**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**[Docket No. DEA-1420]**

**Schedules of Controlled Substances: Temporary Placement of Bromazolam in Schedule I**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Proposed amendment; notification of intent.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this notification of intent to publish a temporary order to schedule 8-bromo-1-methyl-6-phenyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][l ,4]diazepine (commonly known as bromazolam), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers are possible, in schedule I of the Controlled Substances Act. When it is issued, the temporary scheduling order will 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, or possess) or propose to handle bromazolam.

**DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**FOR FURTHER INFORMATION CONTACT:** Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3249.

**SUPPLEMENTARY INFORMATION:** The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug

Enforcement Administration (DEA) intends to issue a temporary scheduling order[1] (in the form of a temporary amendment) to add bromazolam, including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, to schedule I under the Controlled Substances Act (CSA):

- 8-bromo-1-methyl-6-phenyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1 ,4]diazepine (Other name: bromazolam)

The temporary scheduling order will be published in the *Federal Register* on or after **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**Legal Authority**

The CSA provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if she finds that such action is necessary to avoid an imminent hazard to the public safety.[2] In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year.[3]

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355.[4]

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

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[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.
[2] 21 U.S.C. 811(h)(1).
[3] 21 U.S.C. 811(h)(2).
[4] 21 U.S.C. 811(h)(1); 21 CFR part 1308.

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 Safety (HHS), after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the CSA and the FD&C Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance. 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. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of DEA (Administrator).[5]

**Background**

On June 6, 2024, the Secretariat of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 67th session on March 19, 2024, voted to place bromazolam in Schedule IV of the Convention on Psychotropic Substances of 1971 (CND Decisions 67/5). As a signatory to this international treaty, the United States is required to place appropriate controls within the CSA on bromazolam to meet the requirements of the treaty. To meet the minimum requirements of this treaty and to confront these emerging substances, DEA intends to temporarily place bromazolam in schedule I of the CSA.

The CSA requires the Administrator to notify the Secretary of HHS of an intent to temporarily place a substance in schedule I of the CSA (i.e., to issue a temporary scheduling order).[6] By letter dated June 14, 2024, the previous Administrator transmitted the required notice to place bromazolam in schedule I on a temporary basis to the then-Assistant Secretary

[5] 28 CFR 0.100.
[6] 21 U.S.C. 811(h)(4).

for Health of HHS (Assistant Secretary).[7] On June 28, 2024, the previous Assistant Secretary responded to this notice and advised DEA that, based on a review by the Food and Drug Administration (FDA), there were currently no investigational new drug applications or approved new drug applications for bromazolam. The previous Assistant Secretary also stated that HHS had no objection to the temporary placement of this substance in schedule I of the CSA. DEA requested an updated response from HHS, by letter dated June 11, 2025. By letter dated July 10, 2025, the Acting Assistant Secretary of HHS responded that, based on an updated review by FDA, there were currently no approved drug applications or investigational new drug applications for bromazolam. Therefore, HHS had no objections to the temporary placement of bromazolam in schedule I. Bromazolam is not currently listed in any schedule under the CSA, and no exemptions or approvals under FDA's new drug statute, at 21 U.S.C. 355, are in effect for this substance.

To find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c)(4-6): the substance's history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health.[8] This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of bromazolam.[9]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[10] Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug under medical supervision.[11]

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[7] The Secretary of HHS 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).
[8] 21 U.S.C. 811(h)(3).
[9] *Id.*
[10] 21 U.S.C. 811(h)(1).
[11] 21 U.S.C. 812(b)(1).

**Bromazolam**

The dramatic increase in trafficking and abuse of novel psychoactive substances (NPS) in the United States, and particularly the benzodiazepine class of substances, has become a national public health concern in recent years. The availability of benzodiazepine substances, with no currently accepted medical use in the illicit drug market, continues to pose an imminent hazard to public safety. Adverse health effects including slurred speech, ataxia, altered mental state, and respiratory depression associated with the abuse of such drugs known collectively as the "designer benzodiazepines," their continued evolution, and the increased popularity of these substances, have been a serious concern in recent years. The increase in the co-abuse of opioids with the designer benzodiazepines has become a particular concern as the United States continues to experience an unprecedented epidemic of opioid misuse and abuse. The identification of bromazolam in the illicit drug market has been reported in the United States and is currently one of the most commonly identified benzodiazepines in drug seizures. Between April 2021 and July 2025, DEA is aware of at least 240 overdose cases involving bromazolam, of which 189 of these cases were associated with a fatality (see Factors 4 and 5). While the cases were often reported in combination with opioids, at least four fatal cases involved bromazolam either alone or in the absence of other psychoactive substances. Additional sources of information demonstrate additional overdoses, which would suggest that this statistic is likely subject to underreporting in the United States.[12]

Available data and information for bromazolam, summarized below, indicate that this substance has a high potential for abuse, no currently accepted medical uses in treatment in the United States,[13] and a lack of accepted safety for use under medical supervision. DEA's three-

[12] https://www.kentucky.gov/Pages/Activity-stream.aspx?n=AttorneyGeneral&prId=1805

[13] When finding schedule I placement on a temporary basis is necessary to avoid imminent hazard to the public, 21 U.S.C 811(h) does not require DEA to consider whether the substance has a currently accepted medical use in treatment in the United States. Nonetheless, there is no evidence suggesting that bromazolam has a currently accepted medical use in treatment in the United States. First, DEA looks to whether the drug or substance has FDA approval for marketing in interstate commerce. 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

factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at *www.regulations.gov* under Docket Number DEA-1420.

**Factor 4. History and Current Pattern of Abuse**

Since 2012, numerous synthetic drugs belonging to the benzodiazepine class began to emerge in the illicit drug market as evidenced by the identification of these drugs in forensic drug exhibits and toxicology samples. Consequently, on July 26, 2023, DEA temporarily scheduled five synthetic benzodiazepine substances (etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam) in schedule I of the CSA.[14] The dramatic increase in trafficking and abuse associated with these substances, also known as designer benzodiazepines, has become a national public health concern in recent years. According to the Centers for Disease Control and Prevention (CDC), benzodiazepines were involved in 12,499 overdose deaths in the United States between 2019 and 2021.

Bromazolam, a novel designer benzodiazepine, was first encountered by law enforcement in the United States in 2016. Since that time there has been a dramatic rise in its trafficking and abuse. In addition, various health alerts and overdose data have been issued

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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 applied the traditional five-part test 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 providers operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS'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 (April 11, 2024). For purposes of this notice of intent, there is no evidence that health care providers have widespread experience with medical use of bromazolam or that the use of bromazolam is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied. By letter dated June 28, 2024, DEA has been advised by HHS that there are currently no approved new drug applications or investigational new drug applications for bromazolam. Additionally, HHS communicated no objections to the temporary placement of bromazolam into Schedule I of the CSA. In its July 10, 2025 letter, HHS reaffirmed its position and advised DEA that there are currently no approved new drug applications or investigational new drug applications for bromazolam. Additionally, HHS reaffirmed that it had no objections to the temporary placement of bromazolam in schedule I of the CSA.

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

relating to the identification of bromazolam in toxicology samples. The Center for Forensic Science Research and Education's (CFSRE) NPS Discovery first reported identifying bromazolam in overdose samples in a June 2022 alert. Within this alert, it was noted that bromazolam had been identified in more than 250 toxicology cases submitted to NMS Labs, including both antemortem and postmortem investigations. Between the first quarter of 2019 and June 2022, bromazolam was identified in more than 190 toxicology samples tested at CFSRE, displaying an increase in the detection of bromazolam from 1% in the first quarter of 2021 to 13% in the second quarter of 2022. Similarly, between April 2021 and July 2025, DEA's toxicology testing program (DEA TOX[15]) has detected bromazolam in 240 separate cases submitted for expanded analysis. Within these cases, the average age of the user was between 31-40 years old, while greater than 50% of users were between 21 and 40 years of age. The increase of bromazolam identifications in toxicology cases demonstrate the continued rise and serious public health concern related to the abuse of this substance since it was first detected in 2016.

Bromazolam, like other designer benzodiazepines, is often encountered in pill form and can be made to mimic the appearance of legitimately prescribed substances such as alprazolam or other prescription drugs like oxycodone. Designer benzodiazepines have also been encountered in powder or liquid form.

Designer benzodiazepines like bromazolam have been co-abused with other substances, especially fentanyl, according to toxicology reporting. As stated above, between April 2021 through July 2025, DEA TOX results reported a total of 240 cases where bromazolam was detected in a biological sample. Of these 240 cases, fentanyl was identified in 178 cases, or 74.2% of the time. Similar to the large increase in law enforcement encounters observed via the

[15] 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, July 21, 2025.

National Forensic Laboratory Information System (NFLIS), fatal and non-fatal cases submitted to DEA TOX saw a large increase in bromazolam abuse.

**Factor 5. Scope, Duration and Significance of Abuse**

The first law enforcement encounter of bromazolam, as reported by NFLIS, was in the second quarter of 2016. While encounters remained low through 2020, a substantial increase in NFLIS reports was observed in 2021, continuing through the present. The NFLIS database was queried on November 24, 2025, for bromazolam case reports. NFLIS registered 15,241 encounters of bromazolam. Due to the recent emergence of these designer benzodiazepines in the illicit market, it is likely that bromazolam is under-reported as forensic laboratories secure reference standards for use in analyzing these novel substances. Bromazolam has been encountered throughout all 50 states.

**Factor 6. What, if Any, Risk There Is to the Public Health**

The increase in benzodiazepine-related overdoses in the United States has been exacerbated recently by the availability of designer benzodiazepines in the illicit drug market. Bromazolam has pharmacological effects that are similar to other benzodiazepines currently temporarily controlled in schedule I of the CSA. Public health risks associated with bromazolam abuse relate to its pharmacological similarities with known benzodiazepines. Thus, risk to public health is associated with adverse reactions in humans, which are expected to include central nervous system depressant-like effects, such as slurred speech, ataxia, altered mental state, and respiratory depression. While those who abuse bromazolam are likely to obtain it through unregulated sources, the identity, purity, dosage, and adulteration of this substance is uncertain and inconsistent, thus posing significant adverse health risks to the end user. As stated above, between April 2021 through July 2025, DEA TOX results reported a total of 240 cases where bromazolam was detected in a biological sample. Of these 240 cases, a fatality was observed in 189 of these overdose cases.

This rise in bromazolam identifications in toxicology cases has prompted a number of states, including Florida, Ohio, and Indiana, to alert the public of the harms of bromazolam use by issuing public health alerts reporting deaths, non-fatal overdoses, and effects of intoxication. In August 2023, the Indiana Department of Health issued an emerging drug notification to alert law enforcement, first responders, clinicians, and public health professionals about bromazolam. Toxicology results of Indiana decedents from January through June 2023 showed that 35 individuals tested positive for bromazolam, with 8 and 9 results coming in April and May of 2023 respectively. Pharmacological testing has been conducted on bromazolam, showing its activity at the gamma amino butyric acid receptors and ability to substitute for midazolam, an FDA-approved benzodiazepine.

While designer benzodiazepines are often detected in toxicology samples with other substances, especially opioids, evidence of their use alone resulting in serious adverse events have also been encountered. A publication by the CDC's Morbidity and Mortality Weekly Report described three previously healthy young adults who ingested pressed tablets of bromazolam that they reported they believed to be alprazolam (see Factor 6 of the Three Factor Analysis on the docket for more information). In these specific cases, adverse effects following the ingestion of bromazolam included hypertension, tachycardia, hyperthermia, multiple generalized seizures, and myocardial injury as demonstrated by elevated troponin levels. Bromazolam has also been associated with impaired driving which is a hazard to public health and safety. Multiple studies demonstrated either the use of bromazolam alone or in conjunction with polydrug abuse, namely with opioids (e.g., fentanyl) or stimulants (e.g., methamphetamine, cocaine).

In May 2022, the Jefferson County Medical Examiner first detected bromazolam in their case work. A study describing 10 bromazolam-involved deaths was published in 2024, where the results demonstrated that fentanyl was also detected in eight of the ten decedents. Bromazolam was detected alongside the benzimidazole opioid metonitazene in an August 2023

drug overdose in Los Angeles County, California. In a retrospective study evaluating bromazolam-related deaths in Travis County, Texas, bromazolam was identified in 112 deaths from 2021 to 2023. Polydrug use was present in 99% of the bromazolam-positive deaths, which commonly involved fentanyl (82%), methamphetamine (41%), and cocaine (28%).

In summary, bromazolam has been reported to cause serious adverse effects, including death, following its use.

**Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety**

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of bromazolam pose an imminent hazard to public safety. Bromazolam has not been approved by the FDA and has not been marketed in the United States, and DEA is not aware of any currently accepted medical uses for bromazolam in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I must have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for bromazolam indicate that this substance meets the three statutory criteria.

As required by 21 U.S.C. 811(h)(4), the previous Administrator transmitted to the Assistant Secretary, via letter dated June 14, 2024, notice of her intent to place bromazolam in schedule I on a temporary basis. In a letter dated July 28, 2024, the previous Assistant Secretary did not object to the temporary placement of bromazolam in schedule I. DEA requested an updated response from HHS on June 10, 2025. The Acting Assistant Secretary reaffirmed on July 11, 2025, that HHS had no objection to the temporary placement of bromazolam in schedule I.

**Conclusion**

This notice of intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule bromazolam in schedule I of the CSA, and finds that placement of this substance in schedule I is necessary to avoid an imminent hazard to the public safety.

The temporary placement of bromazolam in schedule I of the CSA will take effect upon publication of a temporary scheduling order in the Federal Register, which will not be issued before **[INSERT DATE 30 DAYS AFTER PUBLICATION OF THIS NOTICE IN THE FEDERAL REGISTER]**. Because the Administrator hereby finds this temporary scheduling order necessary to avoid an imminent hazard to the public safety, it will take effect on the date the order is published in the *Federal Register*, and it will remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process.[16] The Administrator intends to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon the temporary order's publication, bromazolam will then be subject to the CSA's schedule I regulatory controls and to administrative, civil, and criminal sanctions applicable to their manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession.

The CSA sets forth specific criteria for scheduling drugs or other substances. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557.[17] The regular scheduling process of formal rulemaking affords interested parties appropriate process and the government any additional relevant information

[16] 21 U.S.C. 811(h)(1) and (2).
[17] 21 U.S.C. 811.

needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review.[18] Temporary scheduling orders are not subject to judicial review.[19]

**Regulatory Analyses**

The CSA provides for expedited temporary scheduling actions where necessary to avoid an imminent hazard to public safety. Under 21 U.S.C. 811(h)(1), the Administrator (as delegated by the Attorney General) may, by order, temporarily schedule substances in schedule I. Such orders may not be issued before the expiration of 30 days from: (1) the publication of a notice in the *Federal Register* of the intent to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary, as delegated by the Secretary.[20]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the *Federal Register* a notice of intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. The APA expressly differentiates between an order and a rule, as it defines an "order" to mean a "final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making*."[21] (Emphasis Added.) This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done "on the record after opportunity for a hearing," and final decisions that conclude the scheduling process and are subject to judicial review.[22] The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator

[18] 21 U.S.C. 877.
[19] 21 U.S.C. 811(h)(6).
[20] 21 U.S.C. 811(h)(1).
[21] 5 U.S.C. 551(6) (emphasis added).
[22] 21 U.S.C. 811(a) and 877.

(as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions,[23] it is noteworthy that, in section 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Even assuming that this notice of intent is subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice-and-comment requirements pursuant to 5 U.S.C. 553(b)(B), as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest given the manifest urgency to avoid an imminent hazard to public safety.

Although DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Acting Assistant Secretary in response to the notice that DEA transmitted to the Acting Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking. As discussed above, DEA is issuing this notice of intent pursuant to DEA's authority to issue a temporary scheduling order.[24] Therefore, in this instance, since DEA believes this temporary scheduling action is not a "rule," it is not subject to the requirements of the RFA when issuing this temporary action.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and

[23] *See* 21 U.S.C. 811(a).
[24] 21 U.S.C. 811(h)(1).

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866. In addition, DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

This action will 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. Therefore, in accordance with E.O. 13132, it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**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 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, add paragraphs (h)(79) to read as follows:

**§ 1308.11 Schedule I**

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(h) * * *

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| (79) 8-bromo-1-methyl-6-phenyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other names: bromazolam) | 2778 |
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## SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on December 7, 2025, 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.*

[FR Doc. 2025-22763 Filed: 12/12/2025 8:45 am; Publication Date: 12/15/2025]