



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1511]

Schedules of Controlled Substances: Extension of Temporary Placement of CUMYL-PEGACLONE in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary scheduling order; extension.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this temporary scheduling order to extend the temporary schedule I status of CUMYL-PEGACLONE. In an order dated December 12, 2023, DEA temporarily placed CUMYL-PEGACLONE in schedule I of the Controlled Substances Act. This temporary order will extend the temporary scheduling of CUMYL-PEGACLONE for one year, or until the permanent scheduling action for this substance is completed, whichever occurs first. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will continue to be imposed 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 CUMYL-PEGACLONE.

DATES: This temporary scheduling order, which extends schedule I control of CUMYL-PEGACLONE covered by an order (88 FR 86040, December 12, 2023), is effective December 12, 2025, and expires on December 12, 2026. 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 December 12, 2026.

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: In this order, the Drug Enforcement Administration (DEA) extends the temporary scheduling of CUMYL-PEGACLONE in schedule I of the Controlled Substances Act (CSA), including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one).

Background and Legal Authority

On December 12, 2023, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the *Federal Register* temporarily placing CUMYL-PEGACLONE in schedule I of the CSA based upon a finding that this substance poses an imminent hazard to the public safety.¹ That temporary order was effective upon the date of publication. 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. In this instance, the temporary scheduling of CUMYL-PEGACLONE expires on December 12, 2025, unless extended.

Proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance under 21 U.S.C. 811(a) 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 any

¹ *Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (December 12, 2023).

interested party.² The Administrator of DEA, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule CUMYL-PEGACLONE. DEA is publishing a notice of proposed rulemaking elsewhere in this issue of the *Federal Register* for the permanent placement of CUMYL-PEGACLONE in schedule I. If that proposed rule is finalized, DEA will publish a final rule in the *Federal Register* to make permanent the schedule I status of this substance.

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

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety.³ This provision of the CSA allows the Attorney General, by order, to temporarily place substances in schedule I.⁴ The 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 the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings to permanently schedule the substance under 21 U.S.C 811(a)(1), 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, the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553,

² 21 U.S.C. 811(a). As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. *Memorandum of Understanding with the National Institute on Drug Abuse*, 50 FR 9518 (Mar. 8, 1985). Because the Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations, see *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, As Amended; Delegation of Authority*, 58 FR 35460 (July 1, 1993), for purposes of this temporary order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

³ 21 U.S.C. 811(h).

⁴ *Id.*

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.*”⁵ 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.⁶ 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,⁷ 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 under 5 U.S.C. 553(b)(B) and (d)(3) 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 this substance would present if scheduling expired, for the reasons expressed in the temporary scheduling order.⁸

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, DEA is not required by the APA at 5 U.S.C. 553 or any other law to publish a general notice of proposed rulemaking.

⁵ 5 U.S.C. 551(6) (emphasis added).

⁶ 21 U.S.C. 811(a) and 877.

⁷ See 21 U.S.C. 811(a).

⁸ See *Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (December 12, 2023).

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 addition, 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 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), 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 subsection 3(f) of E.O. 12866. 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 (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. However, if this were a rule, pursuant to the CRA, “any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.”⁹

It is in the public interest to maintain the temporary placement of CUMYL-PEGACLONE, including its salts, isomers, and salts of isomers, in schedule I because it poses a

⁹ 5 U.S.C. 808(2).

public health risk. 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. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to keep this substance in schedule I because it poses 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. Further, public notice and comment is impracticable in the amount of time remaining before expiration of the temporary scheduling order and considering the manifest urgency to avoid an imminent hazard to the public safety that this substance would present if scheduling expired, for the reasons expressed in the temporary scheduling order. Therefore, in accordance with subsection 808(2) of the CRA, this order extending the temporary scheduling order, for CUMYL-PEGACLONE currently covered under the temporary order, shall take effect immediately upon its publication.

Nonetheless, DEA has submitted 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 December 8, 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.

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