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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-482]

Schedules of Controlled Substances: Extension of Temporary Placement of *N*-Ethylpentylone in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary rule; temporary scheduling order; extension.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this order to extend the temporary schedule I status of a synthetic cathinone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one (*N*-ethylpentylone, ephylone), including its optical, positional and geometric isomers, salts, and salts of isomers. The schedule I status of *N*-ethylpentylone currently is in effect until August 31, 2020. This order extends the temporary scheduling of *N*-ethylpentylone for one year, or until the permanent scheduling action for this substance is completed, whichever occurs first.

DATES: This order, which extends the temporary scheduling order that DEA previously issued for this substance (83 FR 44474, August 31, 2018), is effective August 31, 2020, and expires on August 31, 2021. If DEA publishes a final rule making this scheduling action permanent, this order will expire on the effective date of that rule, if the effective date is earlier than August 31, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-8209.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

On August 31, 2018, the former Acting Administrator of the Drug Enforcement Administration (DEA) published a temporary scheduling order in the *Federal Register* (83 FR 44474) placing 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one (*N*-ethylpentylone, ephylone), a synthetic cathinone, in schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h).[1] That order was effective on the date of publication, and was based on findings by the former Acting Administrator of DEA that the temporary scheduling of this substance was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). The CSA provides that the temporary control of this substance expire two years from the effective date of the temporary scheduling order, or on August 31, 2020. 21 U.S.C. 811(h)(2). However, this same subsection also provides that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) to permanently add the substance to a schedule, the temporary scheduling of that substance can be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be

[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notice adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion.

The Acting Administrator of DEA, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule *N*-ethylpentylone. DEA is simultaneously publishing, elsewhere in this issue of the *Federal Register*, a notice of proposed rulemaking for the permanent placement of *N*-ethylpentylone in schedule I. If that proposed rule is finalized, scheduling of this substance will be made permanent by publication of a final rule in the *Federal Register*.

Pursuant to 21 U.S.C. 811(h)(2), the Acting Administrator of DEA orders that the temporary scheduling of *N*-ethylpentylone, including its optical, positional, and geometric isomers, salts, and salts of isomers, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), the Administrator of DEA, as delegated by the Attorney General, may, by order, place a substance in schedule I on a temporary basis. This same subsection provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of the order scheduling such substance, except that the Administrator may, during the pendency of proceedings to permanently schedule the substance, extend the temporary scheduling for up to one year.

Given that section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended,

DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this extension of the temporary scheduling order. The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an order instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for other kinds of scheduling actions, see 21 U.S.C. 811(a), it is noteworthy that, in subsection 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety that this substance would present if scheduling expired, for the reasons expressed in the temporary scheduling order (83 FR 44474, August 31, 2018). Further, DEA believes that this order extending the temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in Executive Order 13563 (Improving Regulation and Regulatory

Review). Accordingly, this action has not been reviewed by the Office of Management and Budget (OMB). This order is not an Executive Order 13771 regulatory action.

This action will 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. Therefore, in accordance with Executive Order 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, "any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to maintain the temporary placement of *N*-ethylpentylone in schedule I because it poses a public health risk, for the reasons expressed in the temporary scheduling order (83 FR 44474, August 31, 2018). The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. DEA understands that the CSA frames temporary scheduling actions as orders rather than rules to ensure that the process moves swiftly, and this extension of the temporary scheduling order continues to serve that purpose. For the same reasons that underlie 21 U.S.C. 811(h), that

is, the need to place this substance in schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order extending the temporary scheduling order shall take effect immediately upon its publication. DEA has submitted a copy of this extension of the temporary scheduling order to both Houses of Congress and to the Comptroller General, although such filing is not required under the CRA, 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

Dated: August 25, 2020.

Timothy J. Shea,
Acting Administrator.
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