



BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-510]

Listing of Ethylone in Schedule I of Controlled Substances and Assignment of an Administration Controlled Substances Code Number

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This is a final rule issued by the Drug Enforcement Administration (DEA) establishing a specific listing and administration controlled substances code number for ethylone (also known as 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one; 3,4-methylenedioxy-*N*-ethylcathinone; bk-MDEA; MDEC) in schedule I of the Controlled Substances Act (CSA).

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

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Ethylone Control

Ethylone (1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one; 3,4-methylenedioxy-*N*-ethylcathinone; bk-MDEA; MDEC) is a chemical substance which is structurally related to butylone. Butylone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(62), which includes “any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible,” and for which “the term ‘isomer’ includes the optical, position and geometric isomers.” When compared to the chemical structure of butylone, ethylone meets the statutory definition of a positional isomer in 21 CFR 1300.01(b). Both butylone and ethylone possess the same molecular formula, core structure, and 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), ethylone has been and continues to be a schedule I controlled substance.

DEA’s Authority to Control Ethylone

This rule is prompted by a letter dated April 21, 2017, in which the United States Government was informed by the Secretary-General of the United Nations that ethylone 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 60th Session of the Commission on Narcotic Drugs in March 2017 to schedule ethylone under Schedule II of the 1971 Convention. Preceding this decision, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services (HHS), published notice in the Federal Register with an opportunity to submit domestic information and opportunity to comment on this action, 81 FR 64162 and 82 FR 3326. In both instances, FDA noted that ethylone was already controlled as a positional isomer of butylone, and that no additional

controls would be necessary. However, as a signatory Member State to the 1971 Convention, the United States is obligated to control ethylone under its national drug control legislation, *i.e.*, the CSA.

Ethylone is currently controlled domestically in schedule I of the CSA as a positional isomer of butylone, and, as such, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to ethylone. 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. Article 23 of the 1971 Convention allows for adoption of stricter domestic measures of control than those required under the Convention, if those measures are desirable or necessary for the protection of the public health and welfare.

This action has the net effect of establishing a specific listing for ethylone in schedule I of the CSA and assigns an Administration Controlled Substances Number 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 ethylone who had previously been granted individual quotas for such purposes under drug code for butylone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (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. This rule is promulgated in order to

comply with international treaty obligations, and because ethylone is currently controlled in schedule I and has no accepted medical use, DEA has no discretion with respect to these changes.

Pursuant to 5 U.S.C. 553(b)(B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures because the inclusion of ethylone and its Administration Controlled Substances Code Number in the list of schedule I substances in 21 CFR 1308.11(b) 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 and impact, and inconsequential to the industry and public”) (int. quotations and citation omitted). This rule is a “technical amendment” to 21 CFR 1308.11(b) 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 ethylone is already subject to domestic control under schedule I as a positional isomer of butylone 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). As ethylone is already subject to domestic control under schedule I and no additional requirements are being imposed through this action, DEA believes that delaying the effective date of this rule could cause confusion regarding the regulatory status of ethylone. Ethylone is

currently controlled as a schedule I controlled substance, and this level of control does not change with this rulemaking.

Executive Order 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (EO) 12866 and 13563. This rule is not a significant regulatory action under EO 12866. Ethylone has been controlled in the United States as a positional isomer of a schedule I hallucinogen. In this final rule, DEA is merely amending its regulations to formally list ethylone in schedule I and to assign the Administration Controlled Substances Code Number 7547 to the substance. Listing ethylone and its Administration Controlled Substances Code Number will not alter the status of ethylone as a schedule I controlled substance. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Because this final rule is not significant under EO 12866, it is not subject to the requirements of EO 13771.¹

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of EO 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

¹ Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled “Reducing Regulation and Controlling Regulatory Costs” (Feb. 2, 2017).

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of EO 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 EO 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 explained above, the DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply to this interim final rule.

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 million or more (adjusted for inflation) in any one 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 section 804 of 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, 21 CFR part 1308 is amended 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)(80), to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(80) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one (ethylone).....7547

Uttam Dhillon,
Acting Administrator.

[FR Doc. 2020-10295 Filed: 6/5/2020 8:45 am; Publication Date: 6/8/2020]