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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-385E]

Schedules of Controlled Substances: Extension of Temporary Placement of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to extend the temporary schedule I status of four synthetic cannabinoids pursuant to the temporary scheduling provisions of the Controlled Substances Act. The substances are: quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC); quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), including their optical, positional and geometric isomers, salts, and salts of isomers. The current final order temporarily placing PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into schedule I is in effect through February 9, 2016. This final order will extend the temporary scheduling of PB-

22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA for one year, or until the permanent scheduling action for these four substances is completed, whichever occurs first.

DATES: This final order is effective [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette 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 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 February 10, 2014, the DEA published a final order in the *Federal Register* amending 21 CFR 1308.11(h) to temporarily place the four synthetic cannabinoids quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC); quinolin-8-yl 1-(5-

fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 7577. That final order was effective on the date of publication, and was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these four 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 expire two years from the effective date of the scheduling order, which was February 10, 2014. 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 PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse,

[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 final order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

pattern of abuse, and the relative potential for abuse for these four synthetic cannabinoids. On December 30, 2014, 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 PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA, and in accordance with 21 U.S.C. 811 (b) and (c). Upon evaluating the scientific and medical evidence, on January 19, 2016, the HHS submitted to the Administrator of the DEA its four 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 PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in accordance with 21 U.S.C. 811(c). The DEA published a notice of proposed rulemaking for the placement of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA 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 PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA, including their 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.

In accordance with this final order, the schedule I requirements for handling PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA, including their optical, positional and geometric isomers, salts, and salts of isomers, will remain in effect 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 final 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. 5 U.S.C. 808(2). It is in the public interest to maintain the temporary placement of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA 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 final order extending the temporary

scheduling order shall take effect immediately upon its publication. The DEA has submitted a copy of this final 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: February 2, 2016

Chuck Rosenberg,
Acting Administrator.

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