Rules and Regulations

Federal Register
Vol. 91, No. 181
Monday, September 21, 2026

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1155]

Schedules of Controlled Substances: Placement of Diphenidine 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 the substance diphenidine (1-(1,2-diphenylethyl)piperidine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. 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 diphenidine.

DATES: *Effective date:* October 21, 2026.

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

SUPPLEMENTARY INFORMATION: In this final rule, the Drug Enforcement Administration (DEA) permanently schedules diphenidine (1-(1,2-diphenylethyl)piperidine) in schedule I of the Controlled Substances Act (CSA), 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.

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of Health and Human Services (Secretary),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the CSA and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of DEA pursuant to 28 CFR 0.100) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

Diphenidine (1-(1,2-diphenylethyl)piperidine) is a dissociative hallucinogen of the 1,2-diarylethylamine class that has been identified in the United States' illicit drug market. It was first synthesized in 1924 but not encountered for recreational use until 2014. Diphenidine has no approved medical use in the United States.

On June 10, 2021, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 64th Session in April 2021, voted to place diphenidine in Schedule II of the 1971 Convention (CND Decision 64/5). As a signatory to the 1971 Convention, the United States is required, by scheduling under the CSA, to place appropriate controls on diphenidine to meet the minimum requirements of the treaty.

Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for diphenidine, discussed in the above legal authority section, were not followed, DEA is utilizing the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control diphenidine. Such scheduling would satisfy the United States' international obligations.

DEA and HHS Eight-Factor Analyses

On November 26, 2022, in accordance with 21 U.S.C. 811(b), and in response to DEA's January 24, 2022, request, the Department of Health and Human Services (HHS) provided to DEA a scientific and medical evaluation and scheduling recommendation for diphenidine. 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. 812(b)(1), that this substance warrants control in schedule I. Both DEA's 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 DEA1155.

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. *Memorandum of Understanding with the National Institute on Drug Abuse,* 50 FR 9518 (Mar. 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS (Assistant Secretary) the authority to make domestic drug scheduling recommendations. *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91–513, As Amended; Delegation of Authority,* 58 FR 35460 (July 1, 1993).

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

Notice of Proposed Rulemaking To Schedule Diphenidine

On May 26, 2026, DEA published a notice of proposed rulemaking (NPRM) to permanently control diphenidine in schedule I.[3] Specifically, DEA proposed to add diphenidine to the list of hallucinogenic substances under 21 CFR 1308.11(d). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA's regulations on or before June 25, 2026. DEA did not receive any requests for such a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before June 25, 2026.

Comments Received

DEA received two comments from individuals in response to the NPRM for the placement of diphenidine into schedule I of the CSA. One commenter supported the placement of diphenidine in schedule I of the CSA, whereas the second commenter was against the placement of diphenidine in schedule I of the CSA.

Support of Rulemaking: DEA received one comment in support of the placement of diphenidine in schedule I.

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

Opposition to Rulemaking: The other commenter recognized concerns regarding misuse and public safety related to diphenidine, while asserting that placing diphenidine in schedule I may discourage further scientific and medical research with diphenidine. The commenter suggested that DEA consider a less restrictive schedule that ''would maintain regulatory oversight while facilitating legitimate scientific research.''

DEA Response: DEA appreciates this comment and would like to provide further clarification regarding the control of diphenidine. Diphenidine has been placed under international control. In order to comply with treaty obligations, DEA must place diphenidine under the most appropriate schedule, taking into consideration all appropriate scientific data. Additionally, as set forth in the NPRM, diphenidine has no currently accepted medical use in treatment in the United States. Therefore, diphenidine must be placed in schedule I of the CSA along with other substances which have no currently accepted medical use, lack accepted safety for use under medical supervision, and possess a high potential for abuse. With respect to research for potential medical use, the placement of substances in schedule I of the CSA does not preclude research on these substances.[4] Those wishing to conduct research on schedule I substances may do so by registering with the DEA.[5]

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying scheduling recommendations from HHS, and its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of diphenidine. As such, DEA is permanently scheduling diphenidine as a controlled substance under schedule I of the CSA. The permanent scheduling of diphenidine fulfills the United States' obligations as a party to the 1971 Convention.

Determination of Appropriate Schedule

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

(1) Diphenidine's pharmacological profile, including its high binding affinity and function as an antagonist at the *N*-methyl-D-aspartate (NMDA) receptor, is indicative that it has a high potential for abuse. Binding and antagonism to the NMDA receptor are also characteristic of and believed to be important in the subjective and mind-altering effects of other dissociative drugs, such as MXE, PCP, and ketamine, all known drugs that are abused. Published case reports support that the subjective effects and use patterns are similar to other NMDA receptor antagonists that have known high abuse.

(2) Diphenidine is not legally marketed in the United States. As noted in the HHS's review, diphenidine is not FDA-approved for any indication. There are no known medically approved uses worldwide at this time. There is no evidence that diphenidine has a currently accepted medical use in treatment in the United States.[6]

(3) Because diphenidine has no approved medical use and has not been thoroughly investigated as a new drug, its safety for use under medical supervision is not determined. Thus, there is a lack of accepted safety for use of this substance under medical supervision.

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

[3] *Schedules of Controlled Substances: Placement of Diphenidine in Schedule I,* 91 FR 30519 (May 26, 2026).

[4] 21 U.S.C. 822(h); 21 U.S.C. 823(g)(2)(A); 21 U.S.C. 823(n). Of note, the potential impact a proposed rule may have on current or future research opportunities has no bearing on whether a substance meets the three statutory criteria for placement in schedule I of the CSA. *See also See Grinspoon* v. *Drug Enforcement Admin.,* 828 F.2d 881, 897 (1st Cir. 1987) (concluding that ''Congress has already weighed the costs and benefits of legitimate research on dangerous drugs and has determined, in a categorical manner, that if the three Schedule I criteria are satisfied, then the substance should be subject to Schedule I controls even if this action will create administrative and other burdens for researchers'' (citation omitted)).

[5] *See, https://apps.deadiversion.usdoj.gov/webforms2/spring/login?execution=e1s1.*

[6] Pursuant to 21 U.S.C. 812(b)(1)(B), when placing a drug or other substance in schedule I, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. First, DEA looks to whether the drug or substance has FDA approval. When no FDA approval exists, DEA has traditionally applied a five-part test to determine whether a drug or substance has a currently accepted medical use: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *See Marijuana Scheduling Petition; Denial of Petition; Remand,* 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter and concluded the test was not satisfied. In a published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS' two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland, Attorney General, Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this final rule, there is no evidence that health care providers have widespread experience with medical use of diphenidine or that the use of diphenidine is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied.

Requirements for Handling Diphenidine

Diphenidine 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, diphenidine must register with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Any person who currently handles diphenidine and is not registered with DEA must submit an application for registration and may not continue to handle diphenidine, 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.

Notwithstanding the foregoing, pursuant to 21 U.S.C. 822(h), if, on October 21, 2026, a person is conducting research on diphenidine and is already registered to conduct research with another controlled substance in schedule I, the person may continue to conduct research on diphenidine if they submit a completed application for registration or modification of existing registration, as applicable, to conduct research with diphenidine not later than 90 calendar days after the date of effectuation of the final rule. The person may continue to conduct such research until the person withdraws the application or the Administrator serves on the person an order to show cause proposing denial of the application pursuant to 21 U.S.C. 824(c) and in accordance with 21 CFR 1301.37. If the Administrator serves an order to show cause proposing denial of the application or modification, the person may not continue to conduct research with diphenidine and may not receive or otherwise obtain additional diphenidine. If an order to show cause is served and the person requests a hearing in accordance with 21 CFR 1301.37(d), the hearing shall be held in accordance with 21 CFR 1301.41–1301.46 on an expedited basis and not later than 45 calendar days after the request is made, except that the hearing may be held at a later time if so requested by the person. If the person sends a copy of the application to a manufacturer or distributor of diphenidine, receipt of the copy by the manufacturer or distributor constitutes sufficient evidence that the person is authorized to receive diphenidine pursuant to 21 U.S.C. 822(h)(4). Continuation of research under 21 U.S.C. 822(h) does not authorize any other handling (*e.g.,* distribution) of diphenidine.

Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

2. Disposal of Stocks. Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held diphenidine to a person registered with DEA before the effective date of the final scheduling action in accordance with all applicable Federal, State, local, and Tribal laws. Diphenidine 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. Diphenidine 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 diphenidine 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 diphenidine must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

5. Quota. Generally, only registered manufacturers are permitted to manufacture diphenidine 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 diphenidine must take an inventory of diphenidine on hand, pursuant to 21 U.S.C. 827 and 958, 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 diphenidine) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

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

7. Records and Reports. Every DEA registrant must maintain records and submit reports for diphenidine, or products containing diphenidine, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding diphenidine to the Automation of Reports and Consolidated Orders 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 diphenidine 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 diphenidine must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR parts 1304 and 1312.

10. Liability. Any activity involving diphenidine 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, 13563, 14192, and 14294

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. DEA scheduling actions promulgated by formal rulemaking are not regulatory actions under E.O. 14192, Unleashing Prosperity Through Deregulation, and are not subject to E.O. 14294, Overcriminalization of Federal Regulations.

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 on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 through 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 diphenidine (chemical name: 1-(1,2-diphenylethyl)piperidine), including its salts, isomers, and salts of isomers, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle diphenidine.

Based on the review of HHS's scientific and medical evaluation and all other relevant data, DEA determined that diphenidine 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. There appear to be no legitimate sources for diphenidine as a marketed drug in the United States, but DEA notes that this substance is available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of diphenidine from legitimate suppliers. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act of 1995

This rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. Amend § 1308.11, add paragraph (d)(117) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

* * * * * * *	
(117) Diphenidine (other name: 1-(1,2-diphenylethyl)piperidine)	7292
* * * * * * *	

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on September 11, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–19231 Filed 9–18–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice: 13124]

RIN 1400–AG32

Public Access to Information

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State revises its regulations governing the availability to the public of information that is under the control of the