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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-357]

Schedules of Controlled Substances: Extension of Temporary Placement of Methylone Into Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This Final Order is issued by the Administrator of the Drug Enforcement Administration (DEA) to extend the temporary scheduling of methylone (3,4-methylenedioxy-N-methylcathinone) including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule I of the Controlled Substances Act (CSA). The temporary scheduling of methylone is due to expire on October 20, 2012. This document will extend the temporary scheduling of methylone to April 20, 2013, or until rulemaking proceedings are completed, whichever occurs first.

EFFECTIVE DATE: [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Alan G. Santos, Associate Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 307-7165.

SUPPLEMENTARY INFORMATION: On October 21, 2011, the Administrator of the DEA published a Final Order in the Federal Register (76 FR 65371) amending 21 CFR 1308.11(g) to

temporarily place three synthetic cathinones, namely mephedrone (4-methyl-N-methylcathinone), MDPV (3,4-methylenedioxypyrovalerone) and methylone, into Schedule I of the 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 Administrator of the DEA that the temporary scheduling of these three synthetic cathinones 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) (2011)) required that the temporary scheduling of a substance expire at the end of one year from the date of issuance of the order and 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 six months.[1] 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 own motion, at the request of the Secretary of Health and Human Services,[2] or on the petition of any interested party.

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 cathinones. On March 30, 2012, the Administrator of the DEA submitted a letter to the Assistant Secretary for Health of the Department of Health and Human Services, requesting scientific and medical evaluations and scheduling recommendations for these three synthetic cathinones. In response to this letter, on August 14, 2012, the Assistant Secretary

[1] On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) (FDASIA), which amended section 201(h)(2) of the CSA to extend the timeframes applicable to temporary scheduling.

[2] 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."

provided to DEA a scientific and medical evaluation and recommendation that methylone be placed in Schedule I.[3] Proceedings regarding methylone have been initiated 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 methylone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, is extended to April 20, 2013, or until rulemaking proceedings are completed, whichever occurs first.

In accordance with this Final Order, the Schedule I requirements for handling methylone including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, will remain in effect until April 20, 2013, or until rulemaking proceedings are completed, whichever occurs first.

Pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (5 U.S.C. 801-808), DEA has submitted a copy of this Final Order to both Houses of Congress and to the Comptroller General.

Dated**:** October 10, 2012

Michele M. Leonhart
Administrator

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[3]Section 1152 of FDASIA controlled mephedrone and MDPV as Schedule I controlled substances, but it did not similarly control methylone. Accordingly, HHS provided a Scientific and Medical Evaluation and Scheduling Recommendation for methylone, recommending that methylone be placed in Schedule I.