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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–989]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing clonazolam, 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, as identified in this proposed rule, 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 will also enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would make permanent the existing 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 these five specific controlled substances.

DATES: Comments must be submitted electronically or postmarked on or before August 25, 2025.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.47 and/or 1316.49, as applicable. Requests for a hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before August 25, 2025.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–989'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit all comments electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

As required by 5 U.S.C. 553(b)(4), a summary of this proposed rule may be found in the docket for this rulemaking at *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) proposes to permanently schedule the following five controlled substances in schedule I of the Controlled Substances Act (CSA), including 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:

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

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at *http://www.regulations.gov,* unless reasonable cause is given. Such information includes personal or business identifiers (such as name, address, state of federal identifiers, etc.) voluntarily submitted by the commenter.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked ''CONTAINS CONFIDENTIAL INFORMATION'' and should clearly identify all PII or business information the commenter does not want to be made publicly

available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked ''TO BE PUBLICLY POSTED'' and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on *http://www.regulations.gov* for public inspection. DEA generally will not redact additional information contained in the comment marked ''TO BE PUBLICLY POSTED.'' The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and supplemental information to this proposed scheduling action are available at *http://www.regulations.gov.*

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559.[1] Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person with regard to the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing.[2]

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**.[3] Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall only commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam meet the statutory criteria for placement in schedule I, as proposed in this rulemaking.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on her own motion, at the request of the Secretary of the Department of Health and Human Services (HHS), or on the petition of an interested party.[4] This proposed action was initiated on the Acting Administrator's own motion and is supported by, *inter alia,* a recommendation from the Acting Assistant Secretary for Health of HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle these five substances.

In addition, 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 set forth in 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 HHS,[5] 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 (FD&C Act)[6] meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[7] In the event that the Secretary did not 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) 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

On May 7, 2020, the Secretariat of the United Nations advised the Secretary of State of the Unites 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 clonazolam, diclazepam, and flubromazolam in Schedule IV of the 1971 Convention (CND Decisions 64/6, 64/7, 64/8). As a signatory party to this international treaty, the United States is required, by scheduling under the CSA, to place appropriate controls on the 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 clonazolam, 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).[8] That temporary order was effective upon the date of publication.

[1] 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

[2] 21 CFR 1316.49.

[3] 21 CFR 1308.44(b), 1316.53.

[4] 21 U.S.C. 811(a).

[5] 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).

[6] 21 U.S.C. 355.

[7] 21 U.S.C. 811(d)(3).

[8] *Schedules of Controlled Substances: Temporary Placement of Etizolam, Flualprazolam, Clonazolam,*

Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of a substance expires at the end of two years from the date of issuance of the scheduling order, except that DEA may extend temporary scheduling of that substance for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1) with the respect to the temporarily controlled substance. The temporary control of these five substances is set to expire on July 26, 2025. DEA is publishing a temporary scheduling order to extend the temporary schedule I status of these five substances elsewhere in this issue of the **Federal Register**, which will extend the temporary scheduling of these substances for one year, or until the permanent scheduling action for these substances is completed, whichever occurs first.

The Acting Administrator, on his own motion pursuant to 21 U.S.C. 811(a), is initiating proceedings to permanently schedule clonazolam, 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 within the specific chemical designation. DEA gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these substances. On March 17 and 24, 2022, in accordance with 21 U.S.C. 811(b), the former Administrator submitted a request to the former Assistant Secretary to provide DEA with a scientific and medical evaluation of available information and a scheduling recommendation for these five substances.

On June 18, 2025, the Acting Assistant Secretary submitted HHS's scientific and medical evaluation, entitled ''Basis for the Recommendation to Control Clonazolam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam, and Their Salts, in Schedule I of the Controlled Substances Act,'' and scheduling recommendation to the Acting Administrator. Following consideration of the eight factors and findings related to these substances' abuse potential, legitimate medical use, and dependence liability, HHS recommended that clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam and their salts be controlled in schedule I of the CSA under 21 U.S.C. 812(b).

Flubromazolam, and Diclazepam in Schedule I, 88 FR 48112 (July 26, 2023).

Proposed Determination to Permanently Schedule Clonazolam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam

As discussed in the background section, the Acting Administrator is initiating proceedings, pursuant to 21 U.S.C. 811(a), to permanently add clonazolam, 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 within the specific chemical designation, to schedule I. In accordance with 21 U.S.C. 811(c), upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data and conducted its own eight-factor analysis of the abuse potential of these five substances. Included below is a brief summary of each factor as analyzed by HHS and DEA and as considered by DEA in its proposed scheduling action. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' of the public docket for this proposed rule at *http://www.regulations.gov* under ''Docket Number DEA–989.''

1. The Drug's Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation document for clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam, DEA also considered all other relevant data regarding actual or relative potential for abuse of these five substances. The term ''abuse'' is not defined in the CSA; however, the legislative history of the CSA suggests that DEA consider the following criteria when determining whether a particular drug or substance has a potential for abuse: [9]

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Toxicological and epidemiological data, as well as numerous case reports and U.S. poison center data, indicate that individuals are taking the five designer benzodiazepines in amounts sufficient to create a hazard to their health, the safety of other individuals, or the community. The U.S. Food and Drug Administration (FDA) has not approved clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam under the FD&C Act, and thus, these five substances not legally marketed as drugs in the United States. Therefore, HHS has not identified significant diversion of these substances from legitimate drug channels in the United States and is not aware of any research or legitimate manufacturing activities in the United States from which these substances can be diverted. These substances are thus presumed to be obtained from clandestine manufacturing or diverted from international countries for nonmedical use, on an individual's own initiative, rather than on the basis of medical advice from a licensed practitioner.

In addition, law enforcement data indicate that clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam have been encountered in the U.S. illicit drug market. DEA's National Forensic Laboratory Information System (NFLIS) registered a collective total of 50,015 reports, from all 50 states and Washington, DC, pertaining to the trafficking, distribution, and abuse of the five designer benzodiazepines.[10] As such,

[9] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

[10] The National Forensic Laboratory Information System (NFLIS) represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1.0 million distinct annual federal, state, and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only.

Continued

these data suggest that clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam are being abused and thus pose safety hazards to the health of users or the community.

Lastly, based on available data, these five designer benzodiazepines are structurally and pharmacologically related to classical benzodiazepines (*e.g.,* alprazolam), which are positive allosteric modulators of γ-aminobutyric acid type A ($GABA_A$) receptors. This allosteric modulation is thought to be responsible for the sedative-hypnotic, subjective effects commonly reported on drug user forums. According to HHS, in vitro binding data, animal behavioral data, and anecdotal reports involving human use indicate that the five designer benzodiazepines bind to $GABA_A$ receptors and produce similar drug effects, as well as adverse effects, associated with the benzodiazepine class, which have a potential for abuse. Thus, the five designer benzodiazepines have a similar potential for abuse and present a hazard to the health and safety of individuals and the community.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

Published scientific data on the functional activity of the five designer benzodiazepines is limited; however, in vitro binding and animal behavioral studies demonstrate that the pharmacological mechanisms of action of these five substances are similar to those of the benzodiazepine drug class. These substances bind to the $GABA_A$ receptors with high affinity; this affinity increases in the presence of GABA and is blocked by the $GABA_A$ receptor antagonist, flumazenil.[11] In addition, in drug discrimination experiments,[12] the data demonstrate that these substances fully substitute for the discriminative stimulus effects of midazolam, a schedule IV benzodiazepine.[13]

Clinical studies have not been conducted to evaluate the pharmacological effects of clonazolam, diclazepam, flualprazolam, or flubromazolam. However, a few clinical studies exist for etizolam, which select countries have approved for limited use. According to HHS, these studies compared the therapeutic effects of etizolam to known benzodiazepines, such as alprazolam, but did not address the abuse potential of the drug. In addition, trip reports on user forums indicate that these five substances produce CNS depression and sedative-hypnotic effects, similar to other benzodiazepines. These data, collectively with the extensive clinical studies on classical benzodiazepines, strongly suggest that these five designer benzodiazepines have pharmacological effects similar to those of other known benzodiazepines.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

The five designer benzodiazepines share structural similarities with other substances of the benzodiazepine class. Benzodiazepines are named after their parent structure, which is formed from the fusion of two ring systems—the benzene ring and diazepine ring. Diclazepam contains this parent structure and is further modified with the addition of a methyl and keto group. Clonazolam, flualprazolam, and flubromazolam are considered to be part of the class of benzodiazepines known as triazolobenzodiazepines because they contain the parent structure and the addition of a triazole ring fused to the diazepine ring. Etizolam is considered to be a thienotriazolodiazepine because it contains the triazolo-diazepine fused rings, but with a thiophene ring replacing the benzene ring. Although etizolam is structurally different from a classical benzodiazepine, etizolam has similar pharmacological and chemical properties and thus considered to be an analog of benzodiazepines.[14] In addition, all five designer benzodiazepines have a pendant phenyl group that is further substituted with a halogen in the ortho position.

4. Its History and Current Pattern of Abuse

Classical benzodiazepines have been extensively prescribed in the United States; however, these medications have also been used non-therapeutically and recreationally, with initial reports of abuse soon after pharmaceutical development (Loveridge, 1981; Woody et al., 1975). Unlike these classical benzodiazepines that have FDA approval, clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam have no legitimate channel as marketed drug products in the United States. Despite this, available data from user reports, toxicological cases, scientific literature, and law enforcement seizures indicate that each of these substances appear on the illicit drug market and are trafficked for their psychoactive effects. Based on these available data, the five designer benzodiazepines are often used alone or in combination with other substances, such as fentanyl, traditional and NPS benzodiazepines, NPS opioids, and stimulants. The five designer benzodiazepines substances have been encountered in various forms (*e.g.,* powder, tablet, liquid), are primarily reported as orally consumed (at doses less than 4 mg), and lead to toxicity and other adverse health consequences, including death.

The misuse and abuse of benzodiazepines have been demonstrated and are well-characterized.[15] According to the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health 2023 annual report,[16] 4.7 million people reported misusing prescription tranquilizers or sedatives (*e.g.,* benzodiazepines) in the past year. Of the 4.7 million people who reported misusing prescription tranquilizers or sedatives in the past year in 2023, 4.0 million individuals were aged 26 years

While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS data were queried on May 29, 2025.

[11] In vitro pharmacology data was collected through the DEA–Veterans Affairs interagency agreement, ''In Vitro Receptor and Transporter Assays for Abuse Liability Testing for the DEA by the VA.''

[12] Drug discrimination is widely used to determine whether a new test drug or substance is pharmacologically similar to a known drug of abuse. The discriminative stimulus effects of a given drug in animals and its subjective effects in humans are strongly correlated. *See* Balster, R. L., & Bigelow, G. E. (2003). Guidelines and methodological reviews concerning drug abuse liability assessment. *Drug and alcohol dependence, 70*(3 Suppl), S13–S40. *https://doi.org/10.1016/s0376-8716(03)00097-8. See also* Schuster, C. R., & Johanson, C. E. (1988). Relationship between the discriminative stimulus properties and subjective effects of drugs. *Psychopharmacology series, 4,* 161–175. *https://doi.org/10.1007/978-3-642-73223-2_13. See also* Solinas, M., Panlilio, L. V., Justinova, Z., Yasar, S., & Goldberg, S. R. (2006). Using drug-discrimination techniques to study the abuse-related effects of psychoactive drugs in rats. *Nature protocols, 1*(3), 1194–1206. *https://doi.org/10.1038/nprot.2006.167.*

[13] Drug Enforcement Administration Contract 15DDHQ21P00000835, ''Evaluation of synthetic opioid substances using analgesia and drug discrimination assays.'' Annual report for 2022, unpublished.

[14] *See* Sanna, E., Pau, D., Tuveri, F., Massa, F., Maciocco, E., Acquas, C., Floris, C., Fontana, S.N., Maira, G., & Biggio, G. (1999). Molecular and neurochemical evaluation of the effects of etizolam on GABAA receptors under normal and stress conditions. *Arzneimittel-Forschung, 49*(2), 88–95. *https://doi.org/10.1055/s-0031-1300366.*

[15] *See* Votaw, V.R., Geyer, R., Rieselbach, M.M., & McHugh, R.K. (2019). The epidemiology of benzodiazepine misuse: A systematic review. *Drug and alcohol dependence, 200,* 95–114. *https://doi.org/10.1016/j.drugalcdep.2019.02.033.*

[16] Key substance use and mental health indicators in the United States: Results from the 2023 National Survey on Drug Use and Health (HHS Publication No. PEP24–07–021, NSDUH Series H–59). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. *https://www.samhsa.gov/data/report/2023-nsduh-annual-national-report.*

or older and included both males and females. Drug user reports indicate that the population likely to abuse the five designer benzodiazepines appears to be the same as those abusing prescription benzodiazepines, barbiturates, and other sedative-hypnotic substances. This is reflected in available reports for toxicological cases involving flualprazolam; in these cases, users had an average age of 32 years and included both males and females.[17] In addition, available reports for toxicological cases involving etizolam and flubromazolam indicate that users had an average age of 39 years and included both males and females.[18] These users are likely to obtain the substances through unregulated sources and, therefore, with uncertain and inconsistent identity, purity, and quantity of these substances. Consequently, this poses significant, adverse health risks to the end user.

5. The Scope, Duration, and Significance of Abuse

Law enforcement data, including data from DEA's NFLIS, indicate that the abuse of the five designer benzodiazepines have become increasingly widespread across the United States. NFLIS-Drug [19] registered a collective total of 50,015 reports, from all 50 states and Washington, DC, pertaining to the trafficking, distribution, and abuse of the five designer benzodiazepines. Through May 2025, NFLIS-Drug reported 16,326 total encounters of clonazolam since 2015; 706 of diclazepam since 2014; 19,650 of etizolam since 2002; 10,468 of flualprazolam since 2004; and 2,865 of flubromazolam since 2015.

In addition, HHS evaluated reports of human exposure to benzodiazepines to U.S. poison centers and included data over a 10-year period (2012–2021). According to HHS, among the five designer benzodiazepines, etizolam had the highest number of total exposure cases (n = 878) and total abuse cases (n = 377), followed by clonazolam (n = 343 and n = 162, respectively), flubromazolam (n = 96; n = 47), diclazepam (n = 78; n = 32), and flualprazolam (n = 67; n = 30).[20] Moreover, many toxicological cases have involved these five substances, including cases submitted to and analyzed by DEA's Toxicology Testing Program (DEA TOX).[21] Through May 2025, DEA TOX detected clonazolam in 11 cases since 2019, metabolite 8-amino clonazolam [22] in 57 cases since 2021, etizolam in 16 cases since 2019, flualprazolam in 24 cases since 2019, and flubromazolam in 6 cases since 2020. Similarly, according to HHS, the National Medical Service Labs detected clonazolam (n = 14), diclazepam (n = 40), etizolam (n = 772), and flubromazolam (n = 151) among 131,883 postmortem blood samples from January 1, 2018, through June 30, 2020.[23] The Center for Forensic Science Research and Education also reported steady increases in postmortem cases and toxicology reports associated with clonazolam, etizolam, flualprazolam, and flubromazolam through June 2022.[24] Collectively, these data strongly suggest that the clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam are increasingly abused in the United States.

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

The increase in benzodiazepine-related overdoses in the United States has been exacerbated by the availability of NPS benzodiazepines on the illicit drug market. Public health risks associated with clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam abuse relate to their pharmacological similarities with known benzodiazepines. These similarities result in similar adverse reactions in humans and expectedly include CNS depressant-like effects, such as slurred speech, ataxia, altered mental state, and respiratory depression. Abuse of clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam—both alone and in combination with other substances—have resulted in adverse effects, including impaired driving, unintentional overdose, emergency department visits, and fatalities, within the United States and in other countries. Thus, these data collectively indicate that the abuse of clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam pose increased risks to public health.

7. Its Psychic or Physiological Dependence Liability

Published scientific data on the dependence liability of the five designer benzodiazepines is limited; however, collective data from preclinical studies, trip reports on user forums, and case studies strongly suggest that the five designer benzodiazepines produce both psychic and physiological dependence that are consistent with the known dependence produced by classical benzodiazepines. According to HHS, every benzodiazepine that has been studied in a nonclinical or clinical model of dependence has been shown to produce physical dependence—a conclusion that the scientific and medical community generally accepts. Data from preclinical studies demonstrate that the pharmacological

[17] *See* Krotulski, A.J., Papsun, D.M., Homan, J.W., Nelson, L., & Logan, B.K. (2019). Flualprazolam: Potent benzodiazepine identified among death and impaired driving cases in the U.S. (December 2019 Report). Center for Forensic Science Research and Education. *https://www.cfsre.org/images/content/reports/public_alerts/2019.12.05.Public-Alert_Flualprazolam_NPS-Discovery_120519.pdf.*

[18] *See* Aldy, K., Mustaquim, D., Campleman, S., Meyn, A., Abston, S., Krotulski, A., Logan, B., Gladden, M.R., Hughes, A., Amaducci, A., Shulman, J., Schwarz, E., Wax, P., Brent, J., Manini, A., & Toxicology Investigators Consortium Fentalog Study Group (2021). Notes from the field: Illicit benzodiazepines detected in patients evaluated in emergency departments for suspected opioid overdose—Four States, October 6, 2020–March 9, 2021. *MMWR. Morbidity and mortality weekly report, 70*(34), 1177–1179. *https://doi.org/10.15585/mmwr.mm7034a4.*

[19] DEA's National Forensic Laboratory Information System (NFLIS) is a comprehensive information system that collects scientifically verified data on drug items and cases submitted to and analyzed by participating federal, state, and local forensic drug laboratories within the United States. NFLIS-Drug, a component of NFLIS, includes drug chemistry results from completed analyses only. While NFLIS data are not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data were queried on May 29, 2025. NFLIS-Drug reports are still pending for 2024 and 2025 due to normal lag time.

[20] *See* HHS's scientific and medical evaluation, entitled ''Basis for the Recommendation to Control Clonazolam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam, and Their Salts, in Schedule I of the Controlled Substances Act.''

[21] DEA's Toxicology Testing Program (DEA TOX) is a surveillance program that aims to detect novel psychoactive substances (NPS) in fatal and nonfatal overdose cases within the United States. From these cases, biological samples, as well as drug paraphernalia (on limited occasions), are submitted for analysis by hospitals, medical examiners, poison centers, and law enforcement nationwide. DEA TOX data include confirmed detections of NPS through the data query date, May 27, 2025.

[22] The amino metabolite of clonazolam has been noted in literature as both 7-aminoclonazolam and 8-aminoclonazolam; however, the proper nomenclature is 8-aminoclonazolam, based on the International Union of Pure and Applied Chemistry (IUPAC) rules for a triazolobenzodiazepine. *See* Maskell, P.D., Parks, C., Button, J., Liu, H., & McKeown, D.A. (2021). Clarification of the correct nomenclature of the amino metabolite of clonazolam: 8-Aminoclonazolam. *Journal of analytical toxicology, 45*(2), e1–e2. *https://doi.org/10.1093/jat/bkaa169.*

[23] The National Medical Service (NMS) Labs is a reference laboratory that provides clinical and postmortem toxicological testing. NMS Labs data does not include cause-of-death data. According to HHS, FDA contracted NMS Labs (U.S. Food and Drug Administration Solicitation 75F40119R00070) to receive a study report (Loperamide Postmortem Toxicology, November 6, 2020) that tabulated the number of blood specimens in which a specific substance was detected, using liquid chromatography–time-of-flight mass spectrometry, from January 1, 2018 through June 30, 2020.

[24] The Center for Forensic Science Research and Education's quarterly trend reports are available online at *https://www.cfsre.org/nps-discovery/trend-reports/nps-benzodiazepines/report/49?trend_type_id=1* (last accessed June 3, 2025).

mechanisms of action of the five designer benzodiazepines is similar to those of the benzodiazepine drug class; thus, clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam are expected to produce psychic and physiological dependence. In addition, trip reports on user forums indicate that clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam produce benzodiazepine-like effects and can have significantly higher potencies in comparison to other classical benzodiazepine drugs; thus, the five designer benzodiazepines are expected to produce psychic and physiological dependence. Lastly, available case studies for etizolam exemplify the dependence potential of this designer benzodiazepine in young adults. Overall, based on the pharmacological similarities of clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam to classical benzodiazepines that have demonstrated psychic and physiological dependence liability, these five designer benzodiazepines are expected to also produce both psychic and physiological dependence.

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA

The five designer benzodiazepines—clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam—are not known to be immediate precursors of any controlled substance of the CSA, as defined by 21 U.S.C. 802(23).

Conclusion

After considering the scientific and medical evaluation and accompanying recommendation of HHS, and DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam. As such, DEA proposes to permanently schedule these five designer benzodiazepines as controlled substances under the CSA.

Proposed 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.[25] After consideration of the analysis and recommendation of the Assistant Secretary of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam have a high potential for abuse. These five designer benzodiazepines 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. Thus, these five substances have a high potential for abuse.

(2) Clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam have no currently accepted medical use in treatment in the United States. According to HHS, FDA has not approved a marketing application for clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam. In addition, there are no adequate and well-controlled clinical studies for any of these substances, and there are no well-defined finished dosage forms for any of these substances. Furthermore, these five substances have no known therapeutic applications in the United States. Thus, these five substances have no currently accepted medical use in treatment in the United States.[26]

(3) There is a lack of accepted safety for use of clonazolam, 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. Therefore, there is a lack of accepted safety for use of these five substances under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that clonazolam, 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 within the specific chemical designation, warrant continued control in schedule I of the CSA.[27]

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

As discussed above, these five designer benzodiazepines are currently subject to a temporary scheduling order adding them to schedule I under the CSA. If this rule is finalized as proposed, clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam would be subject, on a permanent basis, to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes,

[25] 21 U.S.C. 812(b).

[26] Pursuant to 21 U.S.C. 812(b)(1)(B), 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. 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 substances 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. *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. 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). In its eight-factor assessment, HHS determined that clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam do not satisfy this two-part test. Therefore, since both DEA and HHS have determined that these substances do not satisfy the five-part test, and HHS has determined that the substances do not satisfy the additional two-part test, DEA concludes that clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam do not have a currently accepted medical use.

dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) clonazolam, 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.

2. *Security.* Clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR 1301.71 through 1301.76. Non-practitioners handling these five substances also must comply with the screening requirements of 21 CFR 1301.90 through 1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture clonazolam, 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.

5. *Inventory.* Any person registered with DEA to handle clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam must have an initial inventory of all stocks of controlled substances (including these substances) 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. After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam) on hand every two years pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam pursuant to 21 U.S.C. 827, 832(a), and 958(e) and in accordance with 21 CFR 1301.74(b), 1301.74(c), 1301.76(b), and parts 1304, 1312, and 1317. Manufacturers and distributors would be required to submit reports regarding clonazolam, 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.

7. *Order Forms.* Every DEA registrant who distributes clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam must comply with the order form requirements pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam must be in compliance with 21 U.S.C. 952, 953, 957, and 958 and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving clonazolam, 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 (Regulatory Review)

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for 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, Fighting Overcriminalization in Federal Regulations.

Executive Order 12988, Civil Justice Reform

This proposed 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 proposed 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 the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed 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 proposed rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

On July 26, 2023, DEA published an order to temporarily place five designer benzodiazepines, as defined in the order, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam have already established and implemented systems and processes required to handle these substances. DEA proposes placing clonazolam, diclazepam, etizolam, flualprazolam, and flubromazolam, including its salts, isomers, and salts of isomers, in schedule I on a permanent basis.

According to HHS, these five designer benzodiazepines 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 clonazolam, 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. There is no evidence of significant diversion of these five substances from legitimate suppliers. Therefore, DEA has concluded that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in

research, conduct instructional activities or chemical analysis with, or possess), or propose to handle clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam, including its salts, isomers, and salts of isomers, or any combination thereof. DEA determines the industries that best represent these business activities using the North American Industry Classification System (NAICS).[28] From Statistics of U.S. Businesses (SUSB) data, DEA determined the number of firms and small firms for each of the affected industries, and by comparing the number of affected small entities to the number of small entities for each industry, DEA determined whether a substantial number of small entities are affected in any of the industries. The following table lists the number of firms, small firms, and percent small firms in each affected industry.

TABLE 1—BUSINESS ACTIVITY AND CORRESPONDING NAICS INDUSTRIES

Business activity	NAICS code	NAICS industry description	Firms[29]	SBA size standard[30]	Small firms[31]	Percent small entities
Manufacturer	325412	Pharmaceutical Preparation Manufacturing	1,179	1,300	1,099	93.2
Distributor, Importer, Exporter.	424210	Drugs and Druggists' Sundries Merchant Wholesalers	7,012	250	6,760	96.4
	424690	Other Chemical and Allied Products Merchant Wholesalers.	5,487	175	5,197	94.7
Researcher	541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).	10,042	1,000	9,599	95.6
	611310	Colleges, Universities, and Professional Schools	2,494	$34.5	1,515	60.8

Based on the American Chemical Society's SciFinder database, DEA identified ten entities supplying clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam across the industries 325412, 424210, and 424690. Two of these entities have already registered with DEA to handle controlled substances. Hence, DEA expects only eight entities will be impacted by this rule. Assuming that all affected suppliers were small entities and concentrated in the smallest NAICS industry, 325412, they would account for only 0.73 percent of the small entities in those industries, not a substantial number.[32]

Additionally, DEA expects that the number of researchers working with clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam is small, because each of these substances is not approved for medical use and has a substantial capability to be a hazard to the health of the user and to the safety of the community. Also, DEA believes that the researchers working with clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam may also work with other controlled substances; hence, these researchers are likely already registered with DEA and are qualified to handle controlled substances. For these reasons, DEA believes the number of affected researchers that are small entities is not a substantial number of small entities in the 541715 and 622310 industries.

In summary, the small entities affected by this proposed rule are those in 325412—Pharmaceutical Preparation Manufacturing, 424210—Drugs and Druggists' Sundries Merchant Wholesalers, and 424690—Other Chemical and Allied Products Merchant Wholesalers. The affected small entities account for less than 0.73 percent of the small businesses and are not likely to manufacture or carry inventory of clonazolam, diclazepam, etizolam, flualprazolam, or flubromazolam, including its salts, isomers, and salts of isomers. As such, the proposed rule, if finalized, is not expected to result in 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. 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 proposed rule would not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.[33] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this proposed 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.

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

[28] Executive Office of the President Office of Management and Budget, North American Industry Classification System, United States, 2022, *https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf* (last accessed 4/2/2024).

[29] Statistics of U.S. Businesses, 2022 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html* (last accessed 6/24/2025).

[30] U.S. Small Business Administration (SBA), Table of size standards, Version March 2023, Effective: March 17, 2023, *https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf* (last accessed 6/24/2025).

[31] Based on the estimated number of firms below the SBA size standard for each industry.

[32] 8/1,099 = 0.73%.

[33] 44 U.S.C. 3501–3521.

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

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Signing Authority

This document of the Drug Enforcement Administration was signed on July 22, 2025, by Acting Administrator Robert J. Murphy. 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. 2025–14022 Filed 7–24–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED–2025–0151]

Public Hearing; Negotiated Rulemaking Committees

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Intent to establish negotiated rulemaking committees.

SUMMARY: We announce our intention to establish two negotiated rulemaking committees to prepare regulations for the Federal student financial assistance programs authorized under Title IV of the Higher Education Act (HEA) of 1965, as amended (Title IV, HEA programs). One committee will consider changes to the Federal student loan programs and the other committee will consider changes to institutional and programmatic accountability, the Pell Grant Program, and other changes to the Title IV, HEA programs.

This rulemaking is necessary to implement recent statutory changes to the Title IV, HEA programs included in Pub. L. 119–21, known as the *One Big Beautiful Bill Act,* that President Trump signed into law on July 4, 2025, as well as to implement other Administration priorities.

Prior to submitting draft regulations to the negotiated rulemaking process, the Department invites the public to provide advice and recommendations addressing the implementation of the changes to the Title IV, HEA programs included in Pub. L. 119–21 during a virtual public hearing that will be held on August 7, 2025, from 9:00 a.m. to noon and 1:00 p.m. to 4:00 p.m., Eastern time. As part of the hearing record, the Department will also accept written comments providing advice and recommendations on the implementation of the changes to the Title IV, HEA programs included in Pub. L. 119–21 through August 25, 2025.

DATES: The dates, times, and locations for the virtual public hearing and the schedule for negotiations are listed under the **SUPPLEMENTARY INFORMATION** section of this document. The Department will accept written comments providing advice and recommendations for the hearing record via the Federal eRulemaking portal through August 25, 2025.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal at *regulations.gov*. The Department will not accept comments submitted by fax or by email or comments submitted after the comment period closes. To ensure we do not receive duplicate copies, please submit your comments only once. Additionally, please include the Docket ID at the top of your comments.

Information on using *Regulations.gov,* including instructions for submitting comments, is available on the site under ''FAQ.'' If you require an accommodation or cannot otherwise submit your comments via *Regulations.gov*, please contact *regulationshelpdesk@gsa.gov* or by phone at 1–866–498–2945. If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

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