410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1390]

Specific Listing for Dipentylone, A Currently Controlled Schedule I Substance

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final Rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Controlled Substances Code Number (drug code) for 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)pentan-1-one (dipentylone; *N,N*-dimethylpentylone) in schedule I of the Controlled Substances Act (CSA). Although dipentylone is not specifically listed in schedule I of the CSA with its own unique drug code, it is a schedule I controlled substances in the United States because it is a positional isomer of *N*-ethylpenthylone (controlled August 31, 2018), which is a schedule I hallucinogen. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include dipentylone.

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

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249. As required by 5 U.S.C. 553(b)(4), a summary of this rule may be found in the docket for this rulemaking at www.regulations.gov.

SUPPLEMENTARY INFORMATION:

Dipentylone Control

Dipentylone (also known as, 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)pentan-1-one and *N,N*-dimethylpentylone) is a chemical substance that is structurally related to *N*-ethylpentylone (also known as, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one). *N*-Ethylpentylone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(86). As stated in subsection 1308.11(d), a listed hallucinogenic substance includes "any of 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," and the term "isomer" includes the "optical, position[al,] and geometric isomers."

When compared to the chemical structure of *N*-ethylpentylone, dipentylone meets the definition of a "positional isomer" in 21 CFR 1300.01(b), which cross-references the term "positional isomer" in 21 CFR 1308.11(d). Both *N*-ethylpentylone and dipentylone possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety between functional groups that does not create new chemical functionalities or destroy existing chemical functionalities. Accordingly, under 21 CFR 1308.11(d), dipentylone, as a positional isomer of *N*-ethylpentylone, has been and continues to be a schedule I controlled substance.[1]

Legal Authority

This rule is prompted by a letter dated June 6, 2024, in which the Secretariat of the United Nations informed the United States government that dipentylone had been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. This letter was provoked by a decision at the 67th Session of the Commission on Narcotic Drugs (CND)

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[1] *N*-Ethylpentylone (and its isomers) has been subject to schedule I controls since August 31, 2018, *see* Schedules of Controlled Substances: Temporary Placement of N-Ethylpentylone in Schedule I, 83 FR 44474 (Aug. 31, 2018), a one-year extension of that order, *see* Schedules of Controlled Substances: Extension of Temporary Placement of N-Ethylpentylone in Schedule I of the Controlled Substances Act, 85 FR 52915 (Aug. 31, 2020), and then permanently placed under schedule I, *see* Schedules of Controlled Substances: Placement of N-Ethylpentylone in Schedule I, 86 FR 31427-31429 (June 14, 2021).

in March 2024 to schedule dipentylone under Schedule II of the 1971 Convention (CND Decision 67/3). Preceding this decision, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the *Federal Register* with an opportunity to submit domestic information and opportunity to comment on this action.[2] In the February 8, 2024 notice, FDA noted that dipentylone was already controlled in schedule I of the Controlled Substances Act (CSA) as a positional isomer,[3] and the February 2024 notice stated that no additional permanent controls for dipentylone under the CSA would be necessary to fulfill the United States' obligations as a party to the 1971 Convention.

As discussed above in this final rule, dipentylone – by virtue of being a positional isomer of *N*-ethylpentylone – has been controlled in schedule I of the CSA temporarily since August 31, 2018,[4] and permanently since June 14, 2021.[5] Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to dipentylone. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of dipentylone as a schedule I controlled substance in any way. This action, as an administrative matter, establishes a separate, specific listing for dipentylone in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for this substance. This

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2 *See* International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3-CMC); Dipentylone; 2-Fluorodeschloroketamine (2-FDCK); Nitrous Oxide (N2O); Carisoprodol; Request for Comments, 88 FR 52179 (Aug. 7, 2023); International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Butonitazene; 3-Chloromethcathinone; Dipentylone; 2-Fluorodeschloroketamine; Bromazolam; Request for Comments, 89 FR 8683 (Feb. 8, 2024).

3 In the Feb. 8, 2024 notice (89 FR 8683), dipentylone was incorrectly identified as a positional isomer of Pentylone.

4 *See* Schedules of Controlled Substances: Temporary Placement of N-Ethylpentylone in Schedule I, 83 FR 44474 (Aug. 31, 2018).

5 *See* Schedules of Controlled Substances: Placement of N-Ethylpentylone in Schedule I, 86 FR 31427 (June 14, 2021).

action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of dipentylone, who had previously been granted individual quotas for such purposes under the drug code for *N*-ethylpentylone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest.[6]

Pursuant to 5 U.S.C. 553(b)(B), DEA finds that notice-and-comment rulemaking is unnecessary as dipentylone is currently controlled in schedule I as a positional isomer of *N*-ethylpentylone. The addition of a separate listing for dipentylone and its DEA controlled substances code number in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of this drug as a schedule I controlled substance, but instead is "a minor or merely technical amendment in which the public is not particularly interested."[7] This rule is a "technical amendment" to 21 CFR 1308.11(d) as it is "insignificant in nature and impact, and inconsequential to the industry and public." Therefore, DEA finds that publishing a notice of proposed rulemaking and soliciting public comment are unnecessary and good cause exists to dispense with these procedures.

In addition, DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of dipentylone. With dipentylone

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6 5 U.S.C. 553.

7 *National Nutritional Foods Ass'n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79-752, at 200 (1945)). *See also Utility Solid Waste Activities Group v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001) (the "unnecessary" prong "is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public") (internal quotations and citation omitted).

currently controlled as a schedule I controlled substance as a positional isomer, and with no additional requirements being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3).

Executive Orders 12866, 13563, 14192, and 14294 (Regulatory Review).

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14192. This rule is not a significant regulatory action under section 3(f) of E.O. 12866. Dipentylone is already a controlled substance in the United States under schedule I, as it is a positional isomer of the schedule I hallucinogen *N*-ethylpentylone. In this final rule, DEA is making an administrative change by amending its regulations to separately list dipentylone in schedule I and to assign a DEA controlled substances code number to this substance. A separate listing for dipentylone and its DEA controlled substances code number will not alter the status of this substance as a schedule I controlled substance. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB). DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation.

Executive Order 14294 specifies that all notices of proposed rulemaking (NPRMs) and final rules published in the Federal Register, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense, the authorizing statute, and the mens rea requirement for each element of the offense. This final rule does not involve a criminal regulatory offense and thus E.O. 14294 does not apply.

Executive Order 12988, Civil Justice Reform

This 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, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does 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.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This 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 Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[8] This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to

8 44 U.S.C. 3501–3521.

respond to, a collection of information unless it displays a currently valid OMB control number.

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 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.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

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 amends 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. Amend § 1308.11 by adding paragraph (d)(105) to read as follows:

§ 1308.11 Schedule I.

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(d) * * *

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(105) 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)pentan-1-one (other names: dipentylone; *N,N*-dimethylpentylone)	7552
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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on August 5, 2025, by Administrator Terrance 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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