Bill No 2093 – Controlled Substances Rescheduling
Senate Judiciary Committee – Peace Garden Room
9:00 AM - Wednesday – January 11th, 2023

Proposed Amendments

Page 2 line 19: add dash between "1H" and "benzimidazol"
aa. Isotonitazene (also known as N,N-diethyl-2-(2-(4- isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine.

Page 3 lines 26-27: (remove commas & capitalize)
fff. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (also known as N-pyrrolidino, etonitazene, and etonitazepyne).
Should be: N-Pyrrolidino Etonitazene and Etonitazepyne

Page 9 lines 24-27: (add the word "or" after (a) and (b))
(a) Substitution to the indole ring to any extent; or
(b) Substitution to the phenyl, benzyl, cumyl, naphthyl, adamantyl, cyclopropyl, pyrrolidinyl, piperazinyl, or propionaldehyde group to any extent; or

Page 23 under line 1: (add the following additional depressant compound to schedule I substances)
l. Diclazepam

Page 26 under line 6: (add the following additional stimulant compound to schedule I substances)
o. Methiopropamine (Also known as N-methyl-1-(thiophen-2-yl)propan-2-amine)

Page 28 line 29 to Page 29 line 2: (remove language and renumber accordingly)
~~5. Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: Fenfluramine.~~

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 19, 2022, 87 FR 57569 (September 21, 2022); Notice of November 8, 2022, 87 FR 68015 (November 10, 2022).

■ 2. Supplement No. 4 to part 744 is amended under RUSSIA by revising the entry for "Private Military Company 'Wagner' " to read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
RUSSIA	*	*	*	*
	Private Military Company 'Wagner', a.k.a., the following five aliases: —Chastnaya Voennaya Kompaniya 'Vagner'; —Chvk Vagner; —PMC Wagner; —Wagner Group; *and* —Vagner Group. 15 Zolnaya Street, Saint Petersburg, 195213, Russia	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR). The license requirements under this entry also extend to any export, reexport and transfer (in-country) to the entity wherever located worldwide	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	82 FR 28408, 6/22/17. 87 FR [INSERT FR PAGE NUMBER] 12/23/22.
	*	*	*	*
*	*	*	*	*

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Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–28033 Filed 12–21–22; 4:15 pm]

BILLING CODE 3510–JT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 130 and 131

[Docket No. FDA–2000–P–0126 (formerly Docket No. 2000P–0658)]

RIN 0910–AI40

International Dairy Foods Association and Chobani, Inc.: Response to the Objections and Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of public hearing requests; removal of administrative stay; correction.

SUMMARY: The Food and Drug Administration is correcting a final rule entitled "International Dairy Foods Association and Chobani, Inc.: Response to the Objections and Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt" that appeared in the **Federal Register** of December 15, 2022. The final rule revoked the standards of identity for lowfat yogurt and nonfat yogurt and amended the standard of identity for yogurt in numerous respects. The document was published with an errant reference to its effective date in the preamble discussion. This document corrects that error.

DATES: This correction is effective January 17, 2023, and applicable December 15, 2022.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, or Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, December 15, 2022 (87 FR 765590), appearing on page 76567, in FR Doc. 2022–27040, the following correction is made:

1. On page 76567, in the third column, in the fifth sentence of the third paragraph under IV. Summary and Conclusions, "[DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]" is corrected to read "January 17, 2023".

Dated: December 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27816 Filed 12–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–945]

Schedules of Controlled Substances: Removal of Fenfluramine From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration removes fenfluramine (chemical name: *N*-ethyl-α-methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts is possible, from the schedules of the Controlled Substances Act. Prior to the effective date of this rule, fenfluramine was a

schedule IV controlled substance. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, engage in research, import, export, conduct instructional activities or chemical analysis with, or possess) or propose to handle fenfluramine.

DATES: Effective December 23, 2022.

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:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause.[1] The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, "remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule." The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (DEA).[2]

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 the petition of any interested party.[3] This action was initiated by a petition to remove fenfluramine from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all relevant data by DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle or propose to handle fenfluramine.

Background

Fenfluramine (chemical name: *N*-ethyl-α-methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of such isomers, has been controlled under 21 CFR 1308.14(d) as a schedule IV substance of the CSA since June 15, 1973.[4] On September 25, 2019, Zogenix, Inc. (Zogenix; the Sponsor) submitted to the Food and Drug Administration (FDA) a New Drug Application (NDA) for Fintepla (fenfluramine), for the treatment of seizures associated with Dravet syndrome (DS) in patients two years of age and older. FDA approved the NDA on June 25, 2020, with the labelling listing fenfluramine as a schedule IV controlled substance.

On October 18, 2018, Zogenix submitted to DEA a petition requesting that fenfluramine be removed from schedule IV of the CSA. The petition complied with the requirements of 21 CFR 1308.43(b) and DEA accepted the petition for filing on November 13, 2018.

Notice of Proposed Rulemaking To Decontrol Fenfluramine

On July 19, 2022, DEA published a notice of proposed rulemaking (NPRM) to remove fenfluramine from the schedules of the CSA.[5] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by August 18, 2022. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposal on or before August 18, 2022.

Comment Received

DEA received one comment on the NPRM to remove fenfluramine from control.

Opposition to rulemaking: One commenter opposed decontrol of fenfluramine, however the comment was at times ambiguous. The commenter seemed to be concerned about children using fenfluramine illicitly and the potential harm related to the combined use with a stimulant, specifically noting the fenfluramine-phentermine ("fen-phen") combination and noting "Stimulants+Psychedelics=Psychosis."

DEA Response: DEA acknowledges the commenter's concerns about relative harm, especially related to children. DEA notes FDA approved Fintepla (fenfluramine) on June 25, 2020, for the treatment of DS in patients two years of age and older. Currently Fintepla is the only FDA-approved drug product with fenfluramine. HHS considered the harms the fenfluramine-phentermine combination produced in their April 2021 scientific and medical evaluation, which was provided to DEA as part of this rulemaking process, pursuant to 21 U.S.C. 811(b).

DEA notes that the combination historically produced serious cardiac effects, not psychological effects. The FDA-approved labeling for Fintepla indicates that patients must be enrolled in the Fintepla risk evaluation and mitigation strategy (REMS) program and undergo cardiac monitoring before, during, and after treatment with Fintepla to monitor for serious heart valve changes or high blood pressure in the arteries of the lungs. The FDA-required REMS program for Fintepla, including ongoing cardiac monitoring, would still be applicable under the FDA rules even after fenfluramine is decontrolled by DEA.

Based on FDA's scientific and medical review of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that fenfluramine and its salts be removed from all schedules of the CSA. Pursuant to 21 U.S.C. 811(b), the recommendations of HHS shall be binding on DEA as to such scientific and medical matters and if the Secretary recommends that a drug or other substance not be controlled, DEA shall not control the drug or other substances. As stated in the NPRM, after careful review of all relevant data including HHS' scientific and medical evaluation and scheduling recommendation, DEA is therefore promulgating this final rule to remove fenfluramine, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible, from control under the CSA.

Determination To Decontrol Fenfluramine

Based on consideration of the comment, and the rationale set forth in the NPRM, the Administrator finds that fenfluramine does not meet the requirements for inclusion in any schedule. As such, DEA is removing fenfluramine, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible, from control under the CSA.

[1] 21 U.S.C. 812.

[2] 28 CFR 0.100.

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

[4] 38 FR 15719, May 9, 1973.

[5] 87 FR 42979.

Regulatory Analyses

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

In accordance with 21 U.S.C. 811(a), this 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 removing a drug or other substance from the list of controlled substances. 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 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. This rule does not have substantial direct effects on the States, on the relationship between the Federal 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. This rule 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. The purpose of this rule is to remove fenfluramine from the list of schedules of the CSA. This action will remove regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of fenfluramine. Accordingly, it has the potential for some economic impact in the form of cost savings.

Fenfluramine as a pharmaceutical product (Fintepla) is currently available and marketed in the U.S. Because fenfluramine is currently a schedule IV drug, all legal handling of fenfluramine is currently done under appropriate DEA license. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities that are affected by this rulemaking. There are currently 40 unique registrations authorized to handle fenfluramine specifically, as well as a number of registered analytical labs that are authorized to handle schedule IV controlled substances generally. From review of entity names, DEA estimates these 40 registrations represent 27 entities. Some of these entities are likely to be small entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 27 entities are small entities. Therefore, DEA conservatively estimates as many as 27 small entities are affected by this final rule. However, because this rule would remove fenfluramine from regulatory controls of the CSA, it is likely to result in some cost savings. Any person planning to handle fenfluramine will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements. Because of these factors, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

Administrative Procedure Act

The Administrative Procedure Act requires the publication of a substantive rule to be made not less than 30 days before its effective date.[6] However, this requirement need not apply for "a substantive rule which . . . relieves a restriction."[7] Therefore, DEA makes this rule effective immediately upon publication.

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 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 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 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.

§ 1308.14 [Amended]

■ 2. In § 1308.14, remove and reserve paragraph (d).

Signing Authority

This document of the Drug Enforcement Administration was signed on December 12, 2022, 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. 2022–27400 Filed 12–22–22; 8:45 am]

BILLING CODE 4410–09–P

[6] 5 U.S.C. 553(d).

[7] 5 U.S.C. 553(d)(1).

AIRAC Date	State	City	Airport	FDC No.	FDC date	Subject
29–Dec–22 ...	MS	Greenwood	Greenwood-Leflore	2/6483	8/15/22	VOR RWY 5, Amdt 13B.
29–Dec–22 ...	MS	Corinth	Roscoe Turner	2/7401	10/24/22	RNAV (GPS) RWY 36, Amdt 1C.
29–Dec–22 ...	MS	Corinth	Roscoe Turner	2/7406	10/24/22	ILS OR LOC RWY 18, Amdt 4.
29–Dec–22 ...	MS	Corinth	Roscoe Turner	2/7420	10/24/22	RNAV (GPS) RWY 18, Amdt 1A.
29–Dec–22 ...	IN	Logansport	Logansport/Cass County	2/7662	9/23/22	RNAV (GPS) RWY 9, Amdt 1B.
29–Dec–22 ...	OH	Millersburg	Holmes County	2/8082	10/24/22	RNAV (GPS) RWY 9, Orig-B.
29–Dec–22 ...	OH	Millersburg	Holmes County	2/8083	10/24/22	RNAV (GPS) RWY 27, Orig-B.
29–Dec–22 ...	IA	Vinton	Vinton Veterans Meml Airpark	2/9284	10/26/22	RNAV (GPS) RWY 9, Orig.
29–Dec–22 ...	AL	Troy	Troy Muni At N Kenneth Campbell Fld.	2/9433	9/7/22	RNAV (GPS) RWY 32, Amdt 1C.
29–Dec–22 ...	AL	Troy	Troy Muni At N Kenneth Campbell Fld.	2/9434	9/7/22	ILS OR LOC RWY 7, Amdt 11A.

[FR Doc. 2022–26721 Filed 12–8–22; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–737]

Schedules of Controlled Substances: Placement of Methiopropamine 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 *N*-methyl-1-(thiophen-2-yl)propan-2-amine (methiopropamine), including its salts, isomers, and salts of isomers in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. 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 methiopropamine.

DATES: *Effective date:* January 9, 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:

Legal Authority

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 adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[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. 21 U.S.C. 811(d)(3). In the event that the Secretary of HHS (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 are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General, by rule, may add to such a schedule 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 is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (DEA Administrator or Administrator). 28 CFR 0.100.

[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 Controlled Substances Act, with the concurrence of NIDA. 50 FR 9518 (March 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).

Background

Methiopropamine is a central nervous system (CNS) stimulant and is structurally related to the schedule II stimulants methamphetamine and amphetamine. Methiopropamine is not approved by the Food and Drug Administration for use in the United States. On March 16, 2017, the Commission on Narcotic Drugs voted to place *N*-methyl-1-(thiophen-2-yl)propan-2-amine (methiopropamine) in Schedule II of the 1971 Convention (CND Dec/60/8) during its 60th session.

DEA and HHS Eight Factor Analyses

On August 27, 2020, in accordance with 21 U.S.C. 811(b), and in response to DEA's November 20, 2018, request, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for methiopropamine. DEA reviewed HHS's evaluation and recommendation for schedule I placement, and all other relevant data, and conducted its own eight-factor analysis stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(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 of this rulemaking action at *https://www.regulations.gov,* under docket number "DEA–737."

Notice of Proposed Rulemaking To Schedule Methiopropamine

On September 2, 2021 (86 FR 49267), DEA published a notice of proposed rulemaking (NPRM) to permanently control methiopropamine in schedule I. Specifically, DEA proposed to add methiopropamine to 21 CFR 1308.11(f) (the stimulants category of schedule I). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before October 4, 2021. No requests for such a hearing were

received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on or before October 4, 2021.

Comments Received

In response to the NPRM, DEA received four comments. Three of the submissions were from individuals or anonymous commenters. Of these three, two commenters provided support for the NPRM, and one opposed the NPRM. A fourth comment was either submitted or posted to the wrong docket as it involved a different DEA rulemaking. As such, the fourth comment is outside the scope of this current scheduling action.

Support for NPRM

Two commenters were in support of this rulemaking. One stated that methiopropamine is a stimulant and a user can get high from it, so it should be a controlled substance. The second commenter stated that if there is not an accepted medical use, then it should be a schedule I substance.

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

Opposition to NPRM

One commenter opposed the NPRM to control methiopropamine as a schedule I drug. The commenter stated that scheduling methiopropamine will only expand the number of people in the United States who can be captured in the mass incarceration net. The commenter thought the approach should not be a criminal issue but a public health issue.

DEA Response: Substances are scheduled to protect the public health and provide safety for individuals. Thus, pursuant to 21 U.S.C. 811(a), the CSA authorizes DEA's Administrator, under authority delegated by the Attorney General, to control any drug or other substance if the Administrator finds that the 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).

Scheduling Conclusion

After consideration of the public comments, 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 methiopropamine. DEA is permanently scheduling methiopropamine as a controlled substance 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. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. *Methiopropamine has a high potential for abuse.*

Methiopropamine, similar to the schedule II stimulants amphetamine and methamphetamine, is a CNS stimulant with a high potential for abuse. Data from animal behavioral locomotor studies show that methiopropamine produces stimulation similar to that of methamphetamine. As HHS mentions, methiopropamine abuse in humans has been reported in at least 16 countries, including some countries in North America and Europe. Additionally, typical stimulant effects such as euphoria, psychomotor stimulation, and anxiety have been described from self-reports of methiopropamine abusers. These effects are similar to those of schedule II stimulants such as methamphetamine and amphetamine. These data collectively indicate that methiopropamine has a high potential for abuse similar to other schedule II stimulants such as amphetamine and methamphetamine.

2. *Methiopropamine currently has no accepted medical use in treatment in the United States.*

According to HHS, FDA has not approved a marketing application for a drug product containing methiopropamine for any therapeutic indication. As HHS states, there are also no clinical studies or petitioners that claim an accepted medical use in the United States. Thus, methiopropamine has no currently accepted medical use in treatment in the United States.[2]

3. *There is a lack of accepted safety for use of methiopropamine under medical supervision.*

The safety of methiopropamine or use under medical supervision has not been determined because it has no approved medical use in treatment in the United States and has not been investigated as a new drug. Therefore, there is a lack of accepted safety for use of methiopropamine under medical supervision.

Based on these findings, the Administrator concludes that methiopropamine (chemical name: *N*-methyl-1-(thiophen-2-yl)propan-2-amine), including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling Methiopropamine

Methiopropamine is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) methiopropamine, or who desires to handle methiopropamine 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. Any person who currently handles methiopropamine and is not registered with DEA must submit an application for registration and may not continue to handle methiopropamine, 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.

2. *Disposal of Stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held methiopropamine 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. Methiopropamine 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.* Methiopropamine is subject to schedule I security

[2] Although there is no evidence suggesting that methiopropamine 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 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).

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 methiopropamine must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of methiopropamine 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 methiopropamine 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 methiopropamine must take an inventory of methiopropamine on hand at that time, 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 methiopropamine) 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 methiopropamine) 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 methiopropamine, or products containing methiopropamine, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding methiopropamine 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 methiopropamine 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 methiopropamine 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 methiopropamine 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 and 13563 (Regulatory Planning and Review; Improving Regulation and 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 reaffirmed in E.O. 13563.

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.

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.

Regulatory Flexibility Act

The Administrator, 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 methiopropamine (chemical name: *N*-methyl-1-(thiophen-2-yl)propan-2-amine), including its salts, isomers, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. 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 methiopropamine.

According to HHS, methiopropamine has a 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 methiopropamine in the United States. Therefore, DEA estimates that no United States entity currently handles methiopropamine and does not expect any United States entity to handle methiopropamine in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect 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 the Government Accountability Office, the House, and the Senate.

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. Amend § 1308.11 by:

■ a. Redesignating paragraphs (f)(9) through (11) as (f)(10) through (12); and

■ b. Adding a new paragraph (f)(9).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(9) Methiopropamine (*N*-methyl-1-(thiophen-2-yl)propan-2-amine) 1478

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, 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. 2022–26805 Filed 12–8–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9969]

RIN 1545–BP01

Treatment of Special Enforcement Matters

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that except certain partnership-related items from the centralized partnership audit regime created by the Bipartisan Budget Act of 2015, and sets forth alternative rules that will apply to the examination of excepted items by the IRS. The centralized partnership audit regime does not apply to a partnership-related item if the item involves a special enforcement matter described in these regulations. Additionally, these regulations make changes to the existing centralized partnership audit regime regulations to account for changes to the Internal Revenue Code (Code) as well as changes that clarify those regulations. The regulations affect partnerships and partners to whom special enforcement matters apply.

DATES:

Effective date: These regulations are effective on December 9, 2022.

Applicability date: For dates of applicability, see §§ 301.6221(b)–1(f); 301.6225–1(i)(1); 301.6225–2(g)(1); 301.6225–3(e)(1); 301.6226–2(h)(1); 301.6241–3(g); 301.6241–7(j)

FOR FURTHER INFORMATION CONTACT: Jennifer M. Black of the Office of Associate Chief Counsel (Procedure and Administration), (202) 317–6834 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final amendments to the Procedure and Administration Regulations (26 CFR part 301) regarding special enforcement matters under section 6241(11) of the Code and the collection of amounts due under the centralized partnership audit regime pursuant to section 6241(7) of the Code. Section 6241(11) was enacted by section 206 of the Tax Technical Corrections Act of 2018, contained in Title II of Division U of the Consolidated Appropriations Act of 2018, Public Law 115–141 (TTCA). This document also contains several amendments to the final regulations on the centralized partnership audit regime published in TD 9844 (84 FR 6468) on February 27, 2019.

Section 1101(a) of the Bipartisan Budget Act of 2015, Public Law 114–74 (BBA) amended chapter 63 of the Code (chapter 63) by removing former subchapter C of chapter 63 effective for partnership taxable years beginning after December 31, 2017. Former subchapter C of chapter 63 contained the unified partnership audit and litigation rules enacted by the Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248 (TEFRA) that were commonly referred to as the TEFRA partnership procedures, or simply TEFRA. Section 1101(b) of the BBA removed subchapter D of chapter 63 and amended chapter 1 of the Code (chapter 1) by removing part IV of subchapter K of chapter 1, rules applicable to electing large partnerships, effective for partnership taxable years beginning after December 31, 2017. Section 1101(c) of the BBA replaced the TEFRA partnership procedures and the rules applicable to electing large partnerships with a centralized partnership audit regime that determines adjustments and, in general, determines, assesses, and collects tax at the partnership level. Section 1101(g) of the BBA set forth the effective dates for these statutory amendments, which are effective generally for returns filed for partnership taxable years beginning after December 31, 2017. On December 18, 2015, section 1101 of the BBA was amended by the Protecting Americans from Tax Hikes Act of 2015, Public Law 114–113 (PATH Act). The amendments under the PATH Act are effective as if included in section 1101 of the BBA, and therefore, subject to the effective dates in section 1101(g) of the BBA.

Enacted on March 23, 2018, the TTCA made a number of technical corrections to the centralized partnership audit regime, including adding sections 6241(11) (regarding the treatment of special enforcement matters) and 6232(f) (regarding the collection of the imputed underpayment and other amounts due from partners of the partnership in the event the amounts are not paid by the partnership) to the Code. The amendments to subchapter C of chapter 63 included in the TTCA are effective as if included in section 1101 of the BBA, and therefore, subject to the effective dates in section 1101(g) of the BBA.

On January 2, 2018, the Department of the Treasury (Treasury Department) and the IRS published in the **Federal Register** (82 FR 28398) final regulations under section 6221(b) providing rules

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO GA D Macon, GA [Amended]

Middle Georgia Regional Airport, Macon, GA
(Lat. 32°41′34″ N, long. 83°38′57″ W)
Robins AFB
(Lat. 32°38′25″ N, long. 83°35′31″ W)

That airspace extending upward from the surface to and including 2,900 feet MSL from the intersection of the Middle Georgia Regional Airport 210° bearing and the 5.5-mile radius of the Robins AFB Airport, clockwise along the 4.9-mile radius centered on Middle Georgia Regional Airport to the intersection of Middle Georgia Regional Airport 065° bearing and Robins AFB Airport 5.5-mile radius, counter-clockwise along the Robins AFB Airport 5.5-mile radius to the intersection of the Middle Georgia Regional Airport 055° bearing, directly across to the Middle Georgia Regional Airport 219° bearing and the intersection of the Robins AFB Airport 5.5-mile radius, counter-clockwise along the Robins AFB Airport 5.5-mile radius to the point of beginning. 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.

Paragraph 6002 Class E Surface Airspace

* * * * *

ASO GA E2 Macon, GA [Amended]

Middle Georgia Regional Airport, Macon, GA
(Lat. 32°41′34″ N, long. 83°38′57″ W)
Robins AFB
(Lat. 32°38′25″ N, long. 83°35′31″ W)

That airspace extending upward from the surface from the intersection of the Middle Georgia Regional Airport 210° bearing and the 5.5-mile radius of the Robins AFB Airport, clockwise along the 4.9-mile radius centered on Middle Georgia Regional Airport to the intersection of Middle Georgia Regional Airport 065° bearing and Robins AFB Airport 5.5-mile radius, counter-clockwise along the Robins AFB Airport 5.5-mile radius to the intersection of the Middle Georgia Regional Airport 055° bearing, directly across to the Middle Georgia Regional Airport 219° bearing and the intersection of the Robins AFB Airport 5.5-mile radius, counter-clockwise along the Robins AFB Airport 5.5-mile radius to the point of beginning. 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 GA E5 Macon, GA [Amended]

Middle Georgia Regional Airport, GA
(Lat. 32°41′34″ N, long. 83°38′57″ W)
Macon Downtown Airport
(Lat. 32°49′18″ N, long. 83°33′43″ W)
Robins AFB
(Lat. 32°38′25″ N, long. 83°35′31″ W)
Perry-Houston County Airport
(Lat. 32°30′38″ N, long. 83°46′02″ W)

That airspace extending upward from 700 feet above the surface within a 7.4-mile radius of Middle Georgia Regional Airport, and within a 7.5-mile radius of Macon Downtown Airport, a 7-mile radius of Robins AFB, and a 9.8-mile radius of Perry-Houston County Airport.

Issued in College Park, Georgia, on December 15, 2022.

Andreese C. Davis,

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

[FR Doc. 2022–27931 Filed 12–22–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–989]

Schedules of Controlled Substances: Temporary Placement of Etizolam, Flualprazolam, Clonazolam, Flubromazolam, and Diclazepam in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

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

DATES: This notice of intent is effective December 23, 2022.

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

SUPPLEMENTARY INFORMATION: The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order [1] (in the form of a temporary amendment) to add the following five substances, including their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, to schedule I under the Controlled Substances Act (CSA):

- 4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (commonly known as etizolam),
- 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (commonly known as flualprazolam),
- 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (commonly known as clonazolam),
- 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (alternate chemical name: 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-[1,2,4]triazolo[4,3-*a*][1,4]benzodiazepine and commonly known as, flubromazolam), and
- 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[*e*][1,4]diazepin-2-one (commonly known as diclazepam).

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

The temporary scheduling order will be published in the **Federal Register** on or after January 23, 2023.

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. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Administrator may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308.

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to place a substance in schedule I of the CSA temporarily (*i.e.*, to issue a temporary scheduling order). 21 U.S.C. 811(h)(4). The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[2] by letter dated October 25, 2021, regarding etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. The Assistant Secretary responded to this notice by a letter dated January 3, 2022, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. The Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I. Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam 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 five benzodiazepine substances.

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

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

Five Benzodiazepine Substances: Etizolam, Flualprazolam, Clonazolam, Flubromazolam, and Diclazepam

The dramatic increase in trafficking and abuse associated with novel psychoactive substances (NPS) of the benzodiazepine class in the United States has become a national public health concern in recent years. The availability of NPS benzodiazepine substances in the illicit drug market continues to pose an imminent hazard to the public safety. The Centers for Disease Control and Prevention (CDC) highlights this issue in their Morbidity and Mortality Weekly Report (MMWR) published on August 27, 2021.[3] CDC indicated that, from April 2019 to June 2020, prescription and illicit benzodiazepine-involved overdose deaths increased by 21.8% and 519.6% respectively. Additionally, benzodiazepines were involved in nearly 7,000 overdose deaths in 23 states from January 2019 to June 2020, accounting for 17% of all drug overdose deaths. Adverse health effects associated with the abuse of such substances known collectively as the "designer benzodiazepines," their continued evolution, and increased popularity of these substances have been a serious concern in recent years. The increase in the co-use of opioids with the "designer benzodiazepines" has become a particular concern as the United States continues to experience an unprecedented epidemic of opioid misuse and abuse. CDC's 2021 MMWR further states that between January and June 2020, 92.7% of benzodiazepine-involved deaths also involved opioids and 66.7% involved illicitly manufactured fentanyl. It is well known that the combination of benzodiazepines with opioids substantially enhances the potential for lethality. Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam are benzodiazepine substances recently identified on the illicit drug market in the United States.

The abuse of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam has been associated with numerous fatalities in recent years in the United States. The positive identification of these five substances in post-mortem cases is a serious concern to the public safety. Additionally, law enforcement data indicate that the substances at issue here have significant presence in the United States illicit drug market. In light of the law enforcement encounters and fatalities associated with the abuse of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam these substances pose an imminent hazard to public safety.

Available data and information for etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam, summarized below, indicate that these substances have high potential for abuse, no currently accepted medical use in treatment in the United States, and lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at *www.regulations.gov* under Docket Number DEA–989.

Factor 4. History and Current Pattern of Abuse

The chemical synthesis of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam were previously reported in the scientific literature; however, the research did not lead to any medically approved products in the United States. Since 2012, numerous synthetic drugs belonging to the benzodiazepine class have begun to emerge in the illicit drug market as evidenced by the identification of these drugs in forensic drug exhibits from the National Forensic Laboratory Information System (NFLIS),[4] and toxicology samples.

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

[3] Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report: Trends in Nonfatal and Fatal Overdoses Involving Benzodiazepines—38 States and the District of Columbia, 2019–2020. Vol. 70, No. 34. August 27, 2021.

[4] NFLIS represents an important resource in monitoring illicit drug trafficking, including the

Beginning in 2012, etizolam emerged on the illicit synthetic drug market as evidenced by its identification in drug seizures in the United States. In recent years, there has been a rise in the recreational use of etizolam. As evidenced by their identification in NFLIS-Drug, diclazepam emerged in the United States' illicit drug market in 2014, flubromazolam and clonazolam in 2015, and flualprazolam in 2017. While these substances are not approved for medical use in the United States, etizolam is approved for medical use in Italy, India, and Japan.[5] In a letter dated January 3, 2022, the Assistant Secretary informed DEA that there are no INDs or FDA-approved NDAs for etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in the United States. Hence, there are no legitimate channels for these substances as marketed drug products in the United States. These five benzodiazepine substances are likely to be abused in the same manner as other sedative hypnotics. They have been identified in tablet form, as white to beige powders, or in liquid forms, typically of unknown purity or concentration.

Based on data from NFLIS, law enforcement often encountered etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in counterfeit pills, liquid, or powder. Substances often found in combination with some of these benzodiazepines include substances of abuse such as heroin (schedule I), fentanyl (schedule II), other substances structurally related to fentanyl (schedule I and other non-controlled substances), other benzodiazepines (both FDA-approved schedule IV benzodiazepines and other novel non-controlled benzodiazepines), and tramadol (schedule IV). Evidence suggests that individuals are using these substances to obtain "legal highs" or to self-medicate. Information gathered from case histories and autopsy findings shows that deaths involving etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam were predominantly associated with poly-drug use.

Factor 5. Scope, Duration, and Significance of Abuse

Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam are novel benzodiazepines, and evidence suggests they are abused for their sedative effects (see Factor 6). In death investigations involving polysubstance use, the co-appearance of benzodiazepines and opioids in toxicological analysis was common. Between August 2019 and January 2020, flualprazolam and etizolam were identified in seven and six postmortem blood specimens, respectively, out of 18 deaths associated with the abuse of isotonitazene, a schedule I opioid that was recently controlled. These cases corresponded to four states—Illinois (9), Indiana (7), Minnesota (1), and Wisconsin (1). Most (n = 12) of the decedents were male. The ages ranged from 24 to 66 years old with an average age of 41 years.[6]

In another recent publication, 20 forensic postmortem cases were reviewed and analyzed for the presence of metonitazine, NPS benzodiazepines, and opioids. Results indicated that NPS benzodiazepines were the most commonly identified substances found in combination with metonitazene. Specifically, clonazolam was positively identified in four cases, etizolam in two cases, flualprazolam in two cases, and pyrazolam in one case.[7] Law enforcement encounters of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam as reported to NFLIS (Federal, State and local laboratories) include 34,781 drug reports since 2014 (queried 01/13/2022). NFLIS-Drug registered three encounters of etizolam in 2012 (first year of encounter) and 3,022 reports in 2021. Flualprazolam was first encountered in 2017 when one report was identified in NFLIS-Drug, and then in 2021, 1,305 encounters were reported. A similar trend was seen with clonazolam. During 2015 (its first year of encounter), 57 cases were reported in NFLIS-Drug, while 3,994 drug reports were identified in 2021. NFLIS-Drug registered five diclazepam encounters in 2014 (its first year of encounter) and 54 encounters in 2021. Flubromazolam encounters totaled 14 in 2015 (its first year of encounter) and 414 in 2021.

The population likely to abuse etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam appears to be the same as those abusing prescription benzodiazepines, barbiturates, and other sedative hypnotic substances. This is evidenced by drug user reports associated with these substances. Because abusers of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam are likely to obtain these substances through unregulated sources, the identity, purity, and quantity of these substances are uncertain and inconsistent, thus posing significant adverse health risks to the end user.

The misuse and abuse of benzodiazepines have been demonstrated and are well-characterized.[8] According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[9] as of 2020, an estimated 4.8 million people aged 12 years or older misused prescription benzodiazepines in the past year. This included 1.1 million young adults aged 18 to 25, 3.5 million adults aged 26 or older, and 157,000 adolescents aged 12 to 17. This population abusing prescription benzodiazepines is likely to be at risk of abusing etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. Individuals who initiate

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

[5] Although there is no evidence suggesting that etizolam, flualprazolam, clonazolam, flubromazolam, or diclazepam 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 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).

[6] Krotulski AJ, Papsun DM, Kacinko SL, and Logan BK. Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. Journal of Analytical Toxicology, 2020, 44(6):521–530.

[7] Krotulski AJ, Papsun DM, Walton SE, and Logan BK. Metonitazene in the United States-Forensic toxicology assessment of a potent new synthetic opioid using liquid chromatography mass spectrometry. Drug Testing Analysis, 2021, 13(10):1697–1711.

[8] Votaw VR, Geyer R, Rieselbach MM, and McHugh RK. The epidemiology of benzodiazepine misuse: A systematic review. Drug Alcohol Dependence, 2019, 200:95–114.

[9] The National Survey on Drug Use and Health (NSDUH), formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.*, ever used), past year, and past month abuse or dependence. The 2020 NSDUH annual report is available at *https://www.samhsa.gov/data/* (last accessed February 8, 2022).

use of these five substances (*i.e.*, use a drug for the first time) are likely to be at risk of developing substance use disorder, overdose, and death at rates similar to that of other sedative hypnotics (*e.g.*, alprazolam, clonazolam, etc.). Law enforcement or toxicology reports demonstrate that the five substances at issue are being distributed and abused.

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

The increase in benzodiazepine-related overdose deaths in the United States has been exacerbated recently by the availability of NPS benzodiazepines in the illicit drug market. Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam have been described as derivatives of other known benzodiazepines, each possessing various degrees of potency. Evidence suggests these substances are being abused for their sedative/hypnotic effects (see DEA 3-Factor Analysis). Public health risks associated with the five substances at issue here relate to their pharmacological similarities with known benzodiazepines. Thus, risk to the public health is associated with adverse reactions in humans, which are expected to include CNS depressant-like effects, such as slurred speech, ataxia, altered mental state, and respiratory depression.

Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam have been increasingly identified in toxicology reports, death investigations, and driving under the influence of drugs (DUID) cases since their first appearance in law enforcement seizures. According to the Center for Forensic Science Research and Education (CFSRE), a non-profit organization in collaboration with the Department of Justice and Centers for Disease Control, between 2020 and 2021, etizolam was the most identified NPS benzodiazepine accounting for 697 total toxicology cases in 2020, many of which were co-identified with fentanyl. In 2021, etizolam was identified in 1,012 toxicology cases, while flualprazolam, clonazolam, flubromazolam, and diclazepam were associated with 432, 331, 170, and four toxicology cases, respectively (CSFRE Quarterly Trend Reports: NPS Benzodiazepines in the United States).

Death investigations associated with four of the five NPS benzodiazepines at issue here have increased in recent years. In a 2021 publication by the Orange County Crime Lab in Santa Ana, California, flualprazolam was identified as serving a contributory role in the death of 13 of 24 cases analyzed in the study.[10] In another recently published study, between August 2019 and January 2020, flualprazolam and etizolam were identified in seven and six postmortem blood specimens respectively, out of 18 deaths associated with the abuse of isotonitazene, a schedule I opioid.[11] Then, a study published in 2021 which compiled data from 254 reports published between 2008 and 2021, identified: 33 deaths associated with etizolam, 20 flualprazolam-related deaths, six emergency department (ED) visits associated with clonazolam, 14 flubromazolam-related ED visits, and one death, 12 DUID cases, and four ED visits associated with diclazepam.[12] Additionally, in 2020, the European Monitoring Centre for Drugs and Drug Addiction reported 34 deaths associated with diclazepam use, which were determined through the analysis of biological samples.[13] Furthermore, the National Poison Data System reported that between January 2014 and December 2017, clonazolam was the second most common benzodiazepine associated with poison control center calls, accounting for 50 incidents.[14]

Impaired driving is another risk factor associated with the use and abuse of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. In a recent published report from the Sedgwick County Regional Forensic Science Center in Wichita, Kansas, 12 DUID case samples were analyzed. Etizolam was positively identified in three cases, while flubromazolam was identified in nine of these cases.[15] In a 2021 publication, similar involvement of flubromazolam in drug-impaired driving was reported in Canada where flubromazolam was detected in 10 percent of 113 case samples.[16] Diclazepam has also been implicated in DUID cases domestically and internationally. In a Norwegian study conducted between July 2013 and May 2016, diclazepam was identified in 15 of 77 analyzed samples taken from impaired drivers and individuals involved in other criminal offenses. Then, in 2019, a study of Norwegian drivers was conducted using 575 samples taken predominantly from intoxicated drivers and individuals who committed other criminal offenses.[17] Notably, 334 samples were found to contain diclazepam. Additionally, in a 2021 publication, researchers identified 22 samples that tested positive for flualprazolam in samples obtained from DUID investigations between August 2018 and September 2020.[18]

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 etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam pose imminent hazards to public safety. DEA is not aware of any currently accepted medical uses for these substances in the United States. As required by 21 U.S.C. 811(h)(4), the Administrator transmitted to the Assistant Secretary for Health, via a letter dated October 25, 2021, notice of her intent to place etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in schedule I on a temporary basis. HHS had no objection to the temporary placement of these substances in schedule I.

Conclusion

This notice of intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered

[10] Ha HH and Mata DC. Flualprazolam distribution in postmortem samples. Journal of Forensic Sciences, 2022, 67(1): 297–308.

[11] Krotulski AJ, Papsun DM, Kacinko SL, and Logan BK. Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. Journal of Analytical Toxicology, 2020, 44(6): 521–530.

[12] Brunetti P, Giorgetti R, Tagliabracci A, Huestis MA, Busardò FP. Designer Benzodiazepines: A Review of Toxicology and Public Health Risks. Pharmaceuticals (Basel). 2021 Jun 11;14(6):560.

[13] EMCDDA (2020). EMCDDA response to WHO request for information on the new psychoactive substances, eutylone, α-PHiP, 4F-furanylfentanyl, 2-methyl-AP-237, and, diclazepam.

[14] Carpenter JE, Murray BP, Dunkley C, Kazzi ZN, Gittinger MH. Designer benzodiazepines: a report of exposures recorded in the National Poison Data System, 2014–2017. Clin Toxicol (Phila). 2019 Apr;57(4):282–286.

[15] Rohrig TP, Osawa KA, Baird TR, Youso KB. Driving Impairment Cases Involving Etizolam and Flubromazolam. J Anal Toxicol. 2021 Feb 6;45(1):93–98.

[16] Vaillancourt L, Viel E, Dombrowski C, Desharnais B, Mireault P. Drugs and driving prior to cannabis legalization: A 5-year review from DECP (DRE) cases in the province of Quebec, Canada. Accid Anal Prev. 2021 Jan;149:105832.

[17] Heide G, Høiseth G, Middelkoop G, and Øiestad ÅML. Blood concentrations of designer benzodiazepines: Relation to impairment and findings in forensic cases. Journal of Analytical Toxicology, 2020, 44(8): 905–914.

[18] Ha HH and Mata DC. Flualprazolam distribution in postmortem samples. Journal of Forensic Sciences, 2022, 67(1): 297–308.

available data and information, herein set forth the grounds for her determination that it is necessary to temporarily schedule etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in schedule I of the CSA and finds that placement of these substances in schedule I is necessary to avoid an imminent hazard to the public safety.

The temporary placement of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before January 23, 2023. Because the Administrator hereby finds this temporary scheduling order is necessary to avoid an imminent hazard to the public safety, it will take effect on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). The Administrator intends to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon the temporary order's publication, etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam will then be subject to the CSA's schedule I regulatory controls and to administrative, civil, and criminal sanctions applicable to their manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession.

The CSA sets forth specific criteria for scheduling drugs or other substances. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties appropriate process and the government any additional relevant information needed to make determinations. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Analyses

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

Inasmuch as this section directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the **Federal Register** a notice of intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. The APA expressly differentiates between orders and rules, as it defines an "order" to mean a "final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*" 5 U.S.C. 551(6) (emphasis added). The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in section 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

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

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

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

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this notice of intent is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget, as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866.

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

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11, add paragraphs (h)(63) through (67) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(63) 4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: etizolam) 2780
(64) 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flualprazolam) 2785
(65) 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: clonazolam) 2786
(66) 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flubromazolam) 2788
(67) 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[*e*][1,4]diazepin-2-one, its salts, isomers, and salts of isomers (Other name: diclazepam) 2789

Signing Authority

This document of the Drug Enforcement Administration was signed on December 12, 2022, 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. 2022–27278 Filed 12–22–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0155; FRL–10503–01–R4]

Air Plan Approval; Tennessee; Packaging Corporation of America Nitrogen Oxides SIP Call Alternative Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to conditionally approve a source-specific State Implementation Plan (SIP) revision submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), through a letter dated June 29, 2021, which would establish alternative monitoring, recordkeeping, and reporting requirements under the Nitrogen Oxides (NO_X) SIP Call.

DATES: Comments must be received on or before January 23, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2022–0155 at *www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Steven Scofield, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9034. Mr. Scofield can also be reached via electronic mail at *scofield.steve@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Under Clean Air Act (CAA or Act) section 110(a)(2)(D)(i)(I), also called the good neighbor provision, states are required to address the interstate transport of air pollution. Specifically, the good neighbor provision requires that each state's implementation plan contain adequate provisions to prohibit air pollutant emissions from within the state that will significantly contribute to nonattainment of the national ambient air quality standards (NAAQS), or that will interfere with maintenance of the NAAQS, in any other state.

On October 27, 1998 (63 FR 57356), EPA finalized the "Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone" (NO_X SIP Call). The NO_X SIP Call required eastern states, including Tennessee, to submit SIPs limiting emissions of ozone season NO_X by implementing statewide emissions budgets. The NO_X SIP Call addressed the good neighbor provision for the 1979 ozone NAAQS and was designed to mitigate the impact of transported NO_X emissions, one of the precursors of ozone.[1] EPA developed the NO_X Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. This trading program allowed the following sources to participate in a regional cap and trade program: generally, electricity generating units (EGUs) with capacity greater than 25 megawatts (MW); and large industrial non-EGUs, such as

[1] As originally promulgated, the NO_X SIP Call also addressed good neighbor obligations under the 1997 8-hour ozone NAAQS, but EPA subsequently stayed and later rescinded the rule's provisions with respect to that standard. *See* 65 FR 56245 (September 18, 2000); 84 FR 8422 (March 8, 2019).