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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-414]

Schedules of Controlled Substances: Extension of Temporary Placement of UR-144, XLR11, and AKB48 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 (DEA) is issuing this final order to extend the temporary placement of (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48), including their salts, isomers, 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. The current final order temporarily placing UR-144, XLR11, and AKB48 in schedule I is due to expire on May 15, 2015. This final order will extend the temporary scheduling of UR-144, XLR11, and AKB48 to May 15, 2016, or until the permanent scheduling action for these three substances is completed, whichever occurs first.

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

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION: On May 16, 2013, the Deputy Administrator of the Drug Enforcement Administration published a Final Order in the *Federal Register* (78 FR 28735) amending 21 CFR 1308.11(h) to temporarily place three synthetic cannabinoids, namely (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48), in schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). That final order, which became effective on the date of publication, was based on findings by the Deputy 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). At the time the final order took effect, section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), required that the temporary scheduling of a substance expires at the end of two years from the date of issuance of the order scheduling the substance, except that the Attorney General may, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, extend the temporary scheduling 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 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.

In this case, the DEA initiated permanent scheduling proceedings on its own motion pursuant to 21 U.S.C. 811(a). 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 31, 2013, 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 UR-144, XLR11, and AKB48, pursuant to 21 U.S.C. 811 (b) and (c). Upon evaluating the scientific and medical evidence, the HHS on May 12, 2015, submitted to the Administrator of the DEA its three scientific and medical evaluations entitled, "Basis For the Recommendation to Place 1-pentyl-1*H*-indol-3-yl 2,2,3,3-tetramethylcyclopropyl methanone (UR-144) and its Salts in schedule I of the Controlled Substances Act (CSA)," "Basis For the Recommendation to Place 1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl methanone (XLR11) and its Salts in schedule I of the Controlled Substances Act (CSA)," and "Basis For the Recommendation to Place *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48) and its Salts in schedule I of the Controlled Substances Act (CSA)." 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

[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."

own eight-factor analysis of the abuse potential of UR-144, XLR11, and AKB48 pursuant to 21 U.S.C. 811(c). The DEA is publishing a Notice of Proposed Rulemaking for the Placement of UR-144, XLR11, and AKB48 into schedule I. The Administrator thereby has initiated proceedings regarding UR-144, XLR11, and AKB48 in accordance with 21 U.S.C. 811(a)(1). Therefore, pursuant to 21 U.S.C. 811(h)(2), the Administrator of the DEA hereby orders that the temporary scheduling of UR-144, XLR11, and AKB48, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, be extended to May 15, 2016, or until the proceedings to permanently schedule these three substances is completed, whichever occurs first.

In accordance with this final order, the schedule I requirements for handling UR-144, XLR11, and AKB48, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, will remain in effect until May 15, 2016, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Section 201(h) of the CSA, 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.

Inasmuch as section 201(h) of the CSA 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.

Pursuant to section 808(2) of the Congressional Review Act (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 UR-144, XLR11, and AKB48 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. 21 U.S.C. 811(h) exempted the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moved 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 DEA's 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. Pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (5 U.S.C. 801–808), the DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General.

Dated: May 12, 2015.

Michele M. Leonhart,
Administrator.
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