

thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5026 to subpart F to read as follows:

§ 876.5026 Non-implanted electrical stimulation device for management of premature ejaculation.

(a) **Identification.** A non-implanted electrical stimulation device for management of premature ejaculation is intended to be used in patients with premature ejaculation by delivery of electrical stimulation to the perineal muscles and nerves.

(b) **Classification.** Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Mechanical performance;

(ii) Electrical stimulation parameters; and

(iii) Battery performance.

(4) Performance testing must support shelf life by demonstrating continued device functionality over the identified shelf life.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include:

(i) Specific instructions regarding safe placement and correct use of the device;

(ii) Warning(s) against use by patients with active implanted medical devices; and

(iii) A shelf life.

Dated: May 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-12082 Filed 6-3-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-568]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE), including its salts, isomers, and salts of isomers

whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act 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, methoxetamine.

DATES: Effective July 6, 2022.

FOR FURTHER INFORMATION CONTACT:

Terrence L. Boos, Drug & 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 indicating that a drug or other substance has been added to a specific schedule, the Secretary of the Department Health and Human Services (HHS),¹ after consultation with the Attorney General, shall 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 of HHS did not consult with the Attorney General, and

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).

² 21 U.S.C. 811(d)(3).

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), the Attorney General may, by rule, schedule or transfer between any schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes the findings prescribed by 21 U.S.C. 812(b) to schedule the drug or other substance. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (DEA).³

Background

Methoxetamine, also known as 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one or 2-(3-methoxyphenyl)-2-(N-ethylamino)cyclohexanone or MXE, belongs to the arylcyclohexylamine class of drugs with dissociative anesthetic and hallucinogenic properties, similar to phencyclidine (PCP), a schedule II controlled substance, and ketamine, a schedule III controlled substance. Methoxetamine has no approved medical use in the United States. In March 2016, the Commission on Narcotic Drugs (CND) voted to place methoxetamine in Schedule II of the 1971 Convention (CND Dec/59/6) during its 59th Session due to its dependence and abuse potential.

DEA and HHS Eight Factor Analyses

On April 14, 2018, in accordance with 21 U.S.C. 811(b), and in response to DEA's December 30, 2014, request and April 14, 2017, submission of additional data, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for methoxetamine. 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-568.

³ 28 CFR 0.100.

Notice of Proposed Rulemaking To Schedule Methoxetamine

On December 7, 2021 (86 FR 69187), DEA published a notice of proposed rulemaking (NPRM) to permanently control methoxetamine in schedule I. Specifically, DEA proposed to add methoxetamine to the hallucinogenic substances list under 21 CFR 1308.11(d). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before February 7, 2022. 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 February 7, 2022.

Comments Received

DEA received one comment that recognized the dangers and public health risks, and fully supported the placement of methoxetamine in schedule I.

DEA Response: DEA appreciates this comment in support of this rulemaking.

Scheduling Conclusion

After consideration of the public comment, scientific and medical evaluation and accompanying recommendation of 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 methoxetamine. DEA is permanently scheduling methoxetamine 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 specifies 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 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) Methoxetamine has a high potential for abuse that is comparable to other scheduled substances such as the ethylamine analog of phencyclidine (PCE; schedule I), the thiophene analog of phencyclidine (TCP; schedule I), phencyclidine (PCP; schedule II), and ketamine (schedule III);

(2) Methoxetamine has no currently accepted medical use in treatment in the United States. There are no approved New Drug Applications for methoxetamine and no known therapeutic applications for methoxetamine in the United States.

Therefore, methoxetamine has no currently accepted medical use in treatment in the United States.⁴

(3) There is a lack of accepted safety for use of methoxetamine under medical supervision. Because methoxetamine 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. Therefore, there is a lack of accepted safety for use of methoxetamine under medical supervision.

Based on these findings, the Administrator of DEA concludes that methoxetamine 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.⁵

Requirements for Handling Methoxetamine

Methoxetamine 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, methoxetamine 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 methoxetamine and is not registered with DEA must submit an application for registration and may not continue to handle methoxetamine, 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.

⁴ Although there is no evidence suggesting that methoxetamine 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).

⁵ 21 U.S.C. 812(b)(1).

2. Disposal of stocks. Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held methoxetamine 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. Methoxetamine 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. Methoxetamine 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 methoxetamine 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 methoxetamine 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 methoxetamine 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 methoxetamine must take an inventory of methoxetamine 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 methoxetamine) 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 methoxetamine) 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 methoxetamine, or products containing methoxetamine, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding methoxetamine 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 methoxetamine 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 methoxetamine 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 methoxetamine 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 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

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 methoxetamine (chemical name: 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and/or criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle methoxetamine.

Based on the review of HHS’s scientific and medical evaluation and all other relevant data, DEA determined that methoxetamine 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 methoxetamine in the United States. Therefore, this final 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 both Houses of Congress and to the Comptroller General.

(100) 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE) 7286

* * * * *

Anne Milgram,
Administrator.

[FR Doc. 2022-11933 Filed 6-3-22; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 25A, 33, 34, and 35

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of Web General Licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing four general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GL 25A, GL 33, GL 34, and GL 35, each of which was previously issued on OFAC's website.

DATES: GL 25A, GL 33, GL 34, and GL 35 were each issued on May 8, 2022. See **SUPPLEMENTARY INFORMATION** of this publication for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202-622-2480; Assistant Director for Regulatory Affairs, 202-622-4855; or Assistant Director for Sanctions Compliance & Evaluation, 202-622-2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are

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:

(100) 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE) 7286

available on OFAC's website:
www.treas.gov/ofac.

Background

OFAC issued GL 25A, GL 33, GL 34, and GL 35 on May 8, 2022 on its website to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587. GL 25A does not contain an expiration date. GL 33 expires at 12:01 a.m. eastern daylight time, June 7, 2022. GL 34 expires at 12:01 a.m. eastern daylight time, July 7, 2022. GL 35 expires at 12:01 a.m. eastern daylight time, August 20, 2022. The texts of GLs 25A, 33, 34, and 35 are provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations 31 CFR Part 587

GENERAL LICENSE NO. 25A

Authorizing Transactions Related to Telecommunications and Certain Internet-Based Communications

(a) Except as provided in paragraph (c) of this general license, all transactions ordinarily incident and necessary to the receipt or transmission of telecommunications involving the Russian Federation that are prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), are authorized.

(b) Except as provided in paragraph (c) of this general license, the exportation or reexportation, sale, or supply, directly or indirectly, from the United States or by U.S. persons, wherever located, to the Russian Federation of services, software, hardware, or technology incident to the exchange of communications over the internet, such as instant messaging, videoconferencing, chat and email, social networking, sharing of photos, movies, and documents, web browsing,

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

■ 2. In § 1308.11, add paragraph (d)(100) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

blogging, web hosting, and domain name registration services, that is prohibited by the RuHSR, is authorized.

(c) This general license does not authorize:

(1) The opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under Executive Order (E.O.) 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions*;

(2) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation;

(3) Any transactions prohibited by E.O. 14066 or E.O. 14068; or

(4) Any transactions involving Joint Stock Company Channel One Russia, Joint Stock Company NTV Broadcasting Company, or Television Station Russia-1, unless separately authorized.

(d) Effective May 8, 2022, General License No. 25, dated April 7, 2022, is replaced and superseded in its entirety by this General License No. 25A.

Note to General License No. 25A. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies, including export, reexport, and transfer (in-country) licensing requirements maintained by the Department of Commerce's Bureau of Industry and Security under the Export Administration Regulations, 15 CFR parts 730-774.

Andrea M. Gacki

Director, Office of Foreign Assets Control
Dated: May 8, 2022