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Brian Konie,

Acting Manager, Airspace Rules and Regulations.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1003]

Specific Listing for Eutylone, 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-(ethylamino)butan-1-one (also known as eutylone or bk-EBDB) in schedule I of the Controlled Substances Act (CSA). Although eutylone is not specifically listed in schedule I of the CSA with its own unique drug code, it has been controlled in the United States since March 7, 2014, as a positional isomer of pentylone, a schedule I hallucinogen. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include eutylone.

DATES: Effective April 10, 2023.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Eutylone Control

Eutylone (also known as 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one or bk-EBDB) is a chemical substance which is structurally related to pentylone (also known as 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one or bk-MBDP). Pentylone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(64). The introductory text to paragraph (d) provides: (1) A listed 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 (2) the term ''isomer'' includes the optical, position[al], and geometric isomers.

When compared to the chemical structure of pentylone, eutylone 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 pentylone and eutylone 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. Accordingly, under 21 CFR 1308.11(d), eutylone, as a positional isomer of pentylone, has been and continues to be a schedule I controlled substance.[1]

The Drug Enforcement Administration (DEA)'s Authority To Control Eutylone

This rule is prompted by a letter dated May 27, 2022, in which the United States government was informed by the Secretariat of the United Nations that eutylone has been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention). This letter was prompted by a decision at the 65th Session of the Commission on Narcotic Drugs (CND) in March 2022 to schedule eutylone under Schedule II of the 1971 Convention (CND Dec/65/3). 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, July 23, 2021, 86 FR 39038 and February 15, 2022, 87 FR 8586. In every instance, FDA noted that eutylone was already controlled in schedule I of the Controlled Substances Act (CSA) as a positional isomer of pentylone, and the February 2022 notice stated that no additional permanent controls for eutylone under the CSA would be necessary to fulfill United States' obligations as a party to the 1971 Convention.

As discussed above in this final rule, eutylone—by virtue of being a positional isomer of pentylone—has been controlled in schedule I of the CSA temporarily since March 7, 2014 (79 FR 12938), and permanently since March 1, 2017 (82 FR 12171). Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to eutylone. 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 eutylone as a schedule I controlled substance in any way. This action, as an administrative matter, merely establishes a separate, specific listing for eutylone in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for the substance. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of eutylone, who had previously been granted individual quotas for such purposes under the drug code for pentylone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), 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. Eutylone is currently controlled in schedule I as a positional isomer of pentylone, and eutylone has no currently accepted medical use in treatment to qualify for placement in a schedule other than schedule I (*see* 21 U.S.C. 812(b)(2)–(5)).

Pursuant to 5 U.S.C. 553(b)(3)(B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures. The addition of a separate listing for eutylone 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.'' *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

[1] Pentylone (and its isomers) has been subject to temporary schedule I controls since March 7, 2014, first pursuant to a final order (March 7, 2014, 79 FR 12938) and the subsequent one-year extension of that order (March 4, 2016, 81 FR 11429), and then permanently pursuant to a final rule which continued the imposition of those controls (March 1, 2017, 82 FR 12171).

and impact, and inconsequential to the industry and public'') (internal quotations and citation omitted). 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, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary.

In addition, because eutylone is already subject to domestic control under schedule I as a positional isomer of pentylone and no additional requirements are 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). DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of eutylone. Eutylone is currently controlled as a schedule I controlled substance, and this level of control does not change with this rulemaking.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. This rule is not a significant regulatory action under E.O. 12866. Eutylone already is a controlled substance in the United States under schedule I, as it is a positional isomer of a schedule I hallucinogen, pentylone. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list eutylone in schedule I and to assign the DEA controlled substances code number 7549 to the substance. A separate listing for eutylone and its DEA controlled substances code number will not alter the status of eutylone as a schedule I controlled substance. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

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. 44 U.S.C. 3501–3521. 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 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 new paragraph (d)(101) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(101) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one (other names: eutylone; bk-EBDB)	7549

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Signing Authority

This document of the Drug Enforcement Administration was signed on April 3, 2023, 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.

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