Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–357]

Schedules of Controlled Substances: Placement of Methylone Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing 3,4-methylenedioxy-N-methylcathinone (methylone) 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). This proposed action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking.

DATES: DEA will permit interested persons to file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted and written comments must be postmarked on or before December 17, 2012. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may file a request for hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and 1316.47. Requests for hearing, notices of appearance, and waivers of participation must be received on or before November 16, 2012.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–357'' on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document and supplemental information to this proposed rule are also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/OD, 8701 Morrissette Drive, Springfield, VA 22152. All requests for hearing must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, VA 22152.

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:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION** paragraph.

Request for Hearing, Notice of Appearance at or Waiver of Participation in Hearing

In accordance with the CSA, this action is a formal rulemaking ''on the record after opportunity for a hearing.'' 21 U.S.C. 811(a). Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557) and 21 CFR 1308.41. Pursuant to 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of participation may be submitted only by interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).'' Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b) and 1316.47 or 1316.48, as applicable. A request or notice should state, with particularity, the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and 1316.49, including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of the hearing is restricted to ''(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *'' Requests for hearing, notices of appearance at the hearing, and waivers of participation in the hearing should be submitted to DEA using the address information provided above.

Legal Authority

The DEA 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, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances by statute are found at 21 U.S.C. 812(c) and the current list of scheduled substances are published at 21 CFR Part 1308.

The CSA permits these schedules to be modified by providing that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of HHS, or (3) on the petition of any interested party. 21 U.S.C. 811(a). The Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *'' 21 U.S.C. 811(a). The findings required for the placement of a controlled substance in Schedule I are: ''(A) The drug or other substance has a high potential for abuse. (B) The drug or substance has no currently accepted medical use in treatment in the United States. (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.'' 21 U.S.C. 812(b).

Background

On September 8, 2011, the Administrator of the DEA published a Notice of Intent to temporarily place 3,4-methylenedioxy-N-methylcathinone (methylone) along with two other synthetic cathinones (4-methyl-N-methylcathinone (mephedrone) and 3,4-methylenedioxypyrovalerone (MDPV)) into Schedule I pursuant to the temporary scheduling provisions of the CSA (76 FR 55616). Following this, on October 21, 2011, the Administrator published a Final Order in the **Federal Register** (76 FR 65371) amending 21 CFR 1308.11(g) to temporarily place these three synthetic cathinones into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). This 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 scheduling order, and it provided that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance could be extended for up to six months.[1] Under this provision, the temporary scheduling of methylone expires on October 20, 2012, unless extended pursuant to 21 U.S.C. 811(h)(2). An extension until April 20, 2013, is being ordered by the Administrator in a separate action.

As described in the October 21, 2011, Final Order, methylone is a designer drug of the phenethylamine class and is structurally and pharmacologically similar to amphetamine, 3,4-methylenedioxymethamphetamine (MDMA), cathinone and other related substances. The addition of a beta-keto (β-ketone) substituent to the phenethylamine core structure produces a group of substances that have β-keto-phenethylamine as the core structure. Methylone has a β-keto-phenethylamine core structure. Methylone has been used as research chemical. Based on the review of the scientific literature, there are no known medical uses for methylone. The Assistant Secretary of Health for the U.S. Department of Health and Human Services (HHS) has advised that there are no exemptions or approvals in effect for methylone under section 505 (21 U.S.C. 355) of the Federal Food, Drug and Cosmetic Act.

Proposed Determination To Schedule Methylone

This NPRM proposes the permanent scheduling of methylone pursuant to 21 U.S.C. 811(a)(1). On March 30, 2012, DEA requested a scientific and medical evaluation and scheduling recommendation from the Assistant Secretary of Health for HHS for methylone, mephedrone and MDPV pursuant to 21 U.S.C. 811(b). Upon receipt and evaluation of the scientific and medical evaluation and scheduling recommendation from the Assistant Secretary,[2] DEA concluded its analysis of all other relevant data for the proposal to place methylone into Schedule I of the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in the scheduling decision. Please note that both the DEA and HHS analyses are available under ''Supporting and Related Material'' of the public docket for this proposed rule at *www.regulations.gov* under docket number DEA–357.

1. *The Drug's Actual or Relative Potential for Abuse:* The abuse potential of methylone is associated with its ability to evoke pharmacological effects similar to those evoked by the Schedule I and II substances such as cathinone (Schedule I), methcathinone (Schedule I), 3,4-MDMA (Schedule I), amphetamine (Schedule II), methamphetamine (Schedule II), and cocaine (Schedule II). These Schedule I and II substances have a high potential for abuse.

The legislative history of the CSA suggests the following four prongs to consider in determining whether a particular drug or substance has potential for abuse: [3]

i. There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

ii. There is significant diversion of the drug or substance from legitimate drug channels; or

iii. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or

iv. The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug or other substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

[1] On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA), which amended several provisions of the CSA. Subtitle D of FDASIA is titled the ''Synthetic Drug Abuse Prevention Act of 2012.'' In particular, FDASIA amended Schedule I of section 202(c) of the CSA to include mephedrone and MDPV but not methylone, and amended section 201(h)(2) to increase the maximum timeframes for temporary scheduling. Public Law 112–144, Sections 1152(b) and 1153.

[2] DEA received from HHS Evaluation and Recommendation documents with respect to methylone, but not for mephedrone and MDPV. However, mephedrone and MDPV are listed as Schedule I substances under FDASIA.

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); 1970 U.S.C.C.A.N. 4566, 4601.

With respect to the first prong, a number of case reports and case series have shown that individuals are taking methylone and products containing methylone in amounts sufficient to induce adverse health effects similar to those induced by amphetamine, methamphetamine, and MDMA, Schedule I and II substances. These effects included elevated body temperature, increases in heart rate and respiratory exchange, changes in blood pressure, seizures, erratic behavior, and coma. Even death has been reported following the abuse of methylone or products containing methylone. Further, law enforcement encounters indicate the occurrence of a fatal automotive accident that was caused by a driver under the influence of a product containing methylone.

In considering evidence of significant diversion of the drug or substance from legitimate drug channels under the second prong, it must be noted that as of October 21, 2011, methylone has been temporarily controlled as a Schedule I substance and thus has not been legally available unless for research purposes. However, the National Forensic Laboratory Information System (NFLIS), which details over 2,500 reports from state and local forensic laboratories, identified methylone in drug related exhibits for a period from January 2009 to June 2012 from 42 states. The System to Retrieve Information from Drug Evidence (STRIDE), which details reports from federal forensic laboratories, identified methylone in 220 drug related exhibits from a period from January 2009 to June 2012.

For the third prong, HHS states that there is no currently accepted medical use for methylone and no medical practitioner is currently licensed by law to administer methylone. Indeed, the FDA has not approved a new drug application (NDA) for methylone for any therapeutic indication, and no investigational new drug (IND) application for methylone is currently active. Thus, with no accepted medical use or administering practitioners, individuals currently using products containing methylone are doing so on their own initiative without medical advice from a practitioner licensed to administer methylone.

With regard to the fourth prong, HHS states that methylone produces pharmacological effects similar to those produced by the Schedule I and II central nervous system (CNS) substances such as amphetamine, methamphetamine, cocaine, and MDMA which have a high potential for abuse. Methylone, like these Schedule I and II substances, affects the concentrations of the neurotransmitters dopamine, serotonin and norepinephrine in the CNS. In drug discrimination assays, methylone substitutes for MDMA, amphetamine, methamphetamine, and cocaine, which suggests that methylone will likely produce subjective effects in humans similar to these substances and have a similar pattern of abuse. Methylone, like methamphetamine, amphetamine, and cocaine, is a CNS stimulant and produces locomotor stimulant activity in animals.

Methylone has no known medical use in the United States but evidence demonstrates that methylone is being abused by individuals for its psychoactive effects. Methylone has been encountered by law enforcement throughout the United States as reported in NFLIS and in STRIDE databases suggesting that individuals are abusing methylone. Methylone has also been identified during the toxicological screening of individual human urine samples which also demonstrates that individuals are abusing this substance. In addition, information from poison centers indicates the abuse of synthetic cathinones which likely include methylone. The American Association of Poison Control Centers (AAPCC) [4] reported in a press release that poison centers took 304 calls in 2010 regarding synthetic cathinone exposures and 6,138 calls in 2011. As of September 12, 2012, poison centers have received 2,251 calls relating to these products this year. These calls were received in poison centers representing at least 47 states and the District of Columbia. Although methylone may not be specifically identified during exposure calls or identified by toxicology testing by AAPCC, it is likely that some of these retail products described by the callers contained methylone, based on the identification of methylone in approximately 26% of all synthetic cathinones related exhibits reported to NFLIS from January 2009 to June 2012.

State public health and poison centers have warned of the dangers associated with the use of synthetic cathinones and their associated products being found on the designer drug market. In response to the abuse of methylone and other synthetic cathinones, as of September 2012, at least 42 states have emergency scheduled or enacted legislation placing regulatory controls on some or many of the synthetic cathinones including mephedrone, methylone, MDPV and/or a defined general class of cathinones. At least 27 states specifically control methylone. Numerous local jurisdictions have also placed controls on methylone and other synthetic cathinones. All five branches of the U.S. military prohibit military personnel from possessing or using synthetic cathinones including methylone.

Methylone has been reported to cause a number of adverse effects that are characteristic of stimulants like methamphetamine, amphetamine, and cocaine. Adverse effects associated with the consumption of methylone include those typical of a sympathomimetic agent such as palpitations, hyperthermia, seizures, hyponatremia, bruxism, sweating, hypertension, tachycardia, headache, palpitations, thirst, mydriasis, tremor, fever, sweating, and hypertension. Other effects that have been reported from the use of methylone include psychological effects such as confusion, psychosis, paranoia, hallucinations, combativeness, and agitation. Finally, reports of death for individuals abusing methylone indicate that methylone is a serious public health threat.

2. *Scientific Evidence of the Drug's Pharmacological Effects, If Known:* In the recommendation from HHS for the placement of methylone in Schedule I of the CSA, HHS states that based on the results of preclinical studies and the toxicological profile observed in emergency room cases and medical examiner cases it is probable that methylone produces pharmacological effects in humans that are similar to those produced by the Schedule I and II substances amphetamine, methamphetamine, cocaine, and MDMA. These findings are based on published data on the release of monoamines, inhibition of reuptake of monoamines, and in vivo studies (microdialysis, locomotor activity, body temperature, drug discrimination) and are also based on data from studies (locomotor, drug discrimination, in vitro receptor binding, and functional assays) conducted by National Institute on Drug Abuse (NIDA) contract researchers. The preclinical data showed that methylone can substitute for MDMA or amphetamine in rats trained to discriminate amphetamine or MDMA, respectively. Methylone, like methamphetamine, amphetamine, and cocaine, is a CNS stimulant and produces locomotor stimulant effects in animals. Methylone, like methamphetamine, has a rewarding effect as evidenced by conditioned place preference tests. Methylone is an inhibitor of dopamine, serotonin and norepinephrine uptake and also causes the release of these neurotransmitters in

[4] AAPCC is a non-profit, national organization that represents the poison centers of the United States.

the CNS. Furthermore, studies show that methylone, like MDMA, can be cytotoxic to liver cells. HHS further states that the toxicological profile observed in emergency room and medical examiner cases involving methylone demonstrate that the pharmacological profile observed in humans is in accordance with preclinical data.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Methylone is a β-ketophenethylamine (i.e., synthetic cathinone) that is structurally and pharmacologically similar to amphetamine, methamphetamine, MDMA, cathinone and other related substances. Methylone can be prepared from its corresponding ketone by a two-step synthesis. Studies indicate that humans metabolize methylone and metabolites of methylone have been found in the urine samples of humans and animals given methylone. Research in anti-depressant and anti-parkinson agents resulted in the synthesis and patenting of methylone. According to HHS, methylone has no approved medical use in the United States, does not have an approved NDA, and is not currently marketed in the United States in an FDA-approved drug product. A drug has a ''currently accepted medical use'' if all of the following five elements have been satisfied: the drug's chemistry is known and reproducible; and there are adequate safety studies; and there are adequate and well-controlled studies proving efficacy; and the drug is accepted by qualified experts; and the scientific evidence is widely available. 57 Fed. Reg. 10499 (March 26, 1992). According to HHS, there are no published clinical studies involving methylone. DEA has also not found any references to clinical studies involving methylone's efficacy and safety in the scientific and medical literature. Although the chemistry of methylone is known and has been reproduced, as mentioned above there are no clinical studies involving methylone. Thus, methylone has no currently accepted medical use in treatment in the United States and there is a lack of accepted safety for use of methylone under medical supervision.

4. *Its History and Current Pattern of Abuse:* Methylone is a synthetic cathinone that emerged on the United States' illicit drug market in 2009 and prior to its temporary control was perceived as being a 'legal' alternative to cocaine, methamphetamine, and MDMA. Methylone is falsely marketed as ''research chemicals,'' ''plant food,'' or ''bath salts'' and has been sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations and can also be purchased on the Internet under a variety of product names (White Dove, Explosion, Tranquility etc.). It is commonly encountered in the form of powders, capsules, and tablets. The packages of these commercial products usually contain the warning ''not for human consumption.'' Poison centers reported a large number of toxic exposures to these products as indicated by the number of exposure calls related to synthetic cathinones. A large majority of these exposures were by intentional abuse, misuse, or suspected suicide. Most of these exposures were described as acute. AAPCC data also identified the most common route of administration for the synthetic cathinones as inhalation/nasal. Information from published scientific studies indicate that the most common routes of administration for methylone is ingestion by swallowing capsules or tablets or nasal insufflation by snorting the powder. Evidence from poison centers, published case reports, and law enforcement encounters suggest that the main users of methylone are young adults. These substances are popular among youths and young adults with males appearing to abuse methylone more than females. There is evidence that methylone may be co-ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances.

5. *The Scope, Duration, and Significance of Abuse:* Evidence that methylone is being abused is confirmed by drug courts,[5] calls to poison centers, and encounters by law enforcement. Methylone has been identified in specimens from individuals submitted for testing by drug court participants. Drug courts submitted to DEA 18 reports that detail the analysis of biological specimens that contained synthetic cathinones. Methylone was mentioned in 5 of these reports. Evidence from poison centers also indicates that the abuse of synthetic cathinones like methylone is widespread. The AAPCC reported in a press release that poison centers took 304 calls in 2010 regarding synthetic cathinone exposures and 6,138 calls in 2011. As of September 12, 2012, poison centers have received 2,251 calls relating to these products this year. These calls were received in poison centers representing at least 47 states and the District of Columbia. Methylone may not have been specifically mentioned during the exposure calls but it is likely that some of these retail products described by the callers contained methylone based on the identification of methylone in approximately 26% of all synthetic cathinones related exhibits reported to NFLIS from January 2009 to June 2012. Evidence of the increased abuse of methylone is supported by law enforcement encounters of methylone. Forensic laboratories have analyzed drug exhibits received from state, local, or federal law enforcement agencies that were found to contain methylone. The National Forensic Laboratory Information System (NFLIS) is a program sponsored by DEA's Office of Diversion Control. NFLIS compiles information on exhibits analyzed in state and local law enforcement laboratories. The System to Retrieve Information from Drug Evidence (STRIDE) is a DEA database which compiles information on exhibits analyzed in DEA laboratories. NFLIS and STRIDE together capture data for all substances reported by forensic laboratory analyses. Methylone has been encountered by law enforcement as reported in NFLIS.[6] NFLIS details 2,797 reports from state and local forensic laboratories identifying methylone in drug related exhibits for a period from January 2009 to June 2012 from 42 States. NFLIS registered 4 reports from 3 states containing methylone in 2009. However, there were 71 reports from 18 states related to these substances registered in NFLIS in 2010 and there were 1,655 reports from 41 states in 2011. From January to June 2012 there were 1,067 reports from 36 states. STRIDE also details 220 reports from federal forensic laboratories identifying methylone in drug related exhibits for a period from January 2009 to June 2012. STRIDE (which reports data from 6 DEA laboratories) registered 1 exhibit pertaining to methylone in 2009. There were 7 exhibits pertaining to the trafficking, distribution and abuse of methylone registered in STRIDE in 2010 and 107 drug exhibits in 2011. In 2012, 105 drug exhibits pertaining to the trafficking, distribution and abuse of methylone were recorded in the STRIDE database.

[5] Drug courts were developed to achieve a reduction in recidivism and substance abuse among nonviolent, substance abusing offenders by increasing their likelihood for successful rehabilitation through early, continuous, and intense judicially supervised treatment, mandatory periodic drug testing, and the use of appropriate sanctions and other rehabilitation services. Drug courts analyze specimens from participants for new and existing drugs of abuse.

[6] State and local forensic drug reports from January 2009 to June 2012, analyzed on September 12, 2012. The 2012 drug reports are likely to be incomplete as of September 12, 2012, due to laboratory reporting lag time.

At selected United States ports of entry, the U.S. Customs and Border Protection (CBP) has encountered shipments of products containing methylone. The most commonly identified synthetic cathinone was methylone. As of July 2012, methylone was identified in 127 of 330 shipments encountered by CBP from June 2008 to July 2012. These shipments of methylone were in powdered form ranging from gram to multi-kilogram quantities. Most of the shipments of these synthetic cathinones that contained methylone originated in China and were destined for delivery throughout the United States to places like Alaska, Arizona, Arkansas, California, Colorado, Florida, Hawaii, Illinois, Kansas, Louisiana, Oklahoma, Oregon, Missouri, Nevada, New Mexico, Tennessee, Texas, Washington, and West Virginia.

Concerns over the abuse of methylone and other synthetic cathinones have prompted many states to control these substances. As of September 2012, at least 42 states have emergency scheduled or enacted legislation placing regulatory controls on some or many of the synthetic cathinones including methylone. In addition, the U.S. Armed Forces prohibited the use of synthetic cathinones including mephedrone, methylone and MDPV.

6. *What, if any, Risk There is to the Public Health:* Law enforcement, military, and public health officials have reported exposure incidents that demonstrate the dangers associated with methylone to both the individual abusers and other affected individuals. Numerous individuals have presented at emergency departments following exposure to methylone or products containing methylone. Case reports describe presentations to emergency departments of individuals exposed to methylone with symptoms that include tachycardia, headache, palpitations, agitation, anxiety, mydriasis, tremor, fever, sweating, and hypertension. Some individuals under the influence of methylone have acted violently and unpredictably causing harm, or even death, to themselves or others. In addition, individuals suspected of driving under the influence of intoxicating substances have been found to have positive test results for methylone and some of these incidents involving methylone intoxications have resulted in the deaths of individuals. There are at least three reported deaths in which methylone was ruled as the cause of death by the medical examiner or after an autopsy and there are many reports in which methylone was implicated (i.e., the primary cause of death is not methylone toxicity) in deaths. Additionally, products containing methylone and other synthetic cathinones often do not bear labeling information regarding their ingredients, and if they do it may not contain the expected active ingredients or identify the health risks and potential hazards associated with these products.

7. *Its Psychic or Physiological Dependence Liability:* According to HHS, there are no studies or case reports that document the psychic or physiological dependence potential of methylone. However, HHS states that because methylone shares pharmacological properties with those of the Schedule I and II substances amphetamine, methamphetamine, cocaine, and MDMA, it is probable that methylone has a dependence profile similar to that of these substances which are known to cause substance dependence.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* Methylone is not considered an immediate precursor of any controlled substance of the CSA as defined by 21 U.S.C 802(23).

Conclusion: Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of methylone. As such, DEA hereby proposes to schedule methylone as a controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as Schedules I, II, III, IV, and V. The statute outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendations of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) 3,4-methylenedioxy-N-methylcathinone (methylone) has a high potential for abuse;

(2) 3,4-methylenedioxy-N-methylcathinone (methylone) has no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of 3,4-methylenedioxy-N-methylcathinone (methylone) under medical supervision.

Based on these findings, the Administrator of DEA concludes that 3,4-methylenedioxy-N-methylcathinone (methylone) including its salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in Schedule I of the CSA (21 U.S.C. 812(b)(1)).

Requirements for Handling Methylone

Methylone is currently scheduled on a temporary basis in Schedule I and is subject to the CSA regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, dispensing, importing, and exporting of a Schedule I controlled substance, including those listed below. These controls on methylone will continue on a permanent basis if this rule is finalized as proposed:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with methylone or who desires to manufacture, distribute, dispense, import, export, engage in research or conduct instructional activities with methylone would need to be registered to conduct such activities pursuant to 21 U.S.C. 822 and 958 and in accordance with 21 CFR Part 1301.

Security. Methylone would be subject to Schedule I security requirements and would need to be manufactured and distributed pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71, 1301.72(a), (c) and (d), 1301.73, 1301.74, 1301.75(a) and (c), 1301.76.

Labeling and Packaging. All labels and labeling for commercial containers of methylone which is distributed on or after the effective date of the finalization of this rule would need to be in accordance with 21 CFR 1302.03–1302.07, pursuant to 21 U.S.C. 825.

Quotas. Quotas for methylone will be established based on registrations granted and quota applications received pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of methylone would be required to keep an inventory of all stocks of methylone on hand pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Every registrant who desires registration in Schedule I for methylone would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to keep records pursuant to 21 U.S.C. 827 and in accordance with 21

CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23.

Reports. All registrants required to submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33 would be required to do so regarding methylone.

Order Forms. All registrants involved in the distribution of methylone would be required to comply with the order form requirements pursuant to 21 U.S.C. 828 and 21 CFR 1305.

Importation and Exportation. All importation and exportation of methylone would need to be done in accordance with 21 CFR Part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958.

Criminal Liability. Any activity with methylone not authorized by, or in violation of, Subchapter I Part D and Subchapter II of the CSA occurring on or after effective date of the finalization of this proposed rule would be unlawful.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed 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 proposed rulemaking 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 rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175

This proposed rule will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

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 proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR 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 a new paragraph (d)(36) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(36) 3,4-Methylenedioxy-N-methylcathinone (Methylone)—7540

* * * * *

Dated: October 10, 2012.

Michele M. Leonhart,

Administrator.

[FR Doc. 2012–25509 Filed 10–16–12; 8:45 am]

BILLING CODE 4410–09–P

POSTAL SERVICE

39 CFR Part 111

Implementation of Full-Service Intelligent Mail Requirements for Automation Prices

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service is proposing to revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) throughout various sections to modify eligibility requirements for mailers to obtain automation prices for First-Class Mail®, Standard Mail®, Periodicals®, and Bound Printed Matter® when mailing postcards, letters, and flats. Effective January 2014, use of ''full-service'' Intelligent Mail® would be required to obtain automation prices. Additionally, the 10/24 transitional barcoded tray label format would be eliminated and mailers would be required to use the 24-digit Intelligent Mail barcode (IMb™) format on tray, tub, and sack labels.

DATES: We must receive your comments on or before November 16, 2012.

ADDRESSES: Mail or deliver written comments to the Manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW., Room 4446, Washington, DC 20260–5015. You may inspect and photocopy all written comments at USPS® Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor N., Washington, DC by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday by calling 1–202–268–2906 in advance. Comments and questions can also be emailed to *mailingstandards@usps.gov* using the subject line ''full-service January 2014.''

FOR FURTHER INFORMATION CONTACT:

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William Chatfield, email: *william.a.chatfield@usps.gov,* phone: 202–268–7278.

SUPPLEMENTARY INFORMATION: On April 20, 2012, the Postal Service published an advance notice of proposed rulemaking in the **Federal Register** (77 FR 23643–23647) to require use of full-service Intelligent Mail to obtain automation prices for First-Class Mail (FCM), Standard Mail, Periodicals, and Bound Printed Matter (BPM) when mailing postcards, letters, and flats.

Background

In January 2009, the Postal Service offered the mailing industry two Intelligent Mail options for automation discounts: basic-service and full-service. Currently, a large number of mailers are using these options and reaping significant benefits and value.

When using the full-service option, mailers are required to: Apply unique Intelligent Mail barcodes (IMb) to identify each letter, postcard, and flat mailpiece; individually meet the eligibility requirements for automation prices according to class and shape; apply unique Intelligent Mail tray barcodes (IMtb) on trays, tubs, and sacks; apply unique Intelligent Mail container barcodes (IMcb) on placards for containers, such as pallets; schedule appointments through Facility Access and Shipment Tracking (FAST®) if their mail is accepted at an origin facility and entered at a downstream USPS™ processing facility; and use an approved electronic method to transmit to the Postal Service mailing documentation and postage statements. If the mailing is being prepared or presented on behalf of