Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-565]

Schedules of Controlled Substances: Extension of Temporary Placement of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl 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 temporary scheduling order to extend the temporary schedule I status of cyclopentyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide), isobutyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide), *para*-chloroisobutyryl fentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide), *para*-methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide), and valeryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide) including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers. The schedule I status of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl currently is in effect until February 1, 2020. This temporary order will extend

the temporary scheduling of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl for one year, or until the permanent scheduling action for these substances is completed, whichever occurs first.

DATES: This temporary scheduling order, which extends the order (83 FR 4580, February 1, 2018), is effective February 1, 2020, and expires on February 1, 2021. If this order is made permanent, the DEA will publish a document in the Federal Register on or before February 1, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

On February 1, 2018, the former Acting Administrator of the Drug Enforcement Administration (DEA) published a temporary scheduling order in the *Federal Register* (83 FR 4580) placing cyclopentyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide), isobutyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide), *para*-chloroisobutyryl fentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide), *para*-methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide), and valeryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide), along with two other substances, 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 (Acting Administrator) that the temporary scheduling of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, valeryl fentanyl, and the two other substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

Section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), provides that the temporary control of these substances expires two years from the effective date of the scheduling order, i.e., on February 1, 2020. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) for permanent scheduling of a substance, DEA can extend the temporary scheduling[2] of that substance for up to one year. Proceedings for the permanent scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of Health and Human Services, or on the petition of any interested party.

The Acting Administrator, 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl. The DEA has gathered and reviewed the available

[1] The order also temporarily placed ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(phenethylpiperidin-4-yl)acetamide) and *para*-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide) in schedule I. DEA issued a final order to permanently place ocfentanil and *para*-fluorobutyryl fentanyl in schedule I on November 29, 2018 (83 FR 61320) and October 25, 2019 (84 FR 57327), respectively, pursuant to 21 USC 811(d)(1).

[2] 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.

information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these substances. On November 5, 2018, the DEA submitted a request to the Department of Health and Human Services (HHS) to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for cyclopropyl fentanyl, *para*-fluorobutyryl fentanyl, cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl in accordance with 21 U.S.C. 811(b) and (c). In a letter dated September 6, 2019, DEA notified the HHS that it no longer needed scientific and medical evaluations and scheduling recommendations for cyclopropyl fentanyl and *para*-fluorobutyryl fentanyl. Subsequently, the DEA permanently placed those two substances in schedule I of the CSA on October 25, 2019, pursuant to a different scheduling authority in 21 U.S.C. 811(d)(1). See 84 FR 57323.

After evaluating the scientific and medical evidence, on November 12, 2019, the HHS submitted to the Acting Administrator its scientific and medical evaluation and scheduling recommendation for cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl.[3] Upon receipt of the scientific and medical evaluation and scheduling recommendation from the HHS, in accordance with 21 U.S.C. 811(c) the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl. DEA published a notice of proposed rulemaking for the permanent placement of cyclopentyl fentanyl, isobutyryl fentanyl,

[3] Although HHS also provided information on cyclopropyl fentanyl and *para*-fluorobutyryl fentanyl, those two substances will not be discussed further in this temporary scheduling order, because they have already been permanently controlled.

para-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl in schedule I elsewhere in this issue of the *Federal Register*. If that proposed rule is finalized, the DEA will publish a final rule in the *Federal Register*.

Pursuant to 21 U.S.C. 811(h)(2), the Acting Administrator orders that the temporary scheduling of cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for issuance of an expedited temporary scheduling order to schedule a substance in schedule I on a temporary basis, where such action is necessary to avoid an imminent hazard to the public safety. (21 U.S.C. 811(h)). That section also 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 Attorney General may, during the pendency of proceedings to permanently schedule the substance, extend the temporary scheduling for up to one year.

Inasmuch as 21 U.S.C. 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, which are applicable to rulemaking, do not apply to this extension of the temporary scheduling order. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking

procedures. 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. 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 a regulatory flexibility analysis in 5 U.S.C. 603(a) and 604(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), and section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

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, even 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 cyclopentyl fentanyl, isobutyryl fentanyl, *para*-chloroisobutyryl fentanyl, *para*-methoxybutyryl fentanyl, and valeryl fentanyl in schedule I because they pose an imminent public health risk. The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. The 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 these substances in schedule I because they pose 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. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Congressional Review Act, 5 U.S.C. 801–808, because, as noted above, this action is an order, not a rule.

Dated: January 23, 2020

_____

Uttam Dhillon,
Acting Administrator.
[FR Doc. 2020-01683 Filed: 1/29/2020 8:45 am; Publication Date: 1/30/2020]