

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-509]

Schedules of Controlled Substances: Placement of *para*-Methoxymethamphetamine (PMMA) 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 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine (*para*-methoxymethamphetamine, PMMA), 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, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle PMMA.

DATES: Effective July 26, 2021.

FOR FURTHER INFORMATION CONTACT: 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 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 did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, schedule or transfer between 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). 28 CFR 0.100.

Background

para-Methoxymethamphetamine (PMMA) is a substituted phenethylamine and shares structural similarity to methamphetamine, a schedule II controlled substance, and *para*-methoxyamphetamine (PMA), a schedule I controlled substance. PMMA shares a similar pharmacological profile with 3,4-methylenedioxyamphetamine (MDMA or ecstasy), a schedule I controlled substance with high potential for abuse. Data obtained from preclinical studies show that, similar to MDMA, PMMA's effects are mediated by monoaminergic (dopamine, norepinephrine, and serotonin) transmission, mostly via activation of the serotonergic system. In animals, PMMA mimics MDMA in producing discriminative stimulus effect, which is indicative of similar subjective effects. Law enforcement has encountered PMMA on the recreational drug market where it is sold as "ecstasy," either alone or in combination with MDMA or PMA for oral consumption. For many years, PMMA has been involved in non-fatal and fatal overdoses, primarily in Europe. PMMA has no accepted medical

Administration (FDA) and the National Institute on Drug Abuse (NIDA). FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, March 8, 1985. The Secretary 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.

use in treatment in the United States. In March 2016, the Commission on Narcotic Drugs (CND) voted to place PMMA in Schedule I of the 1971 Convention (CND Dec/59/3) during its 59th Session due to its dependence and abuse potential.

DEA and HHS Eight Factor Analyses

On December 18, 2018, in accordance with 21 U.S.C. 811(b), and in response to DEA's April 7, 2017 request, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for PMMA. DEA reviewed HHS' evaluation and recommendation for schedule I placement, 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. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS 8-Factor analyses are available in their entirety under the tab "Supporting Documents" of the public docket for this action at <http://www.regulations.gov> under Docket Number "DEA-509."

Notice of Proposed Rulemaking to Schedule PMMA

On May 15, 2020 (85 FR 29359), DEA published a notice of proposed rulemaking (NPRM) to permanently control PMMA in schedule I. Specifically, DEA proposed to add PMMA to the hallucinogenic substances list under 21 CFR 1308.11(d), and assign paragraph number 79 under paragraph (d) to PMMA. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before June 15, 2020. 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 June 15, 2020. DEA did not receive any comments.

Scheduling Conclusion

After consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of PMMA. DEA is permanently scheduling PMMA 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

¹ As discussed in a memorandum of understanding entered into by the Food and Drug

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 Acting Administrator of DEA (Acting Administrator), pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) The Drug or Substance Has a High Potential for Abuse

PMMA has a mechanism of action similar to that of MDMA, a schedule I controlled substance. Similar to MDMA, PMMA increases levels of monoamines, specifically DA and 5-HT, in the brain reward circuitry. Data from animal studies demonstrate that PMMA fully substitutes for the discriminative stimulus effect of MDMA, which is indicative of similar subjective effects. Although there is currently no data that has directly assessed the psychological or physiological dependence liability of PMMA, its pharmacological similarities to MDMA suggest it likely has low physical dependence liability. Evidence demonstrates that users of PMMA are often seeking MDMA, which may be mixed with PMMA. PMMA shares a pharmacological mechanism of action and psychoactive effects similar to the schedule I controlled substance MDMA and therefore has a high potential for abuse.

(2) The Drug or Substance Has No Currently Accepted Medical Use in Treatment in the United States

According to HHS, the Food and Drug Administration (FDA) has not approved any marketing application for a drug product containing PMMA for any indication. In addition, there are no clinical studies or petitioners that have claimed an accepted medical use of PMMA in the United States. Thus, PMMA has no currently accepted medical use in treatment in the United States.²

² Although there is no evidence suggesting that PMMA has a currently accepted medical uses 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).

(3) There is a Lack of Accepted Safety for Use of the Drug or Substance Under Medical Supervision

The safety of PMMA for 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 PMMA under medical supervision.

Based on these findings, the Acting Administrator concludes that PMMA as well as its salts, isomers, and salts of isomers whenever the existence of such isomers and salts is possible within the specific chemical designation warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Summary of Minor Change in the Final Rule

As discussed in the above NPRM section, DEA proposed to place PMMA in 21 CFR 1301.11(d) as paragraph number 79. Since the publication of this NPRM, DEA has issued several final rules which updated the numbering of listed hallucinogenic substances in paragraph (d). As a result, this final rule assigns paragraph number 88 to PMMA.

Requirements for Handling PMMA

PMMA 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 of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, PMMA must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle PMMA must surrender all quantities of currently held PMMA, or transfer all quantities of currently held PMMA to a person registered with DEA. PMMA 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.* PMMA is subject to schedule I security requirements and must be handled and stored pursuant to

21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling PMMA 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 PMMA 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 PMMA 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 PMMA must take an inventory of PMMA 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 becomes registered with DEA must take an initial inventory of all stocks of controlled substances (including PMMA) 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 PMMA) 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 PMMA, or products containing PMMA, 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 PMMA 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 PMMA must comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

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

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

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (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 (OMB) 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.

Regulatory Flexibility Act

The Acting 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 PMMA (chemical name 1-(4-methoxyphenyl)-N-methylpropan-2-amine), 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 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 PMMA.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that PMMA 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 PMMA in the United States. Therefore, DEA estimates that no United States entity currently handles PMMA and does not expect any United States entity to handle PMMA 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

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 et seq., DEA has determined and certifies that this action would not result in any Federal

mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501-3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to the Government Accountability Office, the House, and the Senate under the CRA.

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 adding paragraph (d)(88) to read as follows:

§ 1308.11 Schedule I.

* * * * *
(d) * * *

(88) 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-methoxymethamphetamine, PMMA) (1245)

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D. Christopher Evans, Acting Administrator.

[FR Doc. 2021-13460 Filed 6-24-21; 8:45 am]

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