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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-345F]

Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids Into Schedule I

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

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily place five synthetic cannabinoids into the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions. The substances are 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue). This action is based on a finding by the Administrator that the placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the full effect of the CSA and its implementing regulations including criminal, civil and administrative penalties, sanctions and regulatory controls of Schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office

of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, telephone (202) 307-7183, fax (202) 353-1263, or e-mail ode@usdoj.gov.

DATES: *Effective Date:* March 1, 2011.

SUPPLEMENTARY INFORMATION:

Background

The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA for one year without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. The Attorney General may extend the temporary scheduling up to six months during pendency of proceedings under 21 U.S.C. 811(a)(1). A substance may be temporarily scheduled under the emergency provisions of the CSA 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 under 21 U.S.C. 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the DEA Administrator (28 CFR 0.100).

As per section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)), the Deputy Administrator, now Administrator, transmitted notice of her intention to temporarily place JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol into Schedule I of the CSA to the Assistant Secretary for Health of the Department of Health and Human Services (HHS) in a letter dated October 6, 2010. In response to this notification, the Assistant Secretary of Health, HHS communicated in a letter dated November 22, 2010, to the then-DEA Acting Administrator that there are no exemptions or approvals in effect for JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol under Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355). The substances are not listed in any other schedule in 21 U.S.C. 812.

A notice of intent to temporarily place JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol into Schedule I of the CSA was published in the **Federal Register** on November 24, 2010 (75 FR 71635). Before making a

finding that temporarily placing a substance into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors (factors 4, 5, and 6) set forth in section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are the history and current pattern of abuse, the scope, duration, and significance of abuse, and what, if any, risk there is to the public health, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

The temporary placement of these five synthetic cannabinoids into Schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety. First, these substances are not intended for human consumption, but there has been a rapid and significant increase in abuse of these substances in the United States. As a result of this abuse, synthetic cannabinoids are banned in at least 18 states in the United States and several countries, and all five branches of the U.S. military prohibit military personnel from possessing or using synthetic cannabinoids. Second, law enforcement has seized synthetic cannabinoids in conjunction with controlled substances and based on self-reports to law enforcement and health care professionals, synthetic cannabinoids are abused for their psychoactive properties. Third, numerous state and local public health departments and poison control centers have issued health warnings describing the adverse health effects associated with synthetic cannabinoids. Based on scientific data currently available, these five substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

History and Current Pattern of Abuse

A "cannabinoid" is a class of chemical compounds in the marijuana plant that are structurally related. The cannabinoid Δ^9 -tetrahydrocannabinol (THC) is the primary psychoactive constituent of marijuana. "Synthetic cannabinoids" are a large family of chemically unrelated structures functionally (biologically) similar to THC, the active principle of marijuana.

Two of the five synthetic cannabinoids (CP-47,497 and cannabicyclohexanol) were synthesized in the early 1980s for research purposes

in the investigation of the cannabinoid system. JWH-018, JWH-073, and JWH-200 were prepared in the mid-1990s and evaluated to further advance understanding of drug-receptor interactions regarding the cannabinoid system. Developed and evaluated as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids. Furthermore, these five synthetic cannabinoids are not intended for human consumption.

The emergence of these five synthetic cannabinoids represents a recent phenomenon in the U.S. designer drug market. Since the initial identification of JWH-018 by U.S. forensic laboratories, many additional synthetic cannabinoids including JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol have been identified in related herbal incense products and plant food. These synthetic cannabinoids have purported psychotropic effects when smoked or ingested. These substances are typically found in powder form or are dissolved in appropriate solvents, such as acetone, before being sprayed on the plant material contained in the herbal incense products.

The popularity of these THC-like synthetic cannabinoids has significantly increased throughout the United States, and they are being abused for their psychoactive properties as reported by law enforcement, the medical community, and through scientific literature.

Some of the product names include, but are not limited to, "Spice," "K2," and many more. Due to sophisticated marketing, the products that contain these five THC-like synthetic cannabinoids are perceived as "legal" alternatives to marijuana despite the fact that they are typically advertised as herbal incense or plant food (Bonsai-18) by Internet retailers, tobacco shops, head shops, and other domestic brick and mortar retail venues, and labeled "Not For Human Consumption." No evidence exists that these synthetic cannabinoids have value as an additive to herbal incense products due to the absence of odor associated with the substances.

Based on law enforcement encounters, these five substances are typically found laced on plant material. The plant material is packaged in small pouches or packets, and is being sold over the Internet, in tobacco and smoke shops, drug paraphernalia shops, gas stations, and convenience stores as herbal incense products, giving customers of all ages direct access to these five substances. Research articles

propose that the packaging is professional and conspicuous, targeting young people, possibly eager to use cannabis, but who are afraid of the judicial consequences and/or association with illicit drugs.

According to Internet discussion boards and law enforcement encounters reported directly to DEA, these five synthetic cannabinoids are being both abused alone and/or being sprayed on plant material (which is then smoked). The most common route of administration of these synthetic cannabinoids is by smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers).

These five synthetic cannabinoids alone or spiked on plant material have the potential to be extremely harmful due to their method of manufacture and high pharmacological potency. There is little information regarding the pharmacology, toxicology, and safety of these substances in humans given the minimal amount of pre-clinical investigations undertaken regarding these substances; therefore, the full danger of these drugs has not yet been determined.

As of January 31, 2011, 18 states in the United States and other countries have controlled one or more of the five synthetic cannabinoids. Moreover, all five branches of the military prohibit their personnel from possessing or using synthetic cannabinoids associated with products such as Spice and K2.

Scope, Duration, and Significance of Abuse

According to forensic laboratory reports, the initial appearance of these synthetic cannabinoids in herbal incense products in the United States occurred in November 2008 when U.S. Customs and Border Protection first encountered products such as Spice.

The increasing abuse of the five synthetic cannabinoids is demonstrated by the increase in federal, state, and local law enforcement activity associated with these substances. The National Forensic Laboratory Information System, a national repository for drug evidence analyses from forensic laboratories across the United States, has reported in excess of 500 exhibits containing synthetic cannabinoid from January 2010 through September 2010. These exhibits came from numerous states across the nation including Alabama, Arkansas, California, Florida, Hawaii, Iowa, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Missouri, North Dakota, Nebraska, Nevada, Oklahoma,

Pennsylvania, South Carolina, Tennessee, and Virginia.

Even though there is no evidence of legitimate non-research related use for these synthetic cannabinoids, multiple shipments of JWH-018 and JWH-073 have been encountered by U.S. Customs and Border Protection in 2010. One enforcement operation encountered five shipments of JWH-018 totaling over 50 kilograms (110.2 pounds) of powder. In addition, bulk loads of JWH-018 and JWH-200 have been encountered by law enforcement in 2010. For example, in Casper, Wyoming, DEA agents encountered large quantities of herbal incense products laced with the synthetic cannabinoid JWH-018 in conjunction with methamphetamine and other illegal drugs in execution of search and arrest warrants.

On March 24, 2010, the American Association of Poison Control Centers reported receiving 112 calls from 15 states related to synthetic cannabinoids to U.S. poison centers since 2009. Just nine months later, the number of calls increased to over 2,700 from 49 states and the District of Columbia.

What, If Any, Risk There Is to the Public Health

Health warnings have been issued by numerous state and local public health departments and poison control centers describing the adverse health effects associated with these synthetic cannabinoids and their related products, including agitation, anxiety, nausea, vomiting, tachycardia (fast, racing heartbeat), elevated blood pressure, tremor, seizures, hallucinations, paranoid behavior, and non-responsiveness.

Smoking these synthetic cannabinoids for the purpose of achieving intoxication and experiencing the psychoactive effects has been identified as a reason for emergency room visits and calls to poison control centers. In a fact sheet by the National Drug Court Institute, the problem of synthetic cannabinoid abuse is described as "significant and disturbing." This is supported by information that was communicated to DEA from one of the major private toxicology laboratories. Based on laboratory findings from drug screens for the period of July 2010 through November 2010, over 3,700 specimens tested positive for either JWH-018 or JWH-073. They also indicated that they were finding 30–35% positivity for specimens submitted by juvenile probation departments.

Case reports describe psychotic episodes, withdrawal, and dependence associated with use of these synthetic cannabinoids, similar to syndromes

observed in marijuana abuse. In addition, based on law enforcement encounters reported directly to DEA, when responding to incidents involving individuals who have reportedly smoked these synthetic cannabinoids, first responders report that these individuals have suffered from intense hallucinations. Moreover, emergency department physicians and toxicologists have reported the adverse health effects associated with smoking herbal incense products laced with these substances. Furthermore, based on law enforcement encounters, suspected Driving Under the Influence of Drug incidents are attributed to the smoking of synthetic cannabinoids. For example, in September 2010, police in Nebraska responded to an incident involving a teenage male who had careened his truck into the side of a residence. After striking the residence and several more items, the teen continued several more yards before coming to a complete stop. Prior to crashing the truck, the individual had driven past a junior high school and nearly struck a child. Upon further investigation, the driver of the vehicle admitted to smoking "Wicked X," a product marketed as "herbal incense" and known to contain synthetic cannabinoids, prior to the accident. Preliminary toxicology reports indicated that the individual did not have any alcohol or other illegal substances in his system.

Detailed chemical analyses by DEA and other investigators have found these synthetic cannabinoids spiked on plant material in herbal incense products marketed to the general public. Product analyses have found variations in both the synthetic cannabinoid found on the plant material and the amount. As proposed in scientific literature, the risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of synthetic cannabinoids spiked on the plant material.

Self-reported abuse of these THC-like synthetic cannabinoids either alone (e.g., in pills with the substance in powder form) or spiked on plant material appear extensively on Internet discussion boards, and abuse has been reported to public health officials and law enforcement. The abuse of these substances spiked on plant material is corroborated by forensic laboratory analysis of products encountered by law enforcement.

According to the U.S. Customs and Border Protection, a number of the products and synthetic cannabinoids appear to originate from foreign sources. Product manufacturing operations encountered by law enforcement

corroborate that the herbal incense products are manufactured in the absence of quality controls and devoid of regulatory oversight. Law enforcement has encountered the manufacture of herbal incense products occurring in such places as residential neighborhoods. These products and associated synthetic cannabinoids are readily accessible via the Internet.

Based on the above data, the continued uncontrolled manufacture, distribution, importation, exportation, and possession of JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol pose an imminent hazard to the public safety. DEA is not aware of any recognized therapeutic uses of these synthetic cannabinoids in the United States.

DEA has considered the three criteria for placing a substance into Schedule I of the CSA (21 U.S.C. 812). The data available and reviewed for JWH-073, JWH-018, JWH-200, CP-47,497, and cannabicyclohexanol indicate that these synthetic cannabinoids each has a high potential for abuse, no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Administrator has considered the available data and the three factors required to support a determination to temporarily schedule five synthetic cannabinoids: 1-butyl-3-(1-naphthoyl)indole, 1-pentyl-3-(1-naphthoyl)indole, 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole, 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol, and 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol in Schedule I of the CSA and finds that temporary placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Regulatory Requirements

With the issuance of this final order, JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol become subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importation, and exportation of a Schedule I controlled substance under the CSA.

1. *Registration.* Any person who manufactures, distributes, dispenses, imports, exports, or possesses JWH-018, JWH-073, JWH-200, CP-47,497, or

cannabicyclohexanol or who engages in research or conducts instructional activities with respect to JWH-018, JWH-073, JWH-200, CP-47,497, or cannabicyclohexanol, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with 21 U.S.C. 823 and 958. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration and may not continue their activities until DEA has approved that application. Retail sales of Schedule I controlled substances to the general public are not allowed under the Controlled Substances Act.

2. *Security.* JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol are subject to Schedule I security requirements. Accordingly, appropriately registered DEA registrants must manufacture, distribute and store these substances in accordance with 1301.71; 1301.72(a), (c), and (d); 1301.73; 1301.74; 1301.75(a) and (c); and 1301.76 of Title 21 of the Code of Federal Regulations as of March 1, 2011.

3. *Labeling and packaging.* All labeling and packaging requirements for controlled substances set forth in Part 1302 of Title 21 of the Code of Federal Regulations shall apply to commercial containers of JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all labeling and packaging requirements.

4. *Quotas.* Quotas for JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol will be established based on registrations granted and quota applications received pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every DEA registrant who possesses any quantity of JWH-018, JWH-073, JWH-200, CP-47,497, or cannabicyclohexanol is required to keep inventory of all stocks of these substances on hand pursuant to 1304.03, 1304.04, and 1304.11 of Title 21 of the Code of Federal Regulations. Every current DEA registrant who desires registration in Schedule I for JWH-018, JWH-073, JWH-200, CP-47,497, or cannabicyclohexanol shall conduct an inventory of all stocks of these substances. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all inventory requirements.

6. *Records.* All registrants who handle JWH-018, JWH-073, JWH-200, CP-

47,497, or cannabicyclohexanol are required to keep records pursuant to 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all recordkeeping requirements.

7. *Reports.* All registrants are required to submit reports in accordance with 1304.33 of Title 21 of the Code of Federal Regulations. Registrants who manufacture or distribute JWH-018, JWH-073, JWH-200, CP-47,497, or cannabicyclohexanol are required to comply with these reporting requirements and shall do so as of March 1, 2011.

8. *Order Forms.* All registrants involved in the distribution of JWH-018, JWH-073, JWH-200, CP-47,497, or cannabicyclohexanol must comply with order form requirements of part 1305 of Title 21 of the Code of Federal Regulations as of March 1, 2011.

9. *Importation and Exportation.* All importation and exportation of JWH-018, JWH-073, JWH-200, CP-47,497, or cannabicyclohexanol must be conducted by appropriately registered DEA registrants in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after March 1, 2011.

10. *Criminal Liability.* The manufacture, distribution, dispensation, or possession with the intent to conduct these activities; possession; importation; or exportation of JWH-018, JWH-073, JWH-200, CP-47,497, or cannabicyclohexanol not authorized by, or in violation of the CSA or the Controlled Substances Import and Export Act occurring as of March 1, 2011 is unlawful.

Executive Order 12988

This final temporary scheduling order meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This final temporary scheduling order does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this order does not have federalism implications warranting the application of Executive Order 13132.

Congressional Review Act

Pursuant to section 808(2) of the Congressional Review Act, the agency is not required to comply with the Act if it makes a good faith finding that notice

and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. It is in the public interest to schedule these cannabinoids immediately because they pose a public health risk. Use of materials spiked with these cannabinoids has been the cause of emergency room visits and calls to poison control centers. The adverse health effects associated with these synthetic cannabinoids and their related products include agitation, anxiety, nausea, vomiting, tachycardia (fast, racing heartbeat), elevated blood pressure, tremor, seizures, hallucinations, paranoid behavior, and non-responsiveness. The materials have been marketed on products that are available to the general public, and their manufacture is devoid of quality controls and unregulated.

This temporary scheduling action is taken pursuant to section 811(h), which is specifically designed to enable DEA to act in an expeditious manner to avoid an imminent hazard to the public safety from new or designer drugs or abuse of those drugs. Section 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie section 811(h), that is, DEA's need to move quickly to place these five cannabinoids into Schedule 1 because they pose a threat to public health, it would be contrary to the public interest to delay implementation of the temporary scheduling order by requiring DEA to undertake the procedures necessary to comply with the Congressional Review Act prior to the order taking effect.

Unfunded Mandates Reform Act of 1995

This final temporary scheduling order will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$126,400,000 or more (adjusting for inflation) in any one year, and it 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.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by section 201(h) of the CSA (21 U.S.C. 811(h)), the Administrator hereby amends 21 CFR part 1308 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. Section 1308.11 is amended by adding new paragraphs (g)(1), (2), (3), (4), and (5) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(g) * * *

(1) 5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol, its optical, positional, and geometric isomers, salts and salts of isomers—7297 (Other names: CP-47,497)

(2) 5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol, its optical, positional, and geometric isomers, salts and salts of isomers—7298 (Other names: cannabicyclohexanol and CP-47,497 C8 homologue)

(3) 1-Butyl-3-(1-naphthoyl)indole, its optical, positional, and geometric isomers, salts and salts of isomers—7173 (Other names: JWH-073)

(4) 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole, its optical, positional, and geometric isomers, salts and salts of isomers—7200 (Other names: JWH-200)

(5) 1-Pentyl-3-(1-naphthoyl)indole, its optical, positional, and geometric isomers, salts and salts of isomers—7118 (Other names: JWH-018 and AM678)

Dated: February 18, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011-4428 Filed 2-28-11; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 541

[Docket No. BOP-1118-F]

RIN 1120-AB18

Inmate Discipline Program/Special Housing Units: Subpart Revision and Clarification

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule; delay of effective date.

SUMMARY: In this document, the Bureau of Prisons delays the effective date of the final rule that appeared in the **Federal Register** on December 8, 2010, (75 FR 76263) and the subsequent correction which appeared in the

[Federal Register Volume 76, Number 174 (Thursday, September 8, 2011)]

[Proposed Rules]

[Pages 55616-55619]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-357]

Schedules of Controlled Substances: Temporary Placement of Three
Synthetic Cathinones Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of Intent.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily schedule three synthetic cathinones under the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The substances are 4-methyl-N-methylcathinone (mephedrone), 3,4-methylenedioxy-N-methylcathinone (methylone), and 3,4-methylenedioxypyrovalerone (MDPV). This action is based on a finding by the Administrator that the placement of these synthetic cathinones into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Any final order will be published in the Federal Register and may not be issued prior to October 11, 2011. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls of schedule I substances under the CSA on the manufacture, distribution, possession, importation, and exportation of these synthetic cathinones.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Background

The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into schedule I of the CSA for one year without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h); 21 CFR 1308.49. If proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling up to six months. 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 under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the substance. 21 U.S.C. 811(h)(1). The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA. 28 CFR 0.100.

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Administrator to notify the Secretary of Health and Human Services of her intention to temporarily place a substance into schedule I of the CSA.\1\

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The Administrator has transmitted notice of her intent to place mephedrone, methylone, and MDPV in schedule I on a temporary basis to the Assistant Secretary by letter dated June 15, 2011. The Assistant Secretary responded to this notice by letter dated July 25, 2011, and advised that based on review by the Food and Drug Administration (FDA) there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for MDPV, mephedrone, or methylone. The Assistant Secretary also stated that the Department of Health and Human Services has no objection to the temporary placement of MDPV, mephedrone, and methylone into schedule I of the CSA. DEA has taken into consideration the Assistant Secretary's comments. As MDPV, mephedrone, and methylone are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for MDPV, mephedrone, and methylone under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. Any additional comments submitted by the Assistant Secretary in response to this notification shall also be taken into consideration before a final order is published. 21 U.S.C. 811(h)(4).

\1\ Because the Secretary 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 Notice of Intent, all subsequent references to ``Secretary'' have been replaced with ``Assistant Secretary.''

To make a finding that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are as follows: The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)-(6). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(h)(1)) may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. Available data and information for mephedrone, methylone, and MDPV indicate that these three synthetic cathinones have a high potential for abuse, no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision.

Synthetic Cathinones

These synthetic cathinones are not currently listed in any schedule under the CSA. Synthetic cathinones are designer drugs of the

phenethylamine class which are structurally and pharmacologically similar to amphetamine, 3,4-methylenedioxymethamphetamine (MDMA), cathinone and other related substances. The addition of a beta-keto ([beta]-keto) substituent to the phenethylamine core structure produces a group of substances that now have cathinone as the core structure. These substances have been used as research chemicals. There is no evidence in the scientific literature that these substances have any legitimate non-research uses and the Assistant Secretary has advised that there are no exemptions or approvals in effect under section 505 (21 U.S.C. 355) of the Federal Food, Drug and Cosmetic Act. In other words, these synthetic cathinones have not been approved by the FDA for human consumption.

Synthetic cathinones, like amphetamine, cathinone, methcathinone, and methamphetamine, are central nervous system (CNS) stimulants. The three synthetic cathinones proposed for control, 4-methyl-N-methylcathinone (mephedrone), 3,4-methylenedioxy-N-methylcathinone (methylone), and 3,4-methylenedioxypyrovalerone (MDPV) cause sympathomimetic effects such as agitation, tachycardia, dilated pupils, hyperthermia, diaphoresis (profuse sweating), and hypertension. Because the pharmacological effects of synthetic cathinones are similar to those of methamphetamine, cathinone, methcathinone, and MDMA, the abuse of synthetic cathinones is also likely to be similar to these substances and potentially cause serious harm to the users.

Numerous retail products marketed under the guise of ``bath salts'' and ``plant food'' have been analyzed and mephedrone, methylone, and MDPV have been identified in varying mixture profiles and quantities in these products. Mephedrone, methylone, and MDPV are the most commonly encountered synthetic cathinones. These three substances represent more than 98% of the 1429 reported synthetic cathinones that have been seized by law enforcement, as reported to the National Forensic Laboratory Information System (NFLIS), a national repository of drug evidence analysis from forensic laboratories across the United States. Of all the reports of these substances recorded by NFLIS from January 2009 to June 2011, 791 reports (55%) were MDPV, 331 reports (23%) were mephedrone, and 279 reports (20%) were methylone. Thus, these three synthetic cathinones are the subject of this notice of intent.\2\

\2\ See ``Background, Data and Analysis of Synthetic Cathinones: Mephedrone (4-MMC), Methylone (MDMC) and 3,4-Methylenedioxypyrovalerone (MDPV),'' dated August 2011 in this rulemaking docket found at <http://www.regulations.gov>.

Factor 4. History and Current Pattern of Abuse

The synthetic cathinones mephedrone, methylone, and MDPV have recently emerged on the United States' illicit drug market and are being perceived as being `legal' alternatives to cocaine, methamphetamine, and MDMA. Although synthetic cathinones are new to the United States' illicit drug market, they have been popular drugs of abuse in Europe since 2007. MDPV is a derivative of pyrovalerone, which is a psychoactive drug that was used to treat chronic lethargy and fatigue. Research in anti-depressant and anti-parkinson agents resulted in the development and patenting of methylone. Methylone, however, has not been approved for these purposes. There are no currently accepted medical uses in treatment in the United States for mephedrone, methylone, or MDPV.

Mephedrone, methylone, and MDPV are falsely marketed as ``research chemicals,'' ``plant food,'' or ``bath salts.'' They are sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations. They can also be purchased on the Internet and mailed using the U.S. Postal Service or international mail services. The packages of products containing these synthetic cathinones usually have the warning

``not for human consumption,`` most likely in an effort to circumvent statutory restrictions for these substances. Despite disclaimers that the products are not intended for human consumption, retailers promote that routine urinalysis drug tests will not typically detect the presence of these synthetic cathinones. However, analytical methods for the detection of mephedrone, methylone, MDPV, and other synthetic cathinones have recently been developed for these substances.

Evidence indicates that mephedrone, methylone, and MDPV are being abused for their psychoactive properties. Drug surveys found that these and other

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synthetic cathinones are being used as recreational drugs and are used as alternatives to illicit stimulants like MDMA and cocaine. Accordingly, mephedrone, methylone, and MDPV have been identified in human urine samples that were obtained for routine drug screenings, they have been detected in samples from drivers suspected of driving under the influence, and they have been detected by drug courts during mandatory periodic drug screens. They have also been identified in biological specimens from individuals (some exhibiting symptoms of ``extreme agitation`` or ``excited delirium``) who have been arrested for possession of a controlled substance, child endangerment, or homicide. They have been detected in samples from deceased whose causes of death were reported as drug-induced toxicity, multiple drug toxicity, or other causes (e.g., blunt force trauma from a vehicular collision or suicide).

Based on studies in the scientific literature, the marketing of products that contain mephedrone, methylone, and MDPV is geared towards teens and young adults. Accordingly, reports indicate that the main users of synthetic cathinones are young male adults. These substances are also used by mid-to-late adolescents and older adults. Many of these abusers of synthetic cathinones have a previous history of drug abuse.

According to drug surveys, the reported average amount of synthetic cathinones used per dose ranged from approximately 25 to 250 milligrams and the average amount used per session (i.e., repeated administration and binging) ranged from approximately 25 milligrams to five grams depending on the substance consumed, duration of intake, and route of administration. The most common routes of administration of these substances are nasal insufflation by snorting the powder and oral ingestion by swallowing capsules or tablets. Other reported methods of administration include injection, rectal administration, and ``bombing`` (wrapping a dose of powder in a paper wrap and swallowing). Synthetic cathinones have also been reported to be used in binges. Reasons cited for binging include to prolong the duration of effects, to satisfy a ``craving,`` or to satisfy a strong urge to re-dose.

According to information found in drug surveys, clinical case reports, and law enforcement reports, users have reported using products containing mephedrone, methylone, and MDPV with other synthetic cathinones (e.g., butylone, fluoromethcathinone, 4-MEC, etc.), pharmaceutical agents (e.g., lidocaine, caffeine, benzocaine, etc.), or other recreational substances (e.g., amphetamine, MDMA, cocaine, gamma-butyrolactone (GBL), kratom, N,N-benzylpiperazine (BZP), and 1-(3-trifluoromethylphenyl)-piperazine (TFMPP)). Chemical analyses of seized and purchased synthetic cathinone products indicate that some products contain multiple substances. Furthermore, investigative toxicology reports of drug screens in which more than one substance was detected indicate that users have ingested products composed of drug combinations (e.g., a tablet composed of MDPV and BZP) or multiple drug products (e.g., a MDPV powder product and a MDMA tablet).

Factor 5. Scope, Duration and Significance of Abuse

The popularity of synthetic cathinones as recreational drugs has increased since they first appeared on the United States' illicit drug market. According to forensic laboratory reports, the first appearance of these synthetic cathinones in the United States occurred in 2009. In 2009, NFLIS registered 15 exhibits from eight states containing these three synthetic cathinones. In 2010, there were 560 reports from 29 states related to these substances registered in NFLIS and in the first two quarters of 2011 (January to June 2011) there were 391.

Based on reports to DEA from law enforcement and public health officials, synthetic cathinones are becoming increasingly prevalent and abused throughout the United States. At just one United States point of entry, the U.S. Customs and Border Protection (CBP) has encountered at least 96 shipments containing primarily mephedrone, methylone, and MDPV, as well as other synthetic cathinones like 4-MEC, butylone, fluoromethcathinone, and dimethylcathinone. Most of these shipments originated in China or India and were being shipped to destinations throughout the United States such as Arizona, Alaska, Hawaii, Kansas, Louisiana, Oklahoma, Oregon, Pennsylvania, Missouri, Virginia, Washington, and West Virginia. The American Association of Poison Control Centers, a non-profit, national organization that represents the poison control centers of the United States, reported that in 2010, poison control centers took 303 calls about synthetic cathinones. However, in just the first seven months of 2011, poison control centers have already received 4,137 calls relating to these products. These calls were received in poison control centers representing at least 47 states and the District of Columbia. Individual state poison control centers have also reported an increase in the number of calls regarding ``bath salts'' from 2009 to 2011.

Concerns over the abuse of these and other synthetic cathinones have prompted many states to control these substances. As of July 15, 2011, at least 33 states have emergency scheduled or enacted legislation placing regulatory controls on some or many of the synthetic cathinones. These states include Alabama, Arkansas, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Tennessee, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Several countries including all members of the European Union have also placed controls on the possession and/or sale of one or more of these substances. Moreover, the use of synthetic cathinones by members of the U.S. Armed Forces is prohibited.

Factor 6. What, If Any, Risk There Is to the Public Health

The risks to the public health associated with the abuse of mephedrone, methylone, and MDPV relate to acute and long term public health and safety problems. These synthetic cathinones have become a serious drug abuse threat as there have been reports of emergency room admissions and deaths associated with the abuse of these substances.

Clinical case reports indicate that these synthetic cathinones produce a number of stimulant-like adverse effects such as palpitation, seizure, vomiting, sweating, headache, discoloration of the skin, hypertension, and hyper-reflexia. Adverse effects associated with consumption of these drugs as reported by abusers include nose-bleeds, bruxism (teeth grinding), paranoia, hot flashes, dilated pupils, blurred vision, dry mouth/thirst, palpitations, muscular tension in the jaw and limbs, headache, agitation, anxiety, tremor, and fever or sweating. Consequently, numerous individuals have presented at emergency departments in response to exposure incidents and several cases of acute toxicity have been reported for the ingestion of mephedrone, methylone, or MDPV. In addition, case reports have shown that the abuse of synthetic cathinones can lead to psychological dependence like that reported for other stimulant drugs.

According to clinical case reports, investigative toxicological reports, and

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autopsy reports, mephedrone, methylone, and MDPV have been implicated in drug induced overdose deaths. In at least three reported deaths, one of these synthetic cathinones was ruled as the cause of death. Other deaths involved individuals under the influence of these synthetic cathinones who acted violently and unpredictably in causing harm to themselves or others. There have also been reports in the scientific literature of deaths caused by individuals who were driving under the influence of these synthetic cathinones.

A number of synthetic cathinones and their products, as identified by CBP and reported in the scientific literature, appear to originate from foreign sources. The manufacturers and retailers who make and sell these products do not fully disclose the product ingredients including the active ingredients or the health risks and potential hazards associated with these products. This poses significant risk to abusers who may not know what they are purchasing or the risk associated with the use of those products.

Available evidence on the overall health and social risks of mephedrone, methylone, and MDPV indicates that these substances can cause acute health problems, can potentially lead to dependency, or can cause death. The abuse of synthetic cathinones has been characterized by both acute and long term public health and safety problems and has resulted in deaths.

Finding of Necessity of Schedule I Scheduling To Avoid Imminent Hazard to Public Safety

Based on the above data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of mephedrone, methylone, and MDPV pose an imminent hazard to the public safety. DEA is not aware of any recognized therapeutic uses of these synthetic cathinones in the United States. A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(h)(1)) may only be placed in schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. Available data and information for mephedrone, methylone, and MDPV indicate that these three synthetic cathinones have a high potential for abuse, no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision.

Conclusion

This notice of intent initiates expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA (21 U.S.C. 811(h)). In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)), the Administrator has considered available data and information and has set forth herein the grounds for her determination that it is necessary to temporarily schedule three synthetic cathinones, 4-methyl-N-methylcathinone (mephedrone), 3,4-methylenedioxy-N-methylcathinone (methylone), and 3,4-methylenedioxypyrovalerone (MDPV) in Schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place these synthetic cathinones into Schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the Federal Register, and will be in effect for a period of up to 18 months pending completion of the permanent or

regular scheduling process. It is the intention of the Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. Mephedrone, methylone, and MDPV will then be subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importing and exporting of a Schedule I controlled substance under the CSA.

Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ``on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth specific criteria for scheduling a drug or other substance. While temporary scheduling orders are not subject to judicial review (21 U.S.C. 811(h)(6)), the regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions which conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by Section 201(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Administrator of the DEA by Department of Justice regulations (28 CFR 0.100), the Administrator hereby intends to order that 21 CFR Part 1308 be 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. Section 1308.11 is amended by adding new paragraphs (g)(6), (7) and (8) to read as follows:

Sec. 1308.11 Schedule I.

* * * * *

(g) * * *

(6) 4-methyl-N-methylcathinone--1248 (Other names: mephedrone)

(7) 3,4-methylenedioxy-N-methylcathinone--7540 (Other names: methylone)

(8) 3,4-methylenedioxypyrovalerone--7535 (Other names: MDPV)

Dated: September 1, 2011.

Michele M. Leonhart,
Administrator.

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