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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-482]

Schedules of Controlled Substances: Placement of N-Ethylpentylone in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one (known as *N*-ethylpentylone or ephylone) and its optical, positional, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. This action makes permanent the current imposition of the 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, or possess), or propose to handle *N*-ethylpentylone.

DATES: *Effective date:* June 14, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-8207.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (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 (1) on his own motion;

(2) at the request of the Secretary of the Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated on the Attorney General's own motion, as delegated to the Administrator of the Drug Enforcement Administration (DEA), and it is supported by a recommendation from the Assistant Secretary for Health of HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. This action makes permanent the current, temporary imposition of regulatory controls and administrative, civil, and criminal sanctions for schedule I controlled substances on any person who handles or proposes to handle *N*-ethylpentylone.

Background

On August 31, 2018, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one (known as *N*-ethylpentylone or ephylone) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 83 FR 44474. That temporary scheduling order was effective on the date of publication, and was based on findings by the Acting Administrator of DEA that the temporary scheduling of this synthetic cathinone was necessary to avoid an imminent hazard to the public safety pursuant to section 811(h)(1). On August 27, 2020, DEA published an order to extend the temporary scheduling of *N*-ethylpentylone by one year, or until August 31, 2021, pursuant to section 811(h)(2). 85 FR 52915. Also, on that same date and in the same issue of the **Federal Register**, DEA simultaneously published a notice of proposed rulemaking (NPRM) to permanently control *N*-ethylpentylone in schedule I of the CSA. 85 FR 52935. Specifically, DEA proposed to add *N*-ethylpentylone to the hallucinogenic substances list under 21 CFR 1308.11(d).

¹ 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. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

DEA and HHS Eight Factor Analyses

On July 15, 2020, HHS provided DEA with a scientific and medical evaluation document prepared by the Food and Drug Administration (FDA) entitled "Basis for the Recommendation to Control *N*-ethylpentylone and Its Optical, Geometric, and Positional Isomers, Salts, and Salts of Isomers in Schedule I of the Controlled Substances Act." After considering the eight factors in 21 U.S.C. 811(c) pursuant to 21 U.S.C. 811(b), and *N*-ethylpentylone's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the Assistant Secretary recommended that *N*-ethylpentylone be controlled in schedule I of the CSA.

In response, DEA conducted its own eightfactor analysis of *N*-ethylpentylone under 21 U.S.C. 811(c), and concluded that this substance warrants control in schedule I of the CSA, as it meets the findings prescribed by 21 U.S.C. 812(b)(1). Both DEA and HHS eight-factor analyses are available in their entirety in the public docket for this rule (Docket Number DEA-482) at <http://www.regulations.gov> under "Supporting Documents."

Determination to Schedule *N*-Ethylpentylone

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from HHS, DEA published an NPRM entitled "Schedules of Controlled Substances: Placement of *N*-ethylpentylone in Schedule I." This rule proposed to control *N*-ethylpentylone, and its optical, positional, and geometric isomers, salts, and salts of isomers in schedule I of the CSA. 85 FR 52935, August 27, 2020. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before September 28, 2020. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before September 28, 2020.

Comment Received

DEA received one anonymous comment on the proposed rule to control *N*-ethylpentylone in schedule I

of the CSA. However, this comment was not related to the rule; therefore, DEA does not respond to the comment.

Scheduling Conclusion

After consideration of the relevant matter presented through the scientific and medical evaluation and the accompanying scheduling recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of *N*-ethylpentylone. Accordingly, DEA is permanently scheduling *N*-ethylpentylone as a controlled substance under the CSA.

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

- (1) *N*-Ethylpentylone has a high potential for abuse;
- (2) *N*-Ethylpentylone has no currently accepted medical use in treatment in the United States;² and
- (3) There is a lack of accepted safety for use of *N*-ethylpentylone under medical supervision.

Based on these findings, the Acting Administrator concludes that 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one (known as *N*-ethylpentylone or ephylone) and its optical, positional, and geometric isomers, including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrants continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

² Although there is no evidence suggesting that *N*-ethylpentylone has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

- i. The drug's chemistry must be known and reproducible;
- ii. there must be adequate safety studies;
- iii. there must be adequate and well-controlled studies proving efficacy;
- iv. the drug must be accepted by qualified experts; and
- v. the scientific evidence must be widely available.

57 FR 10499 (1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

Requirements for Handling *N*-Ethylpentylone

N-Ethylpentylone will continue³ to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) *N*-ethylpentylone, or who desires to handle *N*-ethylpentylone, 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.* *N*-Ethylpentylone is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling this substance must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-ethylpentylone must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture *N*-ethylpentylone 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 *N*-ethylpentylone must have an initial inventory of all stocks of controlled substances (including *N*-ethylpentylone) on hand on the date the registrant first engages in the handling of the 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 *N*-ethylpentylone) on hand every two years pursuant to 21 U.S.C. 827 and 958,

³ *N*-Ethylpentylone has been subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h), by virtue of the August 31, 2018 temporary scheduling order (83 FR 44474) and the subsequent one-year extension of that order (August 27, 2020, 85 FR 52915).

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 *N*-ethylpentylone pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Order Forms.* Every DEA registrant who distributes *N*-ethylpentylone must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

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

Regulatory Analyses

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

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed “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.

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, minimize litigation, 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 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 Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On August 31, 2018, DEA published an order to temporarily place *N*-ethylpentylone in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). On August 27, 2020, DEA published a temporary scheduling order extending the temporary scheduling of *N*-ethylpentylone for up to one year pursuant to 21 U.S.C. 811(h)(2). Accordingly, all entities that currently handle or plan to handle *N*-ethylpentylone have already been required to establish and implement the systems and processes required to specifically handle *N*-ethylpentylone. There are currently 31 unique registrations authorized to handle *N*-ethylpentylone specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. Some of these entities are likely to be large entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 26 entities are small entities. Therefore, DEA conservatively estimates as many as 26 small entities are affected by this rule.

A review of the 31 registrations indicates that all entities that currently

handle *N*-ethylpentylone also handle other schedule I controlled substances, and thus they have established and implemented (or maintain) the systems and processes required to handle *N*-ethylpentylone as a schedule I substance. Therefore, DEA anticipates that this rule will impose minimal or no economic impact on any affected entities, and, thus, will not have a significant economic impact on any of the 26 affected small entities. Therefore, DEA has concluded that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995 (UMRA)

In accordance with UMRA of 1995, 2 U.S.C. 1501 *et seq.*, 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.

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of *N*-ethylpentylone that has already been in effect since the publication of an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place *N*-ethylpentylone in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 83 FR 44474. The August 2018 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of *N*-ethylpentylone was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Because this rule finalizes the control status of *N*-ethylpentylone that has already been in effect for over two and half years, it does not alter the legal obligations of any person who handles this substance.

Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, DEA is making the rule effective on the date of publication in the **Federal Register**, as any delay in the effective date is unnecessary and would be contrary to the public interest.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information 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.

Congressional Review Act (CRA)

This rule is not a major rule as defined by the CRA, 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final 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. In § 1308.11:

- a. Add paragraph (d)(86); and
■ b. Remove and reserve paragraph (h)(36).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *
(d) * * *

(86) *N*-ethylpentylone (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one) 7543

* * * * *

D. Christopher Evans,
Acting Administrator.

[FR Doc. 2021–12261 Filed 6–11–21; 8:45 am]

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