



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-900E]

Schedules of Controlled Substances: Extension of Temporary Placement of Butonitazene, Flunitazene, and Metodesnitazene in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary rule; temporary scheduling order; extension.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to extend the temporary schedule I status of butonitazene, flunitazene, and metodesnitazene, as identified in this order. The schedule I status of these three substances currently is in effect through April 12, 2024. This temporary order will extend the temporary scheduling of these three substances for one year, or until the permanent scheduling action for these substances is completed, whichever occurs first.

DATES: This temporary scheduling order, which extends schedule I control of three substances covered by an order (87 FR 21556, April 12, 2022), is effective April 12, 2024, and expires on April 12, 2025. If DEA publishes a final rule making this scheduling action permanent, this order will expire on the effective date of that rule, if the effective date is earlier than April 12, 2025.

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SUPPLEMENTARY INFORMATION: In this order, the Drug Enforcement Administration (DEA) extends the temporary scheduling of the following three controlled substances in schedule I of the Controlled Substances Act (CSA), including their isomers, esters, ethers, salts, and salts

of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)-*N,N*-diethylethan-1-amine),
- flunitazene (*N,N*-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine),
- metodesnitazene (*N,N*-diethyl-2-(2-(4-methoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine).

Background and Legal Authority

On April 12, 2022, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the *Federal Register* (87 FR 21556) temporarily placing butonitazene, flunitazene, metodesnitazene, and four¹ additional benzimidazole-opioids in schedule I of the Controlled Substances Act (CSA) based upon a finding that these substances pose an imminent hazard to the public safety. That temporary order was effective upon the date of publication.

Under 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 respect to the substance. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of butonitazene, flunitazene, and metodesnitazene expires on April 12, 2024, unless extended.

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 Administrator of DEA on her own motion under authority delegated by the Attorney General pursuant to 28 CFR 0.100, at the

¹ The four additional benzimidazole-opioids were etodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. DEA pursued separate scheduling actions for metonitazene, *see* 88 FR 56466 (Aug. 18, 2023), and for etodesnitazene, *N*-pyrrolidino etonitazene, and protonitazene, to remain as a schedule I substances under the CSA in order to meet the United States' obligations under the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol.

request of the Secretary of Health and Human Services (HHS),² or on the petition of any interested party.³ The Administrator, on her own motion, has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule butonitazene, flunitazene, and metodesnitazene. DEA is publishing a notice of proposed rulemaking elsewhere in this issue of the **Federal Register** for the permanent placement of butonitazene, flunitazene, and metodesnitazene in schedule I elsewhere in this issue of the *Federal Register*. If that proposed rule is finalized, DEA will publish a final rule in the *Federal Register* to make permanent the schedule I status of these substances.

Pursuant to 21 U.S.C. 811(h)(2), the Administrator orders that the temporary scheduling of butonitazene, flunitazene, and metodesnitazene and their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for expedited temporary scheduling actions where necessary to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h)(1), the Administrator, as delegated by the Attorney General, may, by order, temporarily place substances in schedule I. That same subsection also provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of such temporary scheduling order, except that the Attorney General may, during the pendency of proceedings under 21 U.S.C. 811(a)(1) to permanently schedule the substance, extend the temporary scheduling for up to one year.

To the extent that 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, DEA believes that the notice-and-comment requirements of section 553 of the Administrative

² The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations.

³ 21 U.S.C. 811(a).

Procedure Act (APA), 5 U.S.C. 553, do not apply to this extension of the temporary scheduling action. The APA expressly differentiates between orders and rules, 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*.”⁴ 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.⁵ The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an order instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for other kinds of scheduling actions,⁶ it is noteworthy that, in subsection 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even if this action were subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice-and-comment requirements and the delayed effective date requirements of such section, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety that these substances would present if scheduling expired, for the reasons expressed in the temporary scheduling order.⁷

Further, DEA believes that this order extending the 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, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

⁴ 5 U.S.C. 551(6) (emphasis added).

⁵ 21 U.S.C. 811(a) and 877.

⁶ See 21 U.S.C. 811(a).

⁷ See 87 FR 21556 (Apr. 12, 2022).

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.

Additionally, in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14094, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and 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. E.O. 12866, sec. 3(f), as amended by E.O. 14094, sec. 1(b), provides the definition of a “significant regulatory action,” requiring review by the Office of Management and Budget. Because this is not a rulemaking action, this is not a significant regulatory action as defined in section 3(f) of E.O. 12866. 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 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules.⁸ It is in the public interest to maintain the temporary placement of butonitazene, flunitazene, and metodesnitazene in schedule I because they pose a public health risk, for the reasons expressed in the temporary scheduling order.⁹ The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice-and-comment rulemaking procedures. DEA understands that the CSA frames

⁸ 5 U.S.C. 801, 804(3).

⁹ See 87 FR 21556 (Apr. 12, 2022).

temporary scheduling actions as orders rather than rules to ensure that the process moves swiftly, and this extension of the temporary scheduling order for these three substances continues to serve that purpose. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to keep these three substances in schedule I because they pose an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order extending the temporary scheduling order for butonitazene, flunitazene, and metodesnitazene, shall take effect immediately upon its publication.

DEA will submit a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 5, 2024, by Administrator Anne Milgram. 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.

Scott Brinks

Federal Register Liaison Officer,
Drug Enforcement Administration