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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-368]

Establishment of Drug Codes for 26 Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final Rule.

SUMMARY: On July 9, 2012, the President signed into law the Synthetic Drug Abuse Prevention Act of 2012 (SDAPA). SDAPA amends the Controlled Substances Act by placing 26 substances in Schedule I. DEA is publishing this rule to establish drug codes for these 26 substances, and to make technical and conforming amendments in accordance with SDAPA.

DATES: *Effective Date*: [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Legal Authority

DEA administers, implements, and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended (hereinafter, "CSA"). The implementing regulations for these statutes are found in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, the lack of accepted safety for use under medical supervision, and the degree of dependence the substance may cause. 21 U.S.C. 812. The list of legislatively scheduled controlled substances is found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR Part 1308. These initial schedules may be modified either by legislation or by rulemaking.

Purpose of this Rulemaking

On July 9, 2012, the SDAPA of 2012, Pub. L. 112-144, Title XI, Subtitle D, became effective. SDAPA amended the CSA by legislatively placing "cannabimimetic agents" [1] and 26 substances in Schedule I. Pub. L. 112-144, Title XI, Subtitle D, Section 1152. DEA is publishing this rule to establish drug codes for these 26 substances. These 26 substances include 15 cannabimimetic agents, 9 phenethylamines, and 2 cathinones and are listed in the regulatory text section, below.

[1] SDAPA also included a definition of "cannabimimetic agents." Although this rule is only addressing the 26 specific substances, DEA intends to issue a separate rulemaking that will address the broader definition of cannabimimetic agents. Even in the absence of such a rulemaking as of July 9, 2012, cannabimimetic agents, as defined in SDAPA are controlled under Schedule I.

Related Procedural Matters

At the time SDAPA became effective on July 9, 2012, a total of 8 substances were covered by temporary scheduling final orders: 5 synthetic cannabinoids (JWH-018, JWH-073, JWH-200, CP-47,497, and CP-47,497 C8 homologue)[2] and 3 synthetic cathinones (mephedrone, MDPV, and methylone).[3] DEA also issued a Notice of Proposed Rulemaking (NPRM) in March 2012, to place the 5 synthetic cannabinoids (JWH-018, JWH-073, JWH-200, CP-47,497, and CP-47,497 C8 homologue) permanently in Schedule I.[4] With the sole exception of methylone[5], these substances were specifically placed in Schedule I by SDAPA. Therefore, it is no longer necessary to finalize the NPRM regarding the 5 synthetic cannabinoids (JWH-018, JWH-073, JWH-200, CP-47,497, and CP-47,497 C8 homologue), or to take further action with respect to 2 of the 3 synthetic cathinones (mephedrone and MDPV). However, DEA has posted a copy of the Secretary of Health and Human Services (HHS) Scientific and Medical Evaluation and Scheduling Recommendations regarding the 5 synthetic cannabinoids on www.regulations.gov so that the public can benefit from the scientific review that was

[2] See DEA Notice of Intent entitled "Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids Into Schedule I," published in the Federal Register on November 24, 2010, at 75 FR 71635, DEA Notice of Intent; correction entitled "Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids Into Schedule I; Correction," published in the Federal Register on January 13, 2011, at 76 FR 2287, DEA Final Order entitled "Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids into Schedule I," published in the Federal Register on March 1, 2011, at 76 FR 11075, and DEA Final Order entitled "Schedules of Controlled Substances: Extension of Temporary Placement of Five Synthetic Cannabinoids Into Schedule I of the Controlled Substances Act," published in the Federal Register on February 29, 2012, at 77 FR 12201.

[3] See DEA Notice of Intent entitled "Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cathinones Into Schedule I," published in the Federal Register on September 8, 2011, at 76 FR 55616 and DEA Final Order entitled "Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cathinones Into Schedule I," published in the Federal Register on October 21, 2011, at 76 FR 65371.

[4] See Schedules of Controlled Substances: Placement of Five Synthetic Cannabinoids Into Schedule I, 77 FR 12508, Mar. 1, 2012.

[5] DEA extended the temporary scheduling of methylone in a Final Order published in the Federal Register on October 18, 2012 at 77 FR 64032.

undertaken with respect to these substances.[6] These HHS documents can be found on www.regulations.gov under Docket ID "DEA-2012-0001."

In addition to establishing drug codes for these 26 substances[7], this rulemaking makes several technical and conforming amendments to 21 CFR 1308.11 in accordance with SDAPA. This rulemaking adds a new subsection (g) to 21 CFR 1308.11 and gives it the title "cannabimimetic agents," redesignates the old subsection (g) as (h) and retains its title as "[t]emporary listing of substances subject to emergency scheduling," and transfers 7 of the 8 substances currently listed in 21 CFR 1308.11(g) under the title of "[t]emporary listing of substances subject to emergency scheduling," to either the new subsection (g) entitled "cannabimimetic agents" or to the previously existing subsection (d) entitled "[h]allucinogenic substances." In summary, as a result of SDAPA, a new subsection entitled "cannabimimetic agents" will be created and will initially contain 15 substances, the existing subsection entitled "[h]allucinogenic substances" will increase by 11 substances, and the existing subsection entitled "temporary listing of substances subject to emergency scheduling" will be redesignated from (g) to (h) and will decrease from 8 substances to 1 substance (methylone).

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including notice of proposed

[6] HHS did not provide a Scientific and Medical Evaluation and Scheduling Recommendation regarding mephedrone and MDPV.

[7] Some of these substances (for example, JWH-018) had already received drug codes by virtue of the prior temporary scheduling actions discussed above. Such substances will retain their previously established drug codes but are included in this rule for purposes of completeness and to ensure that each of these 26 substances are properly classified in the Code of Federal Regulations. Substances for which a drug code has not previously been established (for example, 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)) will have a drug code assigned to them by this rule.

rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. This rule merely establishes drug codes for the 26 substances placed in Schedule I by SDAPA, and makes several technical and conforming amendments in accordance with SDAPA. Because DEA has no discretion with respect to these changes, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary. In addition, because the placement of these 26 substances in Schedule I has already been in effect since July 9, 2012, DEA finds good cause exists to make this rule effective immediately upon publication.

Executive Orders 12866 and 13563

This rule, establishing drug codes for the 26 substances placed in Schedule I by SDAPA, and making technical and conforming amendments in accordance with SDAPA has been developed in accordance with the principles of Executive Orders 12866 and 13563.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175

This rule is required by statute, will not have tribal implications, and will not impose substantial direct compliance costs on Indian tribal governments.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act of 1995

This rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3521.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. 2 U.S.C. 1532.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (5 U.S.C. 804). This rule will not result in an annual effect on the economy of $100,000,000 or more, a major increase in cost or prices, or have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies in domestic and export

markets. However, DEA has submitted a copy of this rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308 – SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

AUTHORITY: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Amend § 1308.11 by:

a. Adding new paragraphs (d)(36) through (d)(46);

b. Redesignating paragraph (g) as paragraph (h) and revising newly redesignated paragraph (h)(1); and

c. Adding a new paragraph (g).

The additions and revisions read as follows:

§ 1308.11 Schedule I.

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(d) * * *

(36) 4-methylmethcathinone (Mephedrone)	1248
(37) 3,4-methylenedioxypyrovalerone (MDPV)	7535
(38) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	7509
(39) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	7508
(40) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	7519

(41) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I) 7518

(42) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2) 7385

(43) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4) 7532

(44) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H) 7517

(45) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N) 7521

(46) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P) 7524

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(g) Cannabimimetic agents. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497) 7297

(2) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog) 7298

(3) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678) 7118

(4) 1-butyl-3-(1-naphthoyl)indole (JWH–073) 7173

(5) 1-hexyl-3-(1-naphthoyl)indole (JWH–019) 7019

(6) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200) 7200

(7) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250) 6250

(8) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081) 7081

(9) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122) 7122

(10) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398) 7398

(11) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	7201
(12) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	7694
(13) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4)	7104
(14) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	7008
(15) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	7203
(h) * * *	
(1) 3,4-methylenedioxy-N-methylcathinone (Other names: methylone)	7540

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Dated: December 21, 2012

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Michele M. Leonhart
Administrator

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