accident aircraft was an unapproved modification and the Fletcher FU/24 hopper installation is a similar design to the Cresco 08–600. The MCAI requires reviewing the aircraft records, doing a conformity inspection for an approved design hopper lid installation, and removing the hopper lid installation, if not an approved design.

Actions and Compliance

(f) Unless already done, do the following actions within 150 hours time-in-service (TIS) after the effective date of this AD or within 12 calendar months after the effective date of this AD, whichever occurs first:

(1) Review the aircraft records and determine whether a hopper lid modification has been recorded. If a hopper lid modification has been recorded, determine whether the aircraft was certified for release to service after completion of the modification and whether the applicable approved technical data (supplemental type certificate [STC] or field approval) is referenced. Visually inspect for an unapproved hopper lid modification.

(2) If the hopper lid modification is an approved design, do a conformity inspection and determine whether the hopper lid modification conforms to the applicable approved technical data (supplemental type certificate [STC] or field approval).

(3) If the hopper lid modification is not an approved design (STC or field approval), before further flight, remove the hopper lid installation.

Note 1: The Frontier-Aerospace Incorporated Models Fletcher FU–24 and Fletcher FU–24A airplanes are U.S. type-certificated airplanes and do not have this unsafe condition.

Note 2: The basic hopper installation for the Pacific Aerospace Limited Model FU24–954 airplane does not include a hopper lid due to the canopy sliding partly over the hopper inlet. A separate approval must be obtained to install a hopper lid.

Related Information

(h) MCAI Civil Aviation Authority (CAA) AD DCA/FU24/180, dated July 28, 2011, for related information. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on August 31, 2011.

Earl Lawrence, Acting Manager, Small Airplane Directorate, Aircraft Certification Service. [FR Doc. 2011–22933 Filed 9–7–11; 8:45 am]

BILLING CODE 4910–13–P

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-methylcarbionine (mephedrone), 3,4-methylenedioxy-N-methylcarbionine (methylone), and 3,4-methylenedioxy-phenvalerone (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 Morrissette 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

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
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).

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-methylenedioxyamphetamine (MDMA), cathinone and other related substances. The addition of a beta-keto (β-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-methylenedioxymethylcathinone (methylone), and 3,4-methylenedioxy-4-methylpyrovalerone (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 are sold at smoke shops, head shops, and other retailers. They 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 routine urinalysis drug tests will not typically detect the presence of these synthetic cathinones. However, analytical methods for the detection of Mephedrone, methamphetamine, and MDPV have 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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Accordingly, methedrone, methylene, 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 methedrone, methylene, 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 methedrone, methylene, 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).
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-methycathinone (mephedrone), 3,4-methylenedioxy-N-methylcathinone (methylone), and 3,4-methylenedioxyprovalerone (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:

§ 1308.11 Schedule I.

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<td>(6) 4-methyl-N-methycathinone—1248 (Other names: mephedrone)</td>
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<td>(7) 3,4-methylenedioxy-N-methylcathinone—7540 (Other names: methylone)</td>
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<td>(8) 3,4-methylenedioxyprovalerone—7535 (Other names: MDPV)</td>
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Dated: September 1, 2011.

Michele M. Leonhart, Administrator.

[FR Doc. 2011-23012 Filed 9–7–11; 8:45 am]

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