

interest pursuant to 5 U.S.C. 553(b)(B). CBP and Treasury also believe that affected entities need to be informed as soon as possible of the extension and its length in order to plan and adjust their implementation process accordingly.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104-4; 2 U.S.C. 1532)

CBP and Treasury have concluded the extension of the effective date does not contain a Federal mandate that may result in the expenditure by State, local and Tribal governments, in aggregate, or by the private sector, of \$100 million or more (adjusted for inflation) in any one year.

Kevin K. McAleenan,

Acting Commissioner, U.S. Customs and Border Protection.

Approved: January 25, 2017.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 12 and 127

[USCBP-2016-0056; CBP Dec. 16-28]

RIN 1515-AE13

Delay of Effective Date for Toxic Substance Control Act Chemical Substance Import Certification Process Revisions

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule; delay of effective date.

SUMMARY: On December 27, 2016, U.S. Customs and Border Protection (CBP) published a Final Rule in the **Federal Register** announcing amendments to CBP regulations regarding the requirement to file a Toxic Substances Control Act (TSCA) certification when importing into the customs territory of the United States chemicals in bulk form or as part of mixtures and articles containing a chemical or mixture. That document amended the regulations to establish an electronic option for importers to file the required U.S. Environmental Protection Agency (EPA) TSCA certifications, to clarify and add certain definitions, and to eliminate the paper-based blanket certification process. The changes announced in that

Final Rule were to be effective January 26, 2017. This notice announces that the effective date of the Final Rule is delayed for 60 days from January 20, 2017.

DATES: This regulation is effective January 25, 2017. The effective date of the rule amending 19 CFR parts 12 and 127 published at 81 FR 94980, December 27, 2016 is delayed until March 21, 2017.

FOR FURTHER INFORMATION CONTACT: For questions related to the filing of EPA forms with CBP, please contact William Scopa, Partner Government Agencies Interagency Collaboration Division, Office of Trade, Customs and Border Protection, at *William.R.Scopa@cbp.dhs.gov*. For EPA policy questions, please contact Harlan Weir, at *Weir.Harlan@epa.gov*.

SUPPLEMENTARY INFORMATION: On December 27, 2016, U.S. Customs and Border Protection (CBP) published a Final Rule in the **Federal Register** (81 FR 94980) announcing the amendment of CBP regulations regarding the requirement to file a Toxic Substances Control Act (TSCA) certification when importing into the United States chemicals in bulk form or as part of mixtures and articles containing a chemical or mixture. The document amended the regulations to permit importers to file the required U.S. Environmental Protection Agency (EPA) TSCA certifications electronically, to clarify and add certain definitions, and to eliminate the paper-based blanket certification process. The final rule was to become effective on January 26, 2017.

On January 20, 2017, the Chief of Staff of the White House released a memorandum to ensure that the President's appointees or designees have the opportunity to review any new or pending regulations. The memorandum asks the heads of executive departments and agencies to temporarily postpone the effective date for 60 days from the date of the memorandum of all regulations that had been published in the **Federal Register**, but had not taken effect. In light of this memo, CBP has considered whether entities affected by these final regulations will need additional time to implement new systems or internal procedural changes. To provide additional time for affected entities to become familiar with the increased flexibilities and new processes of the final regulations, CBP believes that extending the effective date until March 21, 2017 is appropriate and will furnish the affected entities with sufficient additional time.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a Regulatory Assessment is not required.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this final rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Administrative Procedure Act

CBP and Treasury, for good cause and the reasons cited above, including the brief length of the extension of the effective date, find that notice and solicitation of comment regarding the extension of the effective date for the final regulation are impracticable, unnecessary, or contrary to the public interest pursuant to 5 U.S.C. 553(b)(B). CBP and Treasury also believe that affected entities need to be informed as soon as possible of the extension and its length in order to plan and adjust their implementation process accordingly.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104-4; 2 U.S.C. 1532)

CBP and Treasury have concluded the extension of the effective date does not contain a Federal mandate that may result in the expenditure by State, local and Tribal governments, in aggregate, or by the private sector, of \$100 million or more (adjusted for inflation) in any one year.

Kevin K. McAleenan,

Acting Commissioner, U.S. Customs and Border Protection.

Approved: January 25, 2017.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-402]

Schedules of Controlled Substances: Extension of Temporary Placement of THJ-2201, AB-PINACA and AB-CHMINACA in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary order to extend the temporary schedule I status of three synthetic cannabinoids pursuant to the temporary scheduling provisions of the Controlled Substances Act. The substances are: [1-(5-Fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201); *N*-1-Amino-3-methyl-1-oxo-2-butanyl]-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA); *N*-[1-Amino-3-methyl-1-oxo-2-butanyl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), including their optical, positional and geometric isomers, salts, and salts of isomers. The current final order temporarily placing THJ-2201, AB-PINACA and AB-CHMINACA into schedule I is in effect through January 29, 2017. This order will extend the temporary scheduling of THJ-2201, AB-PINACA and AB-CHMINACA for one year, or until the permanent scheduling action for these three substances is completed, whichever occurs first.

DATES: This temporary order is effective January 27, 2017. This temporary order will expire on January 29, 2018, or when a permanent scheduling proceeding is completed, whichever occurs first.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801-971. The DEA published the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and

dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated her scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

On January 30, 2015, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place the three synthetic cannabinoids [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201); *N*-1-amino-3-methyl-1-oxo-2-butanyl]-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA); and *N*-[1-amino-3-methyl-1-oxo-2-butanyl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 80 FR 5042. That final order was effective on the date of publication, and was based on findings by the Administrator of the DEA that the temporary scheduling of these three synthetic cannabinoids 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)) requires that the temporary control of these

substances expires two years from the effective date of the scheduling order, or on January 29, 2017. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling of that substance could be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his or her own motion, at the request of the Secretary of Health and Human Services,¹ or on the petition of any interested party.

The Administrator of the 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 THJ-2201, AB-PINACA and AB-CHMINACA. The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these three synthetic cannabinoids. On August 26, 2015, the DEA submitted a request to the HHS to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for THJ-2201, AB-PINACA and AB-CHMINACA, in accordance with 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, on November 14, 2016, the HHS submitted to the Administrator of the DEA its three scientific and medical evaluations for these substances. Upon receipt of the scientific and medical evaluation and scheduling recommendations from the HHS, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of THJ-2201, AB-PINACA and AB-CHMINACA in accordance with 21 U.S.C. 811(c). The DEA has published a notice of proposed rulemaking for the placement of THJ-2201, AB-PINACA and AB-CHMINACA into schedule I elsewhere in this issue of the **Federal Register**.

Pursuant to 21 U.S.C. 811(h)(2), the Administrator of the DEA orders that the temporary scheduling of THJ-2201, AB-PINACA and AB-CHMINACA, including their optical, positional and geometric isomers, salts, and salts of

¹ Because the Secretary of the Department of Health and Human Services has delegated to the Assistant Secretary for Health of the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

isomers, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

In accordance with this temporary order, the schedule I requirements for handling THJ-2201, AB-PINACA and AB-CHMINACA, including their optical, positional and geometric isomers, salts, and salts of isomers, are 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. 21 U.S.C. 811(h). The Attorney General may, by order, schedule a substance in schedule I on a temporary basis. *Id.* 21 U.S.C. 811(h) 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.

To the extent that 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, the 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 action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the 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, the 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, the 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, 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. It is in the public interest to maintain

the temporary placement of THJ-2201, AB-PINACA and AB-CHMINACA in schedule I because they pose a 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. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. 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 Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (5 U.S.C. 801-808) because, as noted above, this action is an order, not a rule.

Dated: January 17, 2017.

Chuck Rosenberg,
Acting Administrator.

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