DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1511]

Schedules of Controlled Substances: Placement of CUMYL-PEGACLONE in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing the substance CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one), including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers, in schedule I of the Controlled Substances Act. CUMYL-PEGACLONE was temporarily scheduled in an order dated December 12, 2023. This action is being taken, in part, to 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, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle CUMYL-PEGACLONE.

DATES: Comments must be submitted electronically or postmarked on or before January 12, 2026. 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.

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 or postmarked on or before January 12, 2026.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). To ensure proper handling of comments, please reference ''Docket No. DEA1356'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit 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 attach a file for lengthier comments. Please go to *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 the 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 *www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) proposes to permanently schedule CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one) in schedule I of the Controlled Substances Act (CSA), including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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 to be 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).[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 regarding 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 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 CUMYL-PEGACLONE meets 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 Health and Human Services (HHS), or on the petition of an interested party.[4] This proposed action is initiated on the Administrator's own motion and supported by, *inter alia,* a recommendation from the then-Assistant Secretary for Health of the 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 CUMYL-PEGACLONE.

In addition, the United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 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 (Secretary),[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 meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[6] 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), 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 June 10, 2021, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 64th Session on April 14, 2021, voted to place CUMYL-PEGACLONE in Schedule II of the 1971 Convention (CND Decision 64/2). As a signatory to the 1971 Convention, the United States is required, by scheduling under the CSA, to place appropriate controls on CUMYL-PEGACLONE to meet the minimum requirements of the treaty. The relevant treaty provisions and domestic statutes executing those provisions are below.

To begin, Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. Pursuant to the 1971 Convention, the United States must require licenses for the manufacture, export and import, and distribution of CUMYL-PEGACLONE. The CSA's registration requirement as set forth in 21 U.S.C. 822, 823, 957, and 958, as well as implementing regulations in 21 CFR parts 1301 and 1312, set forth this licensing requirement.

In addition, the United States must adhere to specific export and import provisions set forth in the 1971 Convention. The CSA's export and import provisions established in 21 U.S.C. 952, 953, 957, and 958, and implemented in 21 CFR part 1312, execute these requirements.

Likewise, under Article 13, paragraphs 1 and 2 of the 1971 Convention, a party to the 1971 Convention may notify through the U.N. Secretary-General that it prohibits the importation of a substance in Schedule II, III, or IV of the 1971 Convention. If such notice is presented to the United States, the United States shall take measures to ensure that the named substance is not exported to the notifying country. The CSA's above-mentioned export provisions set forth these procedures.

Further, under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) In regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured, exported to, and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule III and IV of the 1971 Convention, quantities manufactured, as well as quantities exported and imported; (3) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in

[1] 5 U.S.C. 551–559; 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 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. 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. 58 FR 35460 (July 1, 1993).

[6] 21 U.S.C. 811(d)(3).

the manufacture of exempt preparations; and (4) in regard to each substance in Schedule II–IV of the 1971 Convention, quantities used for the manufacture of non-psychotropic substances or products.

Lastly, under Article 2 of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. Persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action.

DEA notes that there are differences between the schedules of substances in the 1971 Convention and the CSA. The CSA has five schedules (schedules I–V) with specific criteria set forth for each schedule. Schedule I is the only possible schedule in which a drug or other substance may be placed if it has high potential for abuse and no currently accepted medical use in treatment in the United States.[7] In contrast, the 1971 Convention has four schedules (Schedules I–IV) but does not have specific criteria for each schedule. The 1971 Convention simply defines its four schedules, in Article 1, to mean the correspondingly numbered lists of psychotropic substances annexed to the Convention and altered in accordance with Article 2.

Proposed Determination To Schedule CUMYL-PEGACLONE

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on CUMYL-PEGACLONE and, on June 12, 2023, submitted it to the then-Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for CUMYL-PEGACLONE.

On December 12, 2023, the previous Administrator published a temporary scheduling order in the **Federal Register** temporarily placing six synthetic cannabinoids (SCs) in schedule I of the CSA based on the finding that these substances pose an imminent threat to public safety.[8] The six SCs temporarily controlled under the CSA were (1) MDMB-4en-PINACA; (2) methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other name: 4F-MDMB- BUTICA); (3) 4F-MDMB-BICA); N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide (other name: ADB-4en-PINACA); (4) 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (other names: CUMYL-PEGACLONE; SGT-151); (5) ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 5F-EDMB-PICA; 5F-EDMB-2201); and (6) methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate (other name: MMB-FUBICA). These six SCs have not been investigated for medical use. Nor are they intended for human use.

On December 11, 2024, HHS provided DEA a scientific and medical evaluation entitled, ''Basis for the Recommendation to Place CUMYL-PEGACLONE and its salts in Schedule I of the Controlled Substances Act,'' and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b), following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that CUMYL-PEGACLONE be controlled in schedule I of the CSA under 21 U.S.C. 812(b). HHS noted that CUMYL-PEGACLONE is a full agonist at the cannabinoid type 1 (CB1) receptor, has no known medical use in the United States, has no approved new drug applications, and is not known to be marketed anywhere in the world as an approved drug product. HHS also noted that health care practitioners and medical examiners have reported cases of severe clinical adverse events and even death when CUMYL-PEGACLONE was ingested.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, and all other relevant data, and conducted its own eight-factor analysis in accordance with 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in this proposed scheduling determination. Please note that both the DEA and HHS analyses, including the evaluation of the eight factors determinative of control along with their supporting data and citations, are available in their entirety under the tab ''Supporting Documents'' of the public docket of this proposed rule at *https://www.regulations.gov,* under docket number ''DEA1356.''

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 CUMYL-PEGACLONE, DEA also considered all other relevant data regarding actual or relative potential for abuse of CUMYL-PEGACLONE. The term ''abuse'' is not defined in the CSA; however, the legislative history of the CSA suggests the following four prongs in determining whether a particular drug or substances 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 of the community; or

b. There is a significant diversion of the drug or 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.

Both DEA and HHS eight-factor analyses found that CUMYL-PEGACLONE produces pharmacological effects that are similar to those produced by schedule I SCs, such as JWH–018 and AM2201. CUMYL-PEGACLONE has been associated with numerous reports of severe health effects and intoxications including seizures followed by collapse, and deaths. CUMYL-PEGACLONE does not have an approved medical use in the United States, but evidence indicates that CUMYL-PEGACLONE is being abused and trafficked in the United States. Because this substance is not an approved drug product, a practitioner may not legally prescribe it, and it cannot be dispensed to an individual. However, case reports, coroner/medical examiner reports, and law enforcement data[10] demonstrate that CUMYL-PEGACLONE is being used without medical advice. CUMYL-PEGACLONE has been identified during the toxicological screening in both fatal and non-fatal overdoses. Law enforcement

[7] *See* 21 U.S.C. 812(b).

[8] *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 (Dec. 12, 2023).

[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] While law enforcement 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).

data show that CUMYL-PEGACLONE has been encountered in the United States illicit drug market.

Overall, these data demonstrate that CUMYL-PEGACLONE has a high potential for abuse. Thus, based on these data, it is reasonable to conclude that CUMYL-PEGACLONE, having no medical use, and thus no therapeutic value, presents a hazard to the health and safety of individuals and the community.

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

As explained in the 8-factor analyses by HHS and by DEA, the available pharmacology data indicate that CUMYL-PEGACLONE produces pharmacological effects that are similar to those produced by schedule I substances, such as JWH–018 and AM2201. *In vitro* results indicate that CUMYL-PEGACLONE, similar to other schedule I SCs, binds to CB1 receptors and acts as an agonist at CB1 receptors. Data also demonstrates that CUMYL-PEGACLONE produces discriminative stimulus effects that are similar to those of the schedule I JWH–018 and AM2201. These pharmacological characteristics of CUMYL-PEGACLONE are predictive of substances that have a high potential for abuse. Overall, these data indicate that CUMYL-PEGACLONE produces pharmacological effects and hallucinogen-like behaviors that are similar to those of the JWH–018 and AM2201.

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

CUMYL-PEGACLONE is a CB1 receptor agonist that is pharmacologically similar to JWH–018 and AM2201 that is often smoked for recreational purposes. Neither DEA nor HHS are aware of any currently accepted medical use for CUMYL-PEGACLONE. There are no well-controlled clinical studies showing safety or efficacy for this substance. In addition, there is no evidence by qualified experts that CUMYL-PEGACLONE is accepted as having therapeutic uses. In the HHS report, the Food and Drug Administration (FDA) concluded that CUMYL-PEGACLONE has no currently accepted medical use in the United States. Similarly, DEA concludes CUMYL-PEGACLONE has no currently accepted medical use according to established DEA procedure and case law.

4. History and Current Pattern of Abuse

In their review, HHS described how the history and current pattern of abuse of CUMYL-PEGACLONE was evidenced by law enforcement data from DEA regarding drug seizures and poison control center reports, indicating the substance is used for abuse purposes. HHS noted that while law enforcement data is not direct evidence of abuse, it can be inferred that CUMYL-PEGACLONE has been consumed for its psychoactive and intoxicating effects as with other SCs. CUMYL-PEGACLONE was described in a patent from 2014. In addition, CUMYL-PEGACLONE was first reported as an adulterated plant material in Germany in December 2016 and appeared in the United States in September 2018.

5. Scope, Duration and Significance of Abuse

Evidence shows that CUMYL-PEGACLONE is a recreational drug of abuse. HHS noted in their recommendation that SCs continue to be encountered on the illicit market despite scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel substances continue to be encountered that differ only by small chemical structural modifications intended to avoid prosecution, while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products. These encounters of CUMYL-PEGACLONE by law enforcement indicate that this substance is being trafficked and abused in the United States. Furthermore, evidence also indicates that CUMYL-PEGACLONE is abused internationally.

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

Available evidence on the overall public health risks associated with the use of CUMYL-PEGACLONE suggests that CUMYL-PEGACLONE can cause acute health problems leading to emergency department admissions and death. Case reports detailing serious adverse effects have been reported in the literature (*see* additional details at *www.regulations.gov* contained within DEA's 8-factor analysis at docket DEA–1356). Following the ingestion of products containing CUMYL-PEGACLONE, individuals have experienced seizures followed by collapse and death. Serious adverse effects and previously discussed data showing that CUMYL-PEGACLONE shares pharmacological similarities with schedule I substances, including JWH–018 and AM2201, demonstrate that CUMYL-PEGACLONE is a serious public health threat.

7. Its Psychic or Physiological Dependence Liability

In their recommendation, HHS noted that there are no clinical studies evaluating dependence liabilities specific for CUMYL-PEGACLONE. However, scientific data indicate that CUMYL-PEGACLONE has a pharmacological profile that is similar to other schedule I SCs. It is reasonable to assume that CUMYL-PEGACLONE would retain a physiological and psychological dependence liability that is similar to that of other schedule I SCs such as JWH–018 and AM2201. Thus, it is reasonable to conclude that the cannabinoid-like properties of CUMYL-PEGACLONE may produce a psychic and/or physiological dependence liability that is similar to other SCs already controlled in schedule I under the CSA.

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

CUMYL-PEGACLONE is not an immediate precursor of any substance controlled under the CSA, as defined in 21 U.S.C. 802(23).

Conclusion

After considering the scientific and medical evaluation conducted and accompanying recommendation of HHS, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of CUMYL-PEGACLONE. As such, DEA hereby proposes to permanently schedule CUMYL-PEGACLONE as a schedule I controlled substance under the CSA. This action would also enable the United States to meet its obligations under the 1971 Convention.

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

[11] 21 U.S.C. 812(b).

1. CUMYL-PEGACLONE Has a High Potential for Abuse

CUMYL-PEGACLONE has a high potential for abuse, evidenced in part by data from *in vitro* binding affinity and functional activity studies, as well as by data from in vivo drug discrimination tests in animals. In these studies, CUMYL-PEGACLONE is demonstrated to be an agonist at CB1 receptors, which is a mechanism of action shared with other SCs, substances with a high potential for abuse and controlled in schedule I under the CSA. This finding is also consistent with the drug abuse patterns of CUMYL-PEGACLONE and adverse outcomes evident from epidemiological data sources. In summary, CUMYL-PEGACLONE has similar patterns of drug abuse, as well as similar adverse outcomes from its use, as have been observed with other SCs currently controlled in schedule I of the CSA.

2. CUMYL-PEGACLONE Has No Currently Accepted Medical Use in Treatment in the United States

CUMYL-PEGACLONE is not legally marketed in the United States, as FDA has not approved a marketing application for a drug product containing CUMYL-PEGACLONE for any indication. There are no known medically approved uses worldwide at this time. Moreover, there are no clinical studies or petitioners, of which FDA is aware, that claim an accepted medical use in the United States. There is no evidence that CUMYL-PEGACLONE has a currently accepted medical use in treatment in the United States.[12]

3. There is a Lack of Accepted Safety for Use of CUMYL-PEGACLONE Under Medical Supervision

Because CUMYL-PEGACLONE has no approved medical use and has not been thoroughly investigated as new drugs, its safety for use under medical supervision is not determined. Thus, there is a lack of accepted safety for use of these substances under medical supervision.

Based on these findings, the Administrator concludes that CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one), including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers, warrants control in schedule I of the CSA. More precisely, because of its hallucinogenic-like effects, DEA is proposing to place CUMYL-PEGACLONE in 21 CFR 1308.11(d) (the hallucinogens category of schedule I).

Requirements for Handling CUMYL-PEGACLONE

If this rule is finalized as proposed, CUMYL-PEGACLONE would continue [13] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, import, export, engagement in research, conduct of instructional actitities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *1. Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) CUMYL-PEGACLONE 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. CUMYL-PEGACLONE is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling these three substances also must comply with the screening requirements of 21 CFR 1301.90–1301.93.

3. Labeling and Packaging. All labels and labeling for commercial containers of CUMYL-PEGACLONE must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. Quota. Only registered manufacturers would be permitted to manufacture CUMYL-PEGACLONE 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 CUMYL-PEGACLONE must have an initial inventory of all stocks of controlled substances (including this substance) 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 CUMYL-PEGACLONE) on hand every two years pursuant to 21 U.S.C. 827 and 958(e), 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 CUMYL-PEGACLONE, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74 and 1301.76, and parts 1304, 1312, and 1317. Manufacturers and distributors would be required to submit reports regarding CUMYL-PEGACLONE 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 CUMYL-PEGACLONE must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

[12] 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 CUMYL-PEGACLONE does not satisfy this two-part test. Therefore, since both DEA and HHS have determined that this substance does not satisfy the five-part test, and HHS has determined that this substance does not satisfy the additional two-part test, DEA concludes that CUMYL-PEGACLONE does not have a currently accepted medical use.

[13] CUMLY-PEGACLONE is curently subject to schedule 1 controls on a temporary basis, pursuant to 21 U.S.C. 811(h). *See Schedule of Controled Substances: Temporary Placement of MDMB-4en PINACA, 4f-MDMB-BUTICA, ADB-4en-PINACA, CUMLY-PEGACLONE, 5F-EDMB-PICA and MMB-FUBICA into Schedule I,* 88 FR 86040 (Dec. 12, 2023).

8. Importation and Exportation. All importation and exportation of CUMYL-PEGACLONE 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 CUMYL-PEGACLONE not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

In accordance with 21 U.S.C. 811(a), this 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 Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, 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 December 12, 2023, DEA published an order to temporarily place CUMYL-PEGACLONE, including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers, 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 CUMYL-PEGACLONE have already established and implemented systems and processes required to handle these substances. This action was taken to 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, reverse distribute, dispense, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle CUMYL-PEGACLONE.

According to HHS, CUMYL-PEGACLONE has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. There appear to be no legitimate sources for CUMYL-PEGACLONE as a marketed drug in the United States, but DEA notes that this substance is available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of CUMYL-PEGACLONE 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.

The entities affected by this proposed rule include the manufacturers, distributors, importers, exporters, and researchers of CUMYL-PEGACLONE. DEA determines the North American Industry Classification System (NAICS) industries that best represent these business activities. Table 1 lists the business activities and corresponding NAICS industries.[14]

TABLE 1—BUSINESS ACTIVITY AND CORRESPONDING NAICS INDUSTRIES

Business activity	NAICS code	NAICS industry description
Manufacturer	325412	Pharmaceutical Preparation Manufacturing.
Distributor, Importer, Exporter	424210	Drugs and Druggists' Sundries Merchant Wholesalers.
	424690	Other Chemical and Allied Products Merchant Wholesalers.
Researcher	541715	Research and Development in Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).
	611310	Colleges, Universities and Professional Schools.

[14] 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.*

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. Table 2 lists the number of firms, small firms, and percent small firms in each affected industry.

TABLE 2—PERCENT AFFECTED SMALL ENTITIES BY INDUSTRY

NAICS industry	Firms [15]	SBA size standard [16]	Small firms [17]	Percent of small entities (%)
325412—Pharmaceutical Preparation Manufacturing	1,179	1,300 employees ...	1,099	93.2
424210—Drugs and Druggists' Sundries Merchant Wholesalers	7,012	250 employees	6,760	96.4
424690—Other Chemical and Allied Products Merchant Wholesalers	5,487	175 employees	5,197	94.7
541715—Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).	10,042	1,000 employees ...	9,599	95.6
611310—Colleges, Universities and Professional Schools	2,494	$34.5 million	1,515	60.8

Based on the American Chemical Society's SciFinder database,[18] DEA identified three entities supplying CUMYL-PEGACLONE across the industries 325412, 424210, and 424690. However, one entity has already registered with DEA to handle controlled substances. Hence, DEA expects only two of the entities in the 325412, 424210, and 424690 industries will be affected by this rule. Assuming that all affected suppliers were small entities and concentrated in the smallest NAICS industry, 325412—Pharmaceutical Preparation Manufacturing, they would account for insubstantial number of small entities in that industry, 0.18 percent.[19]

Additionally, DEA expects that the number of researchers working with CUMYL-PEGACLONE is small, because CUMYL-PEGACLONE 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 CUMYL-PEGACLONE 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 541715 and 611310 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 0.18 percent of the small businesses and are not likely to manufacture or carry inventory of CUMYL-PEGACLONE. 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. 1532, 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.[20] Also, this propsed 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, 1117–00010, 1117–00012, 1117–00014, 1117–00021, 1117–00023, 1117–00029, 1117–00056. 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 part 1308 continues to read as follows:

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

■ 2. In § 1308.11:

■ a. Add a new paragraph (d)(107) to read as follows:

§ 1308.11 Schedule I.

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[15] 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* (Accessed 6/24/2025).

[16] U.S. Small Business Administration, 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* (Accessed 6/24/2025).

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

[18] SciFinder; Chemical Abstracts Service: Columbus, OH; CAS 2504100–70–1; *https://scifinder.cas.org* (accessed May 14, 2024).

[19] 2/1,099 = 0.18%.

[20] 44 U.S.C. 3501–3521.

(d) * * *

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(106) 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (other names: CUMYL-PEGACLONE; SGT-151)						7093
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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.

[FR Doc. 2025–22495 Filed 12–10–25; 8:45 am]

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