting Administrator of Drug Enforcement Administration temporarily placed fentanyl-related substances in schedule I of the Controlled Substances Act (CSA) (83 FR 5188) to avoid an imminent hazard to public safety. Through the Temporary Reauthorization and Study of Emergency Scheduling of Fentanyl Analogues Act, Public Law 116–114, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. This temporary order was subsequently extended multiple times, most recently through the Consolidated Appropriations Act of 2023, Public Law 117–328, which extended the order until December 31, 2024.

[13] Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, flunitazene, Metodesnitazene, Metonitazene, *N*-Pyrrolidino etonitazene, and Protonitazene in Schedule I, 87 FR 21556 (Apr. 12, 2022); Schedules of Controlled Substances: Temporary Placement of Isotonitazene in Schedule I, 85 FR 51342 (Aug. 20, 2020).

synthetic opioids identified on the illicit drug market.

The continued trafficking and identification of benzimidazole-opioids in toxicology cases pose a significant threat to public health and safety. Adverse health effects associated with the misuse and abuse of synthetic opioids have led to devastating consequences including death. Preclinical pharmacology data demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene have pharmacological profiles similar to those of the potent benzimidazole-opioids etonitazene and isotonitazene, schedule I opioid substances.[14] *N*-Desethyl isotonitazene, an active metabolite of isotonitazene, has been positively identified in at least ten toxicology cases.[15] *N*-Piperidinyl etonitazene has been positively identified in at least three toxicology cases.[16] As the United States continues to experience a high number of opioid-involved overdoses and mortalities, the introduction of new designer opioids further exacerbates the current opioid epidemic.

Available data and information for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene, summarized below, indicate that these substances have high potentials for abuse, no currently accepted medical uses in treatment in the United States,[17] and a lack of accepted safety for use under medical supervision. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene have been positively identified toxicology cases. As the United States continues to experience a high number of opioid-involved overdoses and mortalities, the introduction of new designer opioids further exacerbates the current opioid epidemic Thus, the Administrator concludes that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene meet the statutory requirements to be temporarily placed in schedule I under the CSA. 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–1143.

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 structurally unique benzimidazole derivatives with analgesic properties; however, the research effort did not produce any medically approved analgesic products. These benzimidazole derivatives include schedule I substances, such as synthetic opioids clonitazene, etonitazene, and isotonitazene.

Since 2019, there has been an emergence of nitazene compounds on the illicit drug market, which have been positively identified in numerous cases of fatal overdose events. In August 2020, isotonitazene was placed in schedule I of the CSA (85 FR 51342). Subsequently, seven additional benzimidazole-opioids[18] have been placed in schedule I of the CSA.

Recently, two additional benzimidazole-opioids have emerged on the illicit drug market. Law enforcement officers have encountered *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in several solid forms (*e.g.*, powder and tablets). These substances are not approved pharmaceutical products and are not approved for medical use anywhere in the world. The Assistant Secretary in a letter to DEA dated May 11, 2023, stated that there are no FDA-approved NDAs or INDs for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in the United States. There are no legitimate channels for these substances as marketed drug products.

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

In 2022, *N*-desethyl isotonitazene was identified in counterfeit tablets in the United States and United Kingdom. Recent reporting by Center for Forensic Science Research and Education (CFSRE) indicates that in the United States, *N*-desethyl isotonitazene was identified in counterfeit oxycodone round blue tablets in Florida. Further, in December 2022, *N*-desethyl isotonitazene was co-identified in "dope" samples containing xylazine, fentanyl, *para*-fluorofentanyl, and designer benzodiazepines (*e.g.*, flubromazepam and bromazolam).[19]

In 2021, *N*-piperidinyl etonitazene emerged on the illicit synthetic drug market, as evidenced by its identification in toxicological analysis of biological samples.[20] In addition, there have been encounters of *N*-piperidinyl etonitazene in Europe. As reported in January 2022 by the European Monitoring Center for Drugs

[14] DEA–VA Interagency Agreement. "In Vitro Receptor and Transporter Assays for Abuse Liability Testing for the DEA by the VA". Binding and Functional Activity at Delta, Kappa and Mu Opioid Receptors. 2022.

[15] Walton SE, Krotulski AJ, Logan BK. A Forward-Thinking Approach to Addressing the New Synthetic Opioid 2-Benzylbenzimidazole Nitazene Analogs by Liquid Chromatography-Tandem Quadrupole Mass Spectrometry (LC–QQQ–MS). J Anal Toxicol. 2022 Mar 21;46(3):221–231.

[16] Calello DP, Aldy K, Jefri M, Nguyen TT, Krotulski A, Logan B, Brent J, Wax P, Walton S, Manini AF; ToxIC Fentalog Study Group. Identification of a novel opioid, *N*-piperidinyl etonitazene (etonitazepipne), in patients with suspected opioid overdose. Clin Toxicol (Phila). 2022 Sep;60(9):1067–1069.

[17] When finding that placing a substance in schedule I on a temporary basis is necessary to avoid imminent hazard to the public, 21 U.S.C. 811(h) does not require DEA to consider whether the substance has a currently accepted medical use in treatment in the United States. Nonetheless, there is no evidence suggesting that *N*-desethyl isonitazene and etonitazepipne have a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that the HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this temporary scheduling action, there is no evidence that health care providers have widespread experience with medical use of N-desethyl isonitazene and etonitazepipne, or that the use of N-desethyl isonitazene and etonitazepipne is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

[18] Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. *See* 87 FR 21556 (Apr. 12, 2022).

[19] CFSRE NPS Discovery Public Alert 2023. Case Example—*N*-desethyl isotonitazene. January 2023.

[20] A partnership between the American College of Medical Toxicology (ACMT) and the Center for Forensic Science Research and Education (CFSRE) was established to comprehensively assess the role and prevalence of synthetic opioids and other drugs among suspected overdose events in the United States. CFSRE NPS Monograph. *N*-Piperidinyl etonitazene. November 22, 2021.

and Drug Addiction (EMCDDA), the European Union Early Warning System Network identified *N*-piperidinyl etonitazene in Germany in October 2021. As of January 23, 2023, a total of four European countries have reported identifications of *N*-piperidinyl etonitazene in powder form to the EMCDDA.[21]

Factor 5. Scope, Duration and Significance of Abuse

N-Desethyl isotonitazene and *N*-piperidinyl etonitazene, similar to etonitazene and isotonitazene (schedule I substances), have been described as potent synthetic opioids, and evidence suggests they are abused for their opioidergic effects. The abuse of these benzimidazole-opioids, similar to other synthetic opioids, has resulted in serious adverse health effects. Between October 2019 and January 2020, *N*-desethyl isotonitazene was positively identified as a metabolite of isotonitazene in 13 postmortem samples and 64 driving-under-the-influence-of-drugs (DUID) in the United States. However, beginning in 2023, *N*-desethyl isotonitazene has been identified in 10 toxicology cases.[22] The pharmacological profile of *N*-desethyl isotonitazene demonstrates it is a highly potent synthetic opioid similar to etonitazene, isotonitazene, and fentanyl. As such, the identification of this substance as a parent drug in the recreational drug market is worrisome.

Data from law enforcement suggest that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are being abused in the United States as recreational drugs.[23] Since 2022, there have been 14 reports to DEA's National Forensic Laboratory Information System (NFLIS)-Drug[24] (Federal, State, and local laboratories) database pertaining to the trafficking, distribution, and abuse of *N*-desethyl isotonitazene (n = 5) and *N*-piperidinyl etonitazene (n = 9). These five encounters of *N*-desethyl isotonitazene were reported to NFLIS-Drug from Pennsylvania (2), Florida (2) and Kansas (1). Encounters of *N*-piperidinyl etonitazene occurred in Tennessee (8) and Pennsylvania (1).

Based on information collected from NFLIS-Drug, *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene were identified in tablet form or as residue. Reporting from CFSRE show that *N*-desethyl isotonitazene was identified in a counterfeit oxycodone tablet in Florida,[25] suggesting that it might be present as a substitute for heroin or fentanyl and likely abused in the same manner as either of those substances.

The population likely to be harmed by these benzimidazole-opioids appears to be the same as that harmed by prescription opioid analgesics, fentanyl, and other synthetic drugs.[26] This is evidenced by the types of other drugs co-identified in biological samples and law enforcement reports. Law enforcement and toxicology reports demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are being illicitly distributed and abused. Because users of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are likely to obtain these substances through unregulated sources, the identity, purity, and quantity of these substances are uncertain and inconsistent, thus posing significant adverse health risks to the end user. 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/or death, similar to that of other opioid analgesics (*e.g.*, fentanyl, morphine, etc.).

Factor 6. What, if Any, Risk There Is to the Public Health

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids on the illicit drug market. Data obtained from pre-clinical studies demonstrate that *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene exhibit pharmacological profiles similar to that of etonitazene, isotonitazene, and other mu-opioid receptor agonists.[27] These two benzimidazole-opioids bind to and act as an agonist at the mu-opioid receptors. It is well established that substances that act as mu-opioid receptor agonists have a high potential for addiction and can induce dose-dependent respiratory depression.

Consistent with any mu-opioid receptor agonist, the potential health and safety risks for users of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene are high. *N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene have been positively 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.

N-Piperidinyl etonitazene was detected in suspected opioid overdose cases in three patients from New Jersey over a period of three days in July 2021. Of those patients, two reported the use of cocaine; one reported the use of heroin and alprazolam. Similarly, according to a 2021 CFSRE report, *N*-piperidinyl etonitazene was co-identified with fentanyl in two cases and *para*-fluorofentanyl in one other case.[28]

The pharmacological profile of this substance demonstrates that it is a highly potent synthetic opioid similar to etonitazene, isotonitazene, and fentanyl. As such, the identification of this substance as a parent drug in the recreational drug market is worrisome.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene 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.

[21] Email communication with EMCDDA dated January 23, 2023.

[22] CFSRE NPS Opioids Trend Report, 2023 Q1 and Q2. Accessed September 15, 2023.

[23] While law enforcement data are 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).

[24] NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle 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-Drug, is currently 98.5 percent. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances:* Placement of Carisoprodol Into Schedule IV, 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data was queried on October 2, 2023.

[25] CFSRE NPS Discovery Public Alert January 2023. Accessed January 25, 2023.

[26] According to the most recent data from the National Survey on Drug Use and Health, as of 2022, an estimated 8.9 million people aged 12 years or older misused opioids in the past year, including 8.5 million prescription pain reliever misusers and 1.0 million heroin users. This population abusing opioids is likely to be at risk of abusing *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene.

[27] DEA–VA Interagency Agreement. "In Vitro Receptor and Transporter Assays for Abuse Liability Testing for the DEA by the VA". Binding and Functional Activity at Delta, Kappa and Mu Opioid Receptors. 2022. Unpublished data.

[28] NPS Discovery Program at the Center for Forensic Science Research and Education: Monograph. *N*-Piperidinyl etonitazene Toxicology Analytical Report. November 22, 2021.

811(h)(1), may only be placed in schedule I. Substances in schedule I must have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene indicate that these substances meet the three statutory criteria.

As required by 21 U.S.C. 811(h)(4), the Administrator transmitted to the Assistant Secretary, via letter dated April 3, 2023, notice of her intent to place *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in schedule I on a temporary basis. HHS had no objection to the temporary placement of these substances in schedule I. DEA subsequently published a NOI in the **Federal Register** on October 25, 2023.[29]

Conclusion

In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily schedule *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene 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.

This temporary placement of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in schedule I of the CSA will take effect on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process.[30]

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.[31] The regular scheduling process of formal rulemaking affords interested parties appropriate process and the government any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review.[32] Temporary scheduling orders are not subject to judicial review.[33]

Requirements for Handling

Upon the effective date of this temporary order, *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, possession of, and engagement in research and conduct of instructional activities or chemical analysis with, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (possesses, manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with) or desires to handle, *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene 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 July 29, 2024. Any person who thereafter handles *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene and is not registered with DEA must submit an application for registration and may not continue to handle *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene as of July 29, 2024, 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 July 29, 2024 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 unable to obtain a schedule I registration to handle *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must surrender all currently held quantities of these substances.

3. *Security. N*-Desethyl isotonitazene and *N*-piperidinyl etonitazene are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.93, as of July 29, 2024.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene must comply with 21 U.S.C. 825 and 958(e) and 21 CFR part 1302. Current DEA registrants will have 30 calendar days from July 29, 2024 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene 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 will have 30 calendar days from the effective date of this order to comply with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene) 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 *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR parts 1304, 1312, and 1317, and section 1307.11. Current DEA registrants authorized to handle these two substances shall have 30 calendar days from the effective date of this order to comply with all recordkeeping requirements.

7. *Reports.* All DEA registrants must submit reports with respect to *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, 1312, and 1317, and sections 1301.74(c) and 1301.76(b), as of July 29, 2024. Manufacturers and distributors must also submit reports regarding these substances to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 29, 2024.

9. *Importation and Exportation.* All importation and exportation of *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of July 29, 2024.

10. *Quota.* Only DEA-registered manufacturers may manufacture *N*-desethyl isotonitazene and *N*-piperidinyl etonitazene in accordance

[29] Schedules of Controlled Substances: Temporary Placement of *N*-Desethyl Isotonitazene and *N*-Piperidinyl Etionitazene in Schedule I, 88 FR 73293 (Oct. 25, 2023).

[30] 21 U.S.C. 811(h)(1) and (2).

[31] 21 U.S.C. 811.

[32] 21 U.S.C. 877.

[33] 21 U.S.C. 811(h)(6).

with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of July 29, 2024.

11. *Liability.* Any activity involving *N*-desethyl isotonitazene or *N*-piperidinyl etonitazene not authorized by or in violation of the CSA, occurring as of July 29, 2024, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

The CSA provides for expedited temporary scheduling actions where necessary to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h)(1), the Administrator, as delegated by the Attorney General, may, by order, temporarily place substances in schedule I. Such orders may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intent to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary, as delegated by the Secretary of HHS.[34]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, DEA believes the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this temporary scheduling order. 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). This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done "on the record after opportunity for a hearing," and final decisions that conclude the scheduling process and are subject to judicial review. 21 U.S.C. 811(a) and 877. The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in section 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Assuming for the sake of argument that this action 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 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. Therefore, in this instance, since DEA believes this temporary scheduling action is not a "rule," it is not subject to the requirements of the Regulatory Flexibility Act when issuing this temporary action.

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

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

Signing Authority

This document of the Drug Enforcement Administration was signed on July 16, 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.

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 paragraphs (h)(68) and (69) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

[34] 21 U.S.C. 811(h)(1).

*	*	*	*	*	*	*
(68) *N*-ethyl-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 name: *N*-desethyl isotonitazene)						9760
(69) 2-(4-ethoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1*H*-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: *N*-piperidinyl etonitazene; etonitazepipne)						9761
*	*	*	*	*	*	*

* * * * *

[FR Doc. 2024–16391 Filed 7–26–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0658]

RIN 1625–AA00

Safety Zone; Demolition of Lock and Dam 3, Monongahela River Mile Marker 23.5 to 24.5, Elizabeth, PA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary interim rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Monongahela River from mile marker 23.5 to mile marker 24.5 in Elizabeth, PA. This rule is substantially similar to a temporary safety zone published on June 27, 2024. We must establish this temporary safety zone because of the continuation of lock and dam demolition. This regulation will prohibit entry of vessels or persons into the safety zone to protect personnel, vessels, and the marine environment from potential hazards during demolition activities planned from August 1, 2024, through December 31, 2024.

DATES: This rule is effective from August 1, 2024, through December 31, 2024. Comments and related material must be received by the Coast Guard on or before September 27, 2024.

ADDRESSES: We encourage you to submit comments identified by docket number USCG–2024–0658 using the Federal Decision Making Portal at *https://www.regulations.gov*. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Eyobe Mills, Marine Safety Unit, Pittsburgh, U.S. Coast Guard, at telephone 412–221–0807, email *Eyobe.D.Mills@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The similar rule published at 89 FR 53491 on June 27, 2024. The Coast Guard is issuing this interim temporary rule without prior notice and opportunity to comment pursuant to the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to public interest. The notice allowing the demolition project to proceed and providing updated timelines for the project was only recently finalized and provided to the Coast Guard, which did not give the Coast Guard enough time to publish an NPRM, take public comments, and issue a final rule before ethe existing regulation expires. Timely action is needed to respond to the potential safety hazards associated with demolition of the lock and dam, which involves the use of explosives. It would be impracticable and contrary to the public interest to publish an NPRM because we must establish the safety zone to protect the safety of the waterway users, demolition crew, other personnel associated with the project, and the public. A delay of the project to accommodate a full notice and comment period would delay necessary operations, result in increased costs, and delay the completion date of the demolition project and subsequent opening of the navigation channel. We must establish this safety zone by August 1, 2024, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the reasons stated in the preceding paragraph, delaying the effective date of this rule is impracticable and contrary to public interest because timely action is needed to respond to the potential safety hazards associated with the demolition of the lock and dam starting August 1, 2024.

Although this regulation is published as an interim rule without prior notice, public comment is nevertheless desirable to ensure that the regulation is both workable and reasonable. Accordingly, persons wishing to comment may do so by submitting written comments as set out under **ADDRESSES** in this preamble. Commenters should include their names and addresses, identify the docket number for the regulation, and give reasons for their comments. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this temporary interim rule under the authority in 46 U.S.C. 70034. The Captain of the Port Pittsburgh (COTP) has determined that potential hazards associated with this lock and dam demolition will be a safety concern for anyone on the Monongahela River within mile marker 23.5 through 24.5. The use of explosives and other activities involved in demolishing the lock and dam involve inherent risk. To minimize risk to personnel, vessels, property, and the marine environment, no vessel may moor, anchor, transit, or otherwise be present in the designated safety zone at any time during the periods of enforcement unless receiving prior permission from the COTP or their designated representative.

This temporary interim rule is needed to protect personnel, vessels, and the

(ii) Parker Meggitt Service Bulletin 1111548–25–001–2023, Revision 002, dated April 1, 2024.

(3) For Parker Meggitt material identified in this AD, contact Parker Meggitt Services, 1785 Voyager Avenue, Simi Valley, CA 93063; phone: 877–666–0712; email: *TechSupport@meggitt.com;* website: *meggitt.com/services_and_support/customer_experience/update-on-buckle-assembly-service-bulletins.*

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 21, 2024.

Steven W. Thompson,

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

[FR Doc. 2024–24756 Filed 10–24–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–900N]

Schedules of Controlled Substances: Placement of Butonitazene, Flunitazene, and Metodesnitazene Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places butonitazene, flunitazene, and metodesnitazene including their isomers, esters, ethers, salts and salts of isomers, esters and ethers in schedule I of the Controlled Substances Act. 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 these three specific controlled substances will continue to apply as a result of this action.

DATES: Effective October 25, 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: In this final rule, the Drug Enforcement Administration (DEA) permanently schedules 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).

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of Health and Human Services (HHS), or on the petition of any interested party.[1] This action is supported, *inter alia,* by a recommendation from the Assistant Secretary for Health of HHS (Assistant Secretary for HHS or Assistant Secretary) and an evaluation of all other relevant data by DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or proposes to handle butonitazene, flunitazene, and metodesnitazene.

Background

On April 12, 2022, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the **Federal Register** temporarily placing butonitazene, flunitazene, metodesnitazene, and four 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.[2] 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 date of issuance of the scheduling order, except that DEA may extend temporary scheduling of that substance for up to one year during the pendency of permanent scheduling proceedings under 21 U.S.C. 811(a)(1) with respect to the substance. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of butonitazene, flunitazene, and metodesnitazene was set to expire on April 12, 2024. However, on April 11, 2024, the DEA Administrator extended the temporary order in a separate action.[3] On the same day, the Administrator, on her own motion pursuant to 21 U.S.C. 811(a), initiated scheduling proceedings and published a notice of proposed rulemaking (NPRM) to permanently control butonitazene, flunitazene, and metodesnitazene in schedule I of the CSA.[4] Specifically, DEA proposed to add these substances to the opiates list under 21 CFR 1308.11(b).

DEA and HHS Eight Factor Analyses

On November 15, 2023, the Assistant Secretary submitted HHS's scientific and medical evaluation and scheduling recommendation for butonitazene, flunitazene, metodesnitazene, and three other benzimidazole-opioids and their salts to the Administrator,[5] which recommended placing butonitazene, flunitazene, and metodesnitazene and their salts in schedule I of the CSA. In accordance with 21 U.S.C. 811(c), upon receipt of the scientific and medical evaluation and scheduling

[1] 21 U.S.C. 811(a).

[2] *See* 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). 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, *see* 89 FR 25514 (Apr. 11, 2024) to remain as 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.

[3] *See* Schedules of Controlled Substances: Extension of Temporary Placement of Butonitazene, Flunitazene, and Metodesnitazene in Schedule I of the Controlled Substances Act, 89 FR 25517 (Apr. 11, 2024).

[4] *See* Schedules of Controlled Substances: Placement of Butonitazene, Flunitazene, and Metodesnitazene Substances in Schedule I, 89 FR 25544 (Apr. 11, 2024).

[5] DEA published a final order to permanently place the three other benzimidazole-opioids (etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene) in schedule I of the CSA. *See* Schedules of Controlled Substances: Placement of Etodesnitazene, N-Pyrrolidino Etonitazene, and Protonitazene in Schedule I, 89 FR 25514 (Apr. 11, 2024).

recommendation from HHS, DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of these three substances. Please note that both the DEA and HHS eight-factor analyses are available in their entirety under the tab "Supporting Documents" of the public docket for this action at *http://www.regulations.gov* under Docket Number "DEA–900N."

Determination To Permanently Schedule Butonitazene, Flunitazene, and Metodesnitazene

After review of the available data including the scientific and medical evaluation and the scheduling recommendation from HHS, DEA published an NPRM in the **Federal Register** on April 11, 2024, which proposed the placement of butonitazene, flunitazene, and metodesnitazene in schedule I of the CSA.[6] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before May 13, 2024. DEA received no hearing requests. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before May 13, 2024.

Comments Received

DEA received two comments on the proposed rule to control butonitazene, flunitazene, and metodesnitazene in schedule I of the CSA. One commenter provided support for the rule. This commenter noted that permanent placement of these substances would be beneficial to the community safety. DEA appreciates the support for this rulemaking. The second commenter commended the proposed rule but noted that a class control action for the nitazene drug class would be more appropriate as opposed to individually scheduling substances in the benzimidazole-opioid drug class. DEA appreciates this comment as a potential alternative for consideration. However, due to the current threat of these specific substances, DEA will continue with solely scheduling these three substances.

Scheduling Conclusion

After consideration of the relevant matters presented through public comments, the scientific and medical evaluation and accompanying scheduling recommendation of HHS, and DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of butonitazene, flunitazene, and metodesnitazene. DEA is therefore permanently scheduling these three benzimidazole-opioids as schedule I controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[7] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) Butonitazene, flunitazene, and metodesnitazene have a high potential for abuse. Butonitazene, flunitazene, and metodesnitazene, similar to etonitazene and fentanyl, are mu-opioid receptor agonists. These three benzimidazole-opioids have analgesic effects, and these effects are mediated by mu-opioid receptor agonism. HHS states that substances that produce mu-opioid receptor agonist effects in the central nervous system are considered as having a high potential for abuse (*e.g.* morphine and fentanyl). Data obtained from drug discrimination studies indicate that butonitazene, flunitazene, and metodesnitazene fully substituted for the discriminative stimulus effects of morphine.

(2) Butonitazene, flunitazene, and metodesnitazene have no currently accepted medical use in the United States. There are no FDA-approved drug products for butonitazene, flunitazene, and metodesnitazene in the United States. There are no known therapeutic applications for these benzimidazole-opioids, and DEA is not aware of any currently accepted medical uses for these substances in the United States.[8]

(3) There is a lack of accepted safety for use of butonitazene, flunitazene, and metodesnitazene under medical supervision. Because these substances have no FDA-approved medical use and have not been investigated as new drugs, their safety for use under medical supervision is not determined.

Based on these findings, the Administrator of DEA concludes that butonitazene, flunitazene, and metodesnitazene, 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, warrant continued control in schedule I of the CSA.[9]

Requirements for Handling Butonitazene, Flunitazene, and Metodesnitazene

As discussed above, these three substances are currently subject to a temporary scheduling order, which added them to schedule I. Butonitazene, flunitazene, and metodesnitazene will continue to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I substances, including the following:

[6] *See* Schedules of Controlled Substances: Placement of Butonitazene, Flunitazene, and Metodesnitazene Substances in Schedule I, 89 FR 25544 (Apr. 11, 2024).

[7] 21 U.S.C. 812(b).

[8] To place a drug or other substance in schedule I under the CSA, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B). There is no evidence suggesting that butonitazene, flunitazene, and metodesnitazene have a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this final rule, there is no evidence that health care providers have widespread experience with medical use of butonitazene, flunitazene, and metodesnitazene, or that the use of butonitazene, flunitazene, and metodesnitazene are recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

[9] 21 U.S.C. 812(b)(1).

1. Registration. Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or who desires to handle butonitazene, flunitazene, and metodesnitazene 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. Butonitazene, flunitazene, and metodesnitazene 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. Butonitazene, flunitazene, and metodesnitazene are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling these three substances also must comply with the screening requirements of 21 CFR 1301.90–1301.93.

4. Labeling and Packaging. All labels and labeling for commercial containers of butonitazene, flunitazene, and metodesnitazene 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 butonitazene, flunitazene, and metodesnitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

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

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including butonitazene, flunitazene, and metodesnitazene) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. Records and Reports. Every DEA registrant must maintain records and submit reports with respect to butonitazene, flunitazene, and metodesnitazene, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317. Manufacturers and distributors would be required to submit reports regarding butonitazene, flunitazene, and metodesnitazene to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304 and 1312.

8. Order Forms. Every DEA registrant who distributes butonitazene, flunitazene, and metodesnitazene must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. Importation and Exportation. All importation and exportation of butonitazene, flunitazene, and metodesnitazene must comply with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312.

10. Liability. Any activity involving butonitazene, flunitazene, and metodesnitazene not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

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

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures done "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This regulation 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the states, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

On April 12, 2022, DEA published an order to temporarily place seven benzimidazole-opioids in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle butonitazene, flunitazene, and metodesnitazene have already established and implemented systems and processes required to handle these substances.

There are currently 45 registrations authorized to specifically handle butonitazene, flunitazene, or metodesnitazene, as well as 1,239 registered analytical labs and 861 researchers that are authorized to handle schedule I controlled substances generally. These 45 registrations represent 31 entities. A review of the 45 registrations indicates that all entities that currently handle butonitazene, flunitazene, and metodesnitazene also handle other schedule I controlled substances and have established and implemented (or maintained) systems and processes required to handle these substances. Therefore, DEA anticipates this final rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any affected small entity. Therefore, DEA

has concluded that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 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 the UMRA.

Paperwork Reduction Act of 1995

This rule would not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.[10] Also, this rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this rule would 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.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(62) through (106) as (b)(65) through (109)

■ b. Redesignate paragraphs (b)(44) through (61) as (b)(46) through (63);

■ c. Redesignate paragraphs (b)(24) through (43) as (b)(25) through (44);

■ d. Add new paragraphs (b)(24), (b)(45), and (b)(64); and

■ e. Remove and reserve paragraphs (h)(50), (52), and (53).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *	
(24) Butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)-*N*,*N*-diethylethan-1-amine)	9751
* * * * * * *	
(45) Flunitazene (*N*,*N*-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine)	9756
* * * * * * *	
(64) Metodesnitazene (*N*,*N*-diethyl-2-(2-(4-methoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine)	9764

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on October 15, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–24635 Filed 10–24–24; 8:45 am]

BILLING CODE 4410–09–P

[10] 44 U.S.C. 3501–3521.

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE–2021–0003; EEEE500000245E1700D2 ET1SF0000.EAQ000]

RIN 1014–AA49

Oil and Gas and Sulfur Operations in the Outer Continental Shelf—High Pressure High Temperature Updates; Correction

AGENCY: Bureau of Safety and Environmental Enforcement (BSEE), Interior.

ACTION: Final rule; correction.

SUMMARY: BSEE is correcting a final rule that appeared in the **Federal Register** on August 30, 2024. BSEE is publishing a correction to fix an erroneous statement in the preamble of the final rule. BSEE inadvertently stated it did not receive public comments to an identified section of the rule. However, BSEE had received a comment associated with that section of the rule. BSEE evaluated and addressed that comment in other discussions in the preamble of the final rule.

DATES: Effective October 25, 2024.

FOR FURTHER INFORMATION CONTACT: Kirk Malstrom, Regulations and Standards Branch, (202) 258–1518, or by email: *regs@bsee.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2024–18598 appearing on page 71088 in the **Federal Register** of Friday, August 30, 2024, the following corrections to the preamble are made:

1. Under the heading "How must barrier systems be used (§ 250.207)", which begins near the bottom of the third column on page 71087, the text under the subheading "Summary of Final Rule Revisions", which begins near the top of the first column on page 71088, is corrected to read:

BSEE received and considered a comment regarding proposed § 250.207 and includes the proposed language in the final rule without change.

Summary of Comment: A commenter expressed concerns with the applicability of this section to existing blowout preventer barrier system requirements and asked if new and

as SBSEF–FIN–QTR, SBSEF–FIN–QTR/A, SBSEF–FIN–REQ, and SBSEF–FIN–REQ/A submissions, respectively.[4]

Addition of XBRL Taxonomy for Cybersecurity Disclosures

EDGAR will be updated to allow filers to use the appropriate XBRL Taxonomy for cybersecurity disclosures required to be included in Forms 6–K, 8–K, 10–K, and 20–F (and the variants 10–KT, 10–K/A, 10–KT/A, 20–F/A, 8–K/A, and 6–K/A).[5]

Removal of the Index From Volume II of the EDGAR Filer Manual

Volume II of the Filer Manual will be updated to remove the Index. Filers may continue to use the Table of Contents which links directly to chapters and topics, and the document search function of this online manual.

III. Amendments to Rule 301 of Regulation S–T

Along with the adoption of the updated Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of the current revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual is available at *https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual.*

IV. Administrative Law Matters

Because the Filer Manual and rule amendments relate solely to agency procedures or practice and do not substantially alter the rights and obligations of non-agency parties, publication for notice and comment is not required under the Administrative Procedure Act ("APA").[6] It follows that the amendments do not require analysis under requirements of the Regulatory Flexibility Act[7] or a report to Congress under the Small Business Regulatory Enforcement Fairness Act of 1996.[8]

The effective date for the updated Filer Manual and related rule amendments is October 22, 2024. In accordance with the APA,[9] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the related system upgrades.

V. Statutory Basis

We are adopting the amendments to Regulation S–T under the authority in sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[10] sections 3, 12, 13, 14, 15, 15B, 23, and 35A of the Securities Exchange Act of 1934,[11] section 319 of the Trust Indenture Act of 1939,[12] and sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[13]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l*, 78m, 78n, 78n–1,78*o*(d), 78w(a), 78*ll*, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: "General Information," Version 41 (December 2022). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: "EDGAR Filing," Version 71 (September 2024). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for inspection at the Commission and at the National Archives and Records Administration (NARA). The EDGAR Filer Manual is available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission's Public Reference Room. For information on the availability of the EDGAR Filer Manual at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The EDGAR Filer Manual may also be obtained from *https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual.*

By the Commission.

Dated: September 16, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–24355 Filed 10–21–24; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1142]

Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places ethylphenidate (chemical name: ethyl 2-phenyl-2-(piperidin-2-yl)acetate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. When 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,

[4] Security-Based Swap Execution and Registration and Regulation of Security-Based Swap Execution Facilities, Release No. 34–98845 (Nov. 2, 2023) [88 FR 87156 (Dec. 15, 2023)].

[5] Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure, Release No. 33–11216 (July 26, 2023) [88 FR 51896 (Aug. 4, 2023)].

[6] 5 U.S.C. 553(b)(A).

[7] 5 U.S.C. 601 through 612.

[8] 5 U.S.C. 804(3)(c).

[9] 5 U.S.C. 553(d)(3).

[10] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[11] 15 U.S.C. 78c, 78*l*, 78m, 78n, 78*o*, 78*o*–4, 78w, and 78*ll*.

[12] 15 U.S.C. 77sss.

[13] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle ethylphenidate.

DATES: *Effective date:* November 21, 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 1971 United Nations Convention on Psychotropic Substances (1971 Convention), Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of Health and Human Services (Secretary),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

Ethylphenidate is a central nervous system stimulant and shares structural and pharmacological similarities with other schedule II stimulants, such as methylphenidate. On April 21, 2017, the Secretary-General of the United Nations advised the Secretary of State of the United States that, during its 60th session on March 16, 2017, the Commission on Narcotic Drugs (CND) voted to place ethyl 2-phenyl-2-(piperidin-2-yl)acetate (ethylphenidate) in Schedule II of the 1971 Convention (CND Dec/60/7). Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for ethylphenidate were not followed, as discussed above in the legal authority section, DEA is utilizing the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control ethylphenidate. Permanently scheduling ethylphenidate satisfies the United States' international obligations.

DEA and HHS Eight Factor Analyses

In a letter dated October 26, 2020, in accordance with 21 U.S.C. 811(b), and in response to DEA's April 3, 2019 request, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for ethylphenidate. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that this substance warrants control in schedule I. Both DEA and HHS Eight-Factor analyses are available in their entirety under the tab Supporting Documents of the public docket for this action at *https://www.regulations.gov* under docket number DEA–1142.

Notice of Proposed Rulemaking To Schedule Ethylphenidate

On September 22, 2023, DEA published a notice of proposed rulemaking (NPRM) to permanently control ethylphenidate in schedule I.[3] Specifically, DEA proposed to add ethylphenidate to the list of stimulant substances under 21 CFR 1308.11(f). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before October 23, 2023. DEA did not receive any requests for such a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before November 21, 2023.

Comments Received

DEA received ten comments in response to the notice of proposed rulemaking for the placement of ethylphenidate into schedule I of the CSA. The submissions were from individuals or anonymous commenters. Five commenters provided support for the notice of proposed rulemaking, four commenters were against the placement of ethylphenidate in schedule I of the CSA, and one commenter expressed statements that were neither for nor against the proposed rule.

DEA received five comments in support of the placement of ethylphenidate in schedule I.

DEA Response: DEA appreciates these comments in support of this rulemaking.

DEA received four comments against the placement of ethylphenidate in schedule I of the CSA. The following are DEA's responses to the individual comments against the proposed rulemaking.

DEA received a comment asserting that methylphenidate is already controlled under schedule II of the CSA, thus, ethylphenidate is considered controlled under the Controlled Substances Analogue Act due to their similarities. This commenter concluded that the government should not dictate what researchers may study for legitimate scientific use.

DEA Response: DEA appreciates this comment and would like to provide further clarification regarding the control of ethylphenidate. Ethylphenidate has been placed under international control. In order to comply with treaty obligations, DEA must place ethylphenidate under the most appropriate schedule, taking into consideration all appropriate scientific data. This is true even if this substance could be treated under the Controlled Substances Analogue provision. Additionally, as set forth in the NPRM, ethylphenidate has no currently accepted medical use in treatment in the United States. Therefore, ethylphenidate must be placed in schedule I of the CSA along with other substances which have no currently accepted medical use, lack

[1] As discussed in a memorandum of understanding entered into by the FDA and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (Mar. 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91–513, As Amended; Delegation of Authority,* 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

[3] *Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule* I, 88 FR 65330 (Sept. 22, 2023).

accepted safety for use under medical supervision, and possess a high potential for abuse. With respect to scientific research, the placement of substances in schedule I of the CSA does not preclude academic research on these substances. DEA registrants wishing to conduct research on schedule I substances may apply for permission to do so through the schedule I researcher registration program.[4]

DEA received a comment comparing ethylphenidate to methylphenidate. The commenter questioned the reasonable nature of placing ethylphenidate in schedule I of the CSA considering it is a weaker substance when compared to methylphenidate, a schedule II substance.

DEA Response: DEA appreciates this comment and asserts the following: Ethylphenidate belongs to the stimulant class of drugs and possesses abuse liability similar to that of methylphenidate; however, unlike methylphenidate, ethylphenidate has no currently accepted medical use in treatment in the United States. A qualification for placing substances in schedules II thorough IV of the CSA is that they must have a currently accepted medical use in treatment in the United States. Thus, DEA asserts that the placement of ethylphenidate in schedule I of the CSA is warranted.

DEA received a comment with statements against the NPRM placing ethylphenidate in schedule I of the CSA. The commenter stated that, in the NPRM, DEA failed to provide a reason for the placement of ethylphenidate in a more restrictive schedule (here, schedule I) than methylphenidate, considering the two drugs share significant pharmacological similarities and are considered analogues of one another. The commenter further stated that because ethylphenidate is an analog of methylphenidate, it may be possible in the future for ethylphenidate to be marketed as an alternative to methylphenidate. In particular, the commenter stated the placement of ethylphenidate in schedule I of the CSA would completely hamper future legitimate research regarding its medical efficacy. Thus, the commenter states, by imposing criminal sanctions on those who engage in research or chemical analysis of the drug, DEA would prevent the future discovery of its possible medical use.

DEA Response: DEA appreciates this comment and asserts the following: As stated above, ethylphenidate has been placed under international control. In order to comply with treaty obligations, DEA must place ethylphenidate under the most appropriate schedule, taking into consideration all appropriate scientific data. Additionally, a qualification for placing substances in schedules II thorough IV of the CSA is that they must have a currently accepted medical use in treatment in the United States. Ethylphenidate has no currently accepted medical use in treatment in the United States, lacks accepted safety for use under medical supervision, and possesses a high potential for abuse. Thus, DEA asserts that the placement of ethylphenidate in schedule I of the CSA is warranted. With respect to research, the placement of substances in schedule I of the CSA does not preclude research into this substance. DEA registrants wishing to conduct research on schedule I substances, including ethylphenidate, may apply for permission to do so through the schedule I researcher registration program.

DEA received a comment expressing that ethylphenidate should be categorized as a schedule II drug "until further research has been conducted to prove its viability."

DEA Response: DEA appreciates this comment and asserts the following: According to the CSA, schedule I substances are defined as drugs that have no known medical use in treatment in the United States, and have a high potential for abuse. Additionally, according to the CSA, schedule II substances also have a high potential for abuse but have a currently accepted medical use in treatment. Accordingly, DEA proposed to place ethylphenidate in schedule I of the CSA, due to its lack of a currently accepted medical use in treatment in the United States, its lack of accepted safety for use under medical supervision, and its high potential for abuse.

DEA received one comment that provided statements that were neither explicitly for nor against the proposed rule.

In this comment, the commenter suggested that instead of creating a new rule for the control of ethylphenidate, DEA should simply clarify the existing rule which controlled methylphenidate. According to this commenter, this suggested amendment would extend control to all derivatives of methylphenidate. The commenter also expressed an understanding of DEA's intent to schedule ethylphenidate but questioned whether a standard notice-and-comment procedure was needed for an action that could be addressed by clarifying existing rulemaking.

DEA Response: DEA appreciates this suggestion and asserts the following: Ethylphenidate was placed under international control on March 16, 2017, during the CND's 60th session. As a signatory to the 1971 Convention on Psychotropic Substances, it is incumbent upon DEA to place ethylphenidate in its most appropriate schedule under the CSA. Therefore, DEA proposed to place ethylphenidate in schedule I of the CSA because it has no currently accepted medical use in treatment in the United States, lacks accepted safety for use under medical supervision, and has an abuse potential similar to that of methylphenidate. As explained in the NPRM, because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for ethylphenidate were not followed, DEA utilized the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control ethylphenidate, which required notice and an opportunity for hearing.

Scheduling Conclusion

After consideration of the public comments, scientific and medical evaluation and accompanying scheduling recommendation from HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of ethylphenidate. As such, DEA is permanently scheduling ethylphenidate as a controlled substance under schedule I of the CSA. The permanent scheduling of ethylphenidate will fulfill the United States' obligations as a party to the 1971 Convention.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, II, IV, and V. The CSA also specifies the findings requires to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Acting Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) Ethylphenidate has a high potential for abuse that is comparable to other scheduled substances, such as methylphenidate (a schedule II substance);

(2) Ethylphenidate has no currently accepted medical use in treatment in the United States. In HHS' 2020 recommendation to control ethylphenidate, it was noted there are no approved New Drug Applications for ethylphenidate and no known therapeutic applications for ethylphenidate in the United States. DEA is not aware of any other evidence suggesting that ethylphenidate has

[4] *https://apps.deadiversion.usdoj.gov/webforms2/spring/main?execution=e1s2.*

a currently accepted medical use in treatment in the United States.[5]

(3) There is a lack of accepted safety for use of ethylphenidate under medical supervision. Because ethylphenidate has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined.

Based on these findings, the Administrator of DEA concludes that ethylphenidate, as well as its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule I of the CSA.

Requirements for Handling Ethylphenidate

Ethylphenidate is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct 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, ethylphenidate must register 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. Any person who currently handles ethylphenidate and is not registered with DEA must submit an application for registration and may not continue to handle ethylphenidate, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 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 in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held ethylphenidate to a person registered with DEA before the effective date of a final scheduling action in accordance with all applicable Federal, State, local, and tribal laws. Ethylphenidate 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.* Ethylphenidate is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of this final scheduling action. Non-practitioners handling ethylphenidate must 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 ethylphenidate 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 ethylphenidate 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 ethylphenidate must take an inventory of ethylphenidate on hand, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including ethylphenidate) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including ethylphenidate) on hand every two years, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for ethylphenidate, or products containing ethylphenidate, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding ethylphenidate to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes ethylphenidate must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of ethylphenidate must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR parts 1304 and 1312.

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

Regulatory Analyses

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

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles

[5] When placing a substance in schedule I, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B) There is no evidence suggesting that ethylphenidate has a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand,* 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this final rule, there is no evidence that health care providers have widespread experience with medical use of ethylphenidate or that the use of ethylphenidate is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

reaffirmed in E.O. 13563. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This regulation 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule 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 rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[6] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this proposed rule would 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.

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance ethylphenidate (chemical name: ethyl 2-phenyl-2-(piperidin-2-yl)acetate), including its salts, isomers, and salts of isomers, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. This action imposes 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 ethylphenidate.

Based on the review of HHS's scientific and medical evaluation and all other relevant data, DEA determined that ethylphenidate has high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for ethylphenidate in the United States. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

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

Congressional Review Act

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

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is amended 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 (f)(6) through (f)(12) as (f)(7) through (f)(13); and

■ b. Add a new paragraph (f)(6)

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(6) Ethylphenidate (ethyl 2-phenyl-2-(piperidin-2-yl)acetate)	1727

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on October 10, 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.**

[6] 44 U.S.C. 3501–3521.

Heather Achbach,
Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–24083 Filed 10–21–24; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–0924]

Safety Zone: Fireworks Displays Within the Fifth Coast Guard District; The Wharf, Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for a fireworks display at "The Wharf DC," in Washington, DC, to provide for the safety of life on navigable waterways during this event. Our regulation, "Safety Zones; Fireworks Displays within the Fifth Coast Guard District," identifies the precise location. During the enforcement period, vessels may not enter, remain in, or transit through the safety zone unless authorized to do so by the COTP or his representative, and vessels in the vicinity must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation in 33 CFR 165.506 will be enforced for the location identified in line no. 1 of table 2 to 33 CFR 165.506(h)(2) from 8 p.m. until 9:30 p.m. on December 7, 2024, or if necessary, due to inclement weather, from 8 p.m. until 9:30 p.m. on December 8, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email *MDNCRMarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone regulation for a fireworks display at The Wharf DC from 8 p.m. to 9:30 p.m. on December 7, 2024, or, if necessary due to inclement weather, from 8 p.m. until 9:30 p.m. on December 8, 2024. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation, "Safety Zones; Fireworks Displays within the Fifth Coast Guard District," § 165.506, specifies the location of the safety zone for the fireworks show, which encompasses portions of the Washington Channel in the Upper Potomac River. As reflected in 33 CFR 165.23, vessels in the vicinity of the safety zone may not enter, remain in, or transit through the safety zone during the enforcement period unless authorized to do so by the COTP or his representative, and they must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: October 7, 2024.

Patrick C. Burkett,
Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

[FR Doc. 2024–24284 Filed 10–21–24; 8:45 am]
BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[EPA–HQ–OAR–2024–0234; FRL–11945–01–OAR]

Prevention of Significant Deterioration (PSD): Paragraph Designation Corrections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending its Prevention of Significant Deterioration (PSD) regulations to correct the fourth-level paragraph designations to conform with the Office of the Federal Register (OFR) requirements. This is a ministerial final rule action that involves minor technical corrections.

DATES: This rule is effective October 22, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2024–0234. All documents in the docket are listed on the *https://www.regulations.gov* website. Publicly available docket materials are available either electronically through *https://www.regulations.gov* or in hard copy at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Questions concerning this final rule should be addressed to Mr. Peter Keller, Air Quality Policy Division, Office of Air Quality Planning and Standards (C539–04), U.S. Environmental Protection Agency, Post Office Box 12055, Research Triangle Park, NC 27711; telephone number: (919) 541–2065; email address: *keller.peter@epa.gov.*

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. Does this action apply to me?

No entities will be affected by this final action. The EPA is amending its PSD regulations to correct the fourth-level paragraph designations from the Code of Federal Regulations (CFR) to conform with the OFR requirements. The EPA is responsible for making the required paragraph codification corrections in the EPA PSD regulations and communicating those corrections to stakeholders, including state, local, and Tribal (SLT) permitting authorities and regulated entities. SLT permitting authorities are not required to make corresponding corrections to any of their regulations implementing the PSD program including those approved by the EPA into a State Implementation Plan (SIP).

II. Background and Rationale for This Action

Part C of title I of the Clean Air Act (CAA), 42 U.S.C. 7470 *et seq.*, contains the requirements for a component of the major New Source Review (NSR) program known as the PSD program. This program sets forth procedures for the preconstruction review and permitting of new and modified stationary sources of air pollution located in areas meeting the National Ambient Air Quality Standards (NAAQS) ("attainment" areas) and areas for which there is insufficient information to classify an area as either attainment or nonattainment ("unclassifiable" areas). The EPA's PSD regulations are contained in 40 CFR

Recruiting

Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants With TRD

ClinicalTrials.gov ID NCT05711940

Sponsor **COMPASS Pathways**

Information provided by **COMPASS Pathways** (Responsible Party)

Last Update Posted 2024-12-02

Study Details Tab

Study Overview

Brief Summary

Efficacy, Safety, and Tolerability of two administrations of COMP360 in participants with treatment-resistant depression (TRD)

Detailed Description

This is a phase III, international, multi-centre, randomised, parallel group, fixed repeat dose, double-blind, controlled study. The study population will include participants aged ≥18 years with TRD.

Overall, 568 participants are to be randomised in a 2:1:1 ratio to receive COMP360 25 mg, 10 mg or 1 mg.

The study will last up to 16 weeks including a three- to ten-week Screening Period and six-week follow-up from investigational product (IP) administration.

In this study, the aim is to assess the efficacy of COMP360, administered with psychological support in adult participants with TRD, in improving symptoms of depression.

Official Title

A Phase III, Multicentre, Randomised, Double-blind, Controlled Study to Investigate the Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants With Treatment-resistant Depression

Conditions

Treatment Resistant Depression

Intervention / Treatment

- Drug: Psilocybin

Other Study ID Numbers

- COMP 006

Study Start (Actual)

2023-02-14

Primary Completion (Estimated)

2025-03

Study Completion (Estimated)

2025-05

Enrollment (Estimated)

568

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine