



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-989]

Schedules of Controlled Substances: Placement of Clonazepam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final Rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam and their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. These five substances were temporarily scheduled in an order dated July 26, 2023, and subsequently extended until July 26, 2026, pursuant to an extension published elsewhere in this issue of the *Federal Register*. This action also enables the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action makes permanent the existing 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, or possess), or propose to handle these five specific controlled substances.

DATES: Effective date: [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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 places clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam and their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act (CSA).

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 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 CSA and the Federal Food, Drug, and Cosmetic Act² meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.³ 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

¹ As discussed in a memorandum of understanding entered into by the U.S. 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 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. 355.

³ 21 U.S.C. 811(d)(3).

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 she 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

Clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam are central nervous system depressants that are structurally and pharmacologically related to classical benzodiazepines, such as alprazolam. On May 7, 2020, the Secretariat of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 63rd Session on March 4, 2020, voted to place etizolam and flualprazolam in Schedule IV of the 1971 Convention (CND Decisions 63/12, 63/13). On June 10, 2021, the Secretariat advised the Secretary of State that the CND, during its 64th Session, voted to place clonazepam, diclazepam, and flubromazolam in Schedule IV of the 1971 Convention (CND Decisions 64/6, 64/7, 64/8). As a signatory to the 1971 Convention, the United States is required, by scheduling under the CSA, to place appropriate controls on these five designer benzodiazepines to meet the requirements of this treaty.

To meet the minimum requirements of this treaty and to confront these emerging substances, DEA published an order in the *Federal Register* on July 26, 2023, temporarily placing clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety under 21 U.S.C. 811(h)(1).⁴ That temporary order was effective upon the date of publication. On July 25, 2025, DEA published a temporary scheduling order to extend the temporary schedule I status of these five substances for one year, or until the permanent scheduling action

⁴ *Schedules of Controlled Substances: Temporary Placement of Etizolam, Flualprazolam, Clonazepam, Flubromazolam, and Diclazepam in Schedule I*, 88 FR 48112 (July 26, 2023).

for these substances is completed, whichever occurs first.⁵

DEA and HHS Eight-Factor Analyses

In letters dated March 17 and 24, 2022, in accordance with 21 U.S.C. 811(b), the former Administrator requested that the former Assistant Secretary for Health of HHS provide DEA with a scientific and medical evaluation of available information and a scheduling recommendation for clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam. In a letter dated June 18, 2025, HHS provided DEA with a scientific and medical evaluation of available information for these five substances and a scheduling recommendation for schedule I placement of these substances under the CSA.

DEA reviewed HHS's scientific and medical evaluation and scheduling recommendation, as well as 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 these substances warrant control in schedule I. Both DEA's and HHS's 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-989.

Notice of Proposed Rulemaking to Schedule Clonazepam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam

On July 25, 2025, DEA published a notice of proposed rulemaking (NPRM) to permanently control clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam in schedule I.⁶ Specifically, DEA proposed to add clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam to the list of depressant substances under 21 CFR 1308.11(e). The NPRM provided an opportunity for interested persons to file a request for a hearing, in accordance with DEA regulations, on or before August 25, 2025. DEA did not receive any

⁵ *Schedules of Controlled Substances: Placement of Clonazepam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam in Schedule I of the Controlled Substances Act*, 90 FR 35236 (July 25, 2025).

⁶ *Schedules of Controlled Substances: Placement of Clonazepam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam in Schedule I of the Controlled Substances Act*, 90 FR 35253 (July 25, 2025).

requests for such a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before August 25, 2025.

Comments Received

DEA received 19 comments in response to the NPRM for the placement of clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam into schedule I of the CSA. The submissions were from individuals or anonymous commenters. Of these 19 submissions, 5 commenters provided support for the NPRM; 6 commenters were against the placement of clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam in schedule I of the CSA; 2 commenters requested placement in another schedule; and 6 commenters provided statements that were neither explicitly for nor against the proposed rule.

Support of rulemaking: DEA received five comments, including from medical professionals, in support of the placement of clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam in schedule I of the CSA.

DEA response: DEA appreciates these comments in support of this rulemaking.

Opposition to rulemaking: DEA received six comments explicitly against the placement of clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam in schedule I of the CSA. Of these six comments, three commentors asserted that these five substances are analogues of benzodiazepines with therapeutic use; four commentors noted that etizolam is prescribed clinically in other countries; and two commentors expressed concerns that research would be restricted due to schedule I status. The following is DEA's response to the comments against the proposed rulemaking.

DEA response: DEA appreciates these comments and would like to provide further clarification regarding the control of clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam. These five substances have been internationally controlled. To comply with treaty obligations, DEA must place these five substances under the most appropriate schedule, taking into consideration all appropriate scientific data. As set forth in the NPRM, these five

substances have no currently accepted medical use in treatment in the United States, nor were there any New Drug Applications. Regarding etizolam specifically, HHS noted in its scientific and medical evaluation that etizolam is used as an approved medical drug in other countries for the treatment of anxiety disorders, insomnia, and neurosis. Nevertheless, HHS concluded that etizolam lacked a currently accepted medical use in the United States, finding that the few published clinical studies on etizolam in particular (1) had important limitations, (2) did not address the human abuse potential of etizolam, and (3) did not meet the threshold for findings of safety or efficacy of etizolam for any medical uses. HHS also stated that no qualified experts or groups have been identified in the United States who have asserted or supported that etizolam has a currently accepted medical use in treatment in the United States. Therefore, these five substances must be placed in schedule I of the CSA, alongside other substances that have no currently accepted medical use, lack accepted safety for use under medical supervision, and possess high potential for abuse. With respect to research for potential for medical use, the placement of substances in schedule I of the CSA does not preclude academic research on these substances.⁷ Those wishing to conduct research on clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam must seek permission to do so with DEA.⁸

Considerations for rulemaking: DEA received two comments that did not oppose scheduling clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam under the CSA. Of these two comments, one commentor requested placement of these five substances in another schedule, such that research on the therapeutic potential of these substances may be accomplished; and the other commenter did not oppose placement of four of the five substances in schedule I, requesting a different schedule for etizolam specifically. The following is DEA's response to the comments requesting modifications to the proposed rulemaking.

DEA response: DEA appreciates these comments and would like to provide further

⁷ 21 U.S.C. 822(h); 21 U.S.C. 823(g)(2)(A); 21 U.S.C. 823(n); *see also Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881, 897 (1st Cir. 1987).

⁸ <https://apps.deadiversion.usdoj.gov/webforms2/spring/login?execution=e1s1>.

clarification regarding the control of clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam. As noted above, DEA must place these five substances under the most appropriate schedule, taking into consideration all appropriate scientific data, to comply with treaty obligations. These five substances have no currently accepted medical use in treatment in the United States, nor were there any New Drug Applications. Therefore, these five substances must be placed in schedule I of the CSA, which does not preclude academic research, and those who wish to conduct research on the therapeutic potential of clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam must seek permission to do so with DEA.

General comments: DEA received six comments that were neither explicitly for nor against the proposed rule.

DEA response: DEA appreciates these comments.

Scheduling Conclusion

After consideration of the public comments, scientific and medical evaluation and accompanying scheduling recommendation 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 clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam. As such, DEA is permanently scheduling clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam as controlled substances under schedule I of the CSA. The permanent scheduling of these five benzodiazepines 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 specifies the findings required to place a drug or other substance in any particular schedule.⁹ After consideration of the interested persons' comments above, analysis and recommendation of the Assistant Secretary for Health of HHS, and all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

⁹ 21 U.S.C. 812(b).

(1) Clonazepam, diazepam, etizolam, flualprazolam, and flubromazepam have a high potential for abuse. These five substances are pharmacologically similar to classical benzodiazepines (e.g., diazepam), which have been shown to produce dependence and are abused by millions of individuals in the United States. In vitro binding affinity and functional activity studies, as well as in vivo drug discrimination studies, demonstrate that these substances are highly potent positive allosteric modulators of GABA_A receptors—a mechanism of action that accounts for the inhibitory effects of GABA, decreased neuronal activity, and result in the pharmacological properties of the benzodiazepine class. These pharmacological properties include CNS depressant effects, such as anxiolytic, amnesic, anticonvulsant, sedative-hypnotic, respiratory depressant, and muscle relaxant effects. This finding is consistent with drug abuse patterns and adverse outcomes from epidemiological data sources.

(2) Clonazepam, diazepam, etizolam, flualprazolam, and flubromazepam have no currently accepted medical use in treatment in the United States. According to HHS, FDA has not approved a marketing application for clonazepam, diazepam, etizolam, flualprazolam, or flubromazepam. In addition, these five substances have no known therapeutic applications in the United States. DEA is not aware of any evidence suggesting that these five substances have a currently accepted medical use in treatment in the United States.¹⁰

¹⁰ When placing a drug or other substance in schedule I of the CSA, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B). There is no evidence suggesting that clonazepam, diazepam, etizolam, flualprazolam, and flubromazepam have a currently accepted medical use in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: (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 recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which the part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (Apr. 11, 2024). For purposes of this final rule, there is no

(3) There is a lack of accepted safety for use of clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam under medical supervision. As stated by HHS, because these five substances have no approved medical use and have not been investigated as new drugs, their safety for use under medical supervision has not been determined.

Based on these findings, the Administrator of DEA concludes that clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrant continued control in schedule I of the CSA.

Requirements for Handling Clonazepam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam

Clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam are 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, clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam 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 clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam and is not registered with DEA must submit an application for registration and may not continue to handle clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam, unless DEA has approved

evidence that health care providers have widespread experience with medical use of clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam or that the use of clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied.

that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam 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. Clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam 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.* Clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of this final scheduling action. Non-practitioners handling these five substances also must comply with the screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam 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 clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam 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 clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam must take an inventory of these substances 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 these five substances) 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 these five substances) 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 with respect to clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam to the Automation of Reports and Consolidated Order System pursuant 21 U.S.C. 827, and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam 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 clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam 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 clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam 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 are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Overcriminalization in 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.

Paperwork Reduction Act of 1995

This action does not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.¹¹ Also, this rule does not impose new

¹¹ 44 U.S.C. 3501–3521.

or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this rule would require compliance with the following existing OMB collections: 1117-0003, 1117-0004, 1117-0006, 1117-0008, 1117-0009, 1117-0010, 1117-0012, 1117-0014, 1117-0021, 1117-0023, 1117-0029, and 1117-0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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 clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam, including its salts, isomers, and salts of isomers, in schedule I of the CSA on a permanent basis 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 clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam.

Based on DEA's review of HHS's scientific and medical evaluation and all other relevant data, DEA determined that, in agreement with HHS, the five designer benzodiazepines—clonazepam, diclazepam, etizolam, flualprazolam, and flubromazolam—have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. There appear to be no legitimate sources for clonazepam, diclazepam, etizolam, flualprazolam, or flubromazolam as a marketed drug in the United States, but DEA notes that these substances are available for purchase from legitimate suppliers for scientific research. Significant diversion of these five substances from legitimate

suppliers is not evident. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined 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

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 the final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. In § 1308.11:

- a. Redesignate paragraphs (e)(1) through (3) as paragraphs (e)(6) through (8);
- b. Add new paragraphs (e)(1) through (5); and
- c. Remove and reserve paragraphs (h)(57) through (61).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(e) * * *

(1) Clonazepam (Other name: 6-(2-chlorophenyl)-1-methyl-8-nitro-4 <i>H</i> -benzo[<i>f</i>][1,2,4]triazolo[4,3- <i>a</i>][1,4]diazepine)	2786
(2) Diclazepam (Other name: 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2 <i>H</i> -benzo[<i>e</i>][1,4]diazepin-2-one)	2789
(3) Etizolam (Other name: 4-(2-chlorophenyl)-2-ethyl-9-methyl-6 <i>H</i> -thieno[3,2- <i>f</i>][1,2,4]triazolo[4,3- <i>a</i>][1,4]diazepine)	2780
(4) Flualprazolam (Other name: 8-chloro-6-(2-fluorophenyl)-1-methyl-4 <i>H</i> -benzo[<i>f</i>][1,2,4]triazolo[4,3- <i>a</i>][1,4]diazepine)	2785
(5) Flubromazolam (Other name: 8-bromo-6-(2-fluorophenyl)-1-methyl-4 <i>H</i> -benzo[<i>f</i>][1,2,4]triazolo[4,3- <i>a</i>][1,4]diazepine)	2788
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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on February 24, 2026, by 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.

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