DOE will provide a grace period of 180 days for the manufacturer to begin to use the DOE test procedure or the alternate test procedure specified in the decision and order on the petition to make representations of energy efficiency.

* * * * *

(h) *Duration.* (1) Interim waivers remain in effect until the earlier of the following:

(i) DOE publishes a decision on a petition for waiver pursuant to paragraph (f) of this section in the **Federal Register**; or

(ii) DOE publishes in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–495]

Schedules of Controlled Substances: Temporary Placement of *N*-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-Chloro-α-PVP in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule the synthetic cathinones, *N*-ethylhexedrone; *alpha*-pyrrolidinohexanophenone (trivial name: α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (trivial name: 4-MEAP); 4′-methyl-alpha-pyrrolidinohexiophenone (trivial name: MPHP); alpha-pyrrolidinoheptaphenone (trivial name: PV8); and 4-chloro-*alpha*-pyrrolidinovalerophenone (trivial name: 4-chloro-α-PVP), in schedule I. When it is issued, the temporary scheduling order will impose regulatory requirements under the Controlled Substances Act (CSA) on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, conduct of instructional activities, and chemical analysis of these synthetic cathinones, as well as administrative, civil, and criminal remedies with respect to persons who fail to comply with such requirements or otherwise violate the CSA with respect to these substances.

DATES: May 1, 2019.

FOR FURTHER INFORMATION CONTACT: Lynnette M. Wingert, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: This notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) placing *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I of the Controlled Substances Act (CSA).[1] The temporary scheduling order will be published in the **Federal Register** on or after May 31, 2019.

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year. 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 for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated March 9, 2018. The Acting Assistant Secretary responded to this notice of intent by letter dated March 27, 2018, and advised that based on a review by the Food and Drug Administration (FDA), there were currently no approved new drug applications or active investigational new drug applications for *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP. The Acting Assistant Secretary also stated that the HHS had no objection to the temporary placement of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I of the CSA. *N*-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP under section 505 of the FDCA, 21 U.S.C. 355.

In order to find that placing a substance temporarily in 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 21 U.S.C. 811(c): 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(h)(3). 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 may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States,

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Synthetic Cathinones

Recently, novel synthetic cathinones that mimic the biological effects of substances with stimulant-like effects have emerged on the illicit drug market. These novel cathinones, also known as designer drugs, are structurally similar to several drugs of abuse such as schedule I synthetic cathinones (*e.g.,* methcathinone, mephedrone, methylone, pentylone, and 3,4-methylenedioxypyrovalerone (MDPV)). The illicit use of synthetic cathinones has continued throughout the United States, resulting in severe adverse effects, overdoses, and deaths. Indeed, hospital reports, scientific publications and/or law enforcement reports demonstrate that these types of substances are being abused for their psychoactive properties and they cause harm (*see* DEA 3-Factor Analysis). Recreational effects reported by abusers of synthetic cathinones include euphoria, sense of well-being, increased sociability, energy, empathy, increased alertness, improved concentration, and focus. Adverse effects such as tachycardia, hypertension, rhabdomyolysis, hyponatremia, seizures, and altered mental status (paranoia, hallucinations, and delusions) have also been reported from the abuse of synthetic cathinones. Consequently, there are documented reports of emergency room admissions and deaths associated with the abuse of synthetic cathinone substances. With many generations of synthetic cathinones having been encountered since 2009, the abuse of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP is impacting or will negatively impact communities.

Law enforcement data indicate that *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP have appeared in the United States' illicit drug market (*see* DEA 3-Factor Analysis). Law enforcement encounters include those reported to the National Forensic Laboratory Information System (NFLIS), a DEA sponsored program that systematically collects drug identification results and associated information from drug cases analyzed by Federal, State, and local forensic laboratories. From January 2012 to September 24, 2018, NFLIS registered 1,131 drug exhibits pertaining to the trafficking, distribution and abuse of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP. These exhibits had a net weight of approximately 18.7 kilograms and were encountered in powder, crystal, rock, resin, capsule, and tablet forms.

As observed by the DEA and by the United States Customs and Border Protection (CBP), synthetic cathinones originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. Encounters of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP have occurred by the CBP (*see* DEA 3-Factor Analysis).

N-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP have no accepted medical use in the United States. *N*-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP have been seized by law enforcement in the United States. The misuse of α-PHP, 4-MEAP, MPHP, and PV8 has been reported to result in adverse effects in humans in the United States. Although no overdose information is currently available for *N*-ethylhexedrone and 4-chloro-α-PVP, law enforcement seizures of these two substances and their pharmacological similarity to currently controlled schedule I synthetic cathinones (*e.g.,* methcathinone, mephedrone, methylone, pentylone, MDPV) suggest that these two synthetic cathinones are likely to produce adverse effects similar to those produced by other synthetic cathinones.

N-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are synthetic cathinones that have pharmacological effects similar to schedule I synthetic cathinone substances such as methcathinone, mephedrone, methylone, pentylone, and MDPV and schedule II stimulants such as methamphetamine and cocaine. The misuse of α-PHP, 4-MEAP, MPHP, and PV8 has been associated with one or more overdoses with some requiring emergency medical intervention in the United States. With no approved medical use and limited safety or toxicological information, *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP have emerged on the designer drug market, and the abuse or trafficking of these substances for their psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

N-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are synthetic cathinones that have been identified in the United States' illicit drug market. Evidence indicates that these substances are being substituted for schedule I synthetic cathinones. Products containing synthetic cathinones have been falsely marketed as ''research chemicals,'' ''jewelry cleaner,'' ''stain remover,'' ''plant food or fertilizer,'' ''insect repellants,'' or ''bath salts.'' They have been sold at smoke shops, head shops, convenience stores, adult bookstores, and gas stations. They can also be purchased on the internet. These substances are commonly encountered in the form of powders, crystals, tablets, and capsules. Other encountered forms include resin, rock, liquid, and deposits on plant matter. Law enforcement has encountered *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in powder, crystal, resin, rock, capsule, or tablet forms. The packages of these commercial products usually contain the warning ''not for human consumption,'' most likely in an effort to circumvent statutory restrictions for these substances.

N-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are likely to be abused in the same manner as schedule I synthetic cathinones such as methcathinone, mephedrone, methylone, pentylone, and MDPV. Information from published scientific studies indicate that the most common routes of administration for synthetic cathinones are nasal insufflation by snorting the powder and ingestion by swallowing capsules or tablets. The powder can also be injected or swallowed. Other methods of intake include rectal administration, ingestion by ''bombing'' (wrapping a dose of powder in a paper wrap and swallowing) and intramuscular injection.

Based upon the information collected from case reports, medical journals, and scientific publications including survey data, the main users of synthetic cathinones are youths and young adults. Given that *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are newly emerging synthetic cathinones, it is likely that these substances will be used by the same population. This is consistent with data collected from the use of schedule I synthetic cathinones (*e.g.,* mephedrone, methylone, pentylone, MDPV). According to Monitoring the Future (MTF) survey data,[3] the 2017 annual

[3] Monitoring the Future (MTF) is a research program conducted at the University of Michigan's Institute for Social Research under grants from NIDA. MTF tracks drug use trends among United States adolescents in the 8th, 10th, and 12th grades

prevalence rate of synthetic cathinone use was 0.6% for high school seniors and 0.3% for young adults (19–30 years). However, there was an 18 percentage point increase in the perceived risk of trying ''bath salts'' in young adults (aged 19–26 years).

N-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are likely to have duration of effects similar to those of schedule I synthetic cathinones because of their structural and pharmacological similarities. Users report (drug surveys, scientific and medical literature, *etc.*) that the effects of synthetic cathinones occur a few minutes to 15 minutes after administration, depending on the synthetic cathinone and the route of administration (oral, insufflation, intravenous, *etc.*), and can last up to three hours.

Evidence indicated that *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are ingested with other substances. This is likely to either heighten the effects or ameliorate the come-down effects of the synthetic cathinones. Co-ingestions can be from the ingestion of multiple products separately or a single product that is composed of multiple substances (*e.g.,* one tablet containing *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, 4-chloro-α-PVP and other illicit substances). Indeed, law enforcement routinely encounters synthetic cathinone mixtures. Substances found in combination with *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, or 4-chloro-α-PVP are: Other synthetic cathinones (*e.g.,* MDPV, 4-chloromethcathinone, *N*-ethylpentylone, α-PVP), common cutting agents (*e.g.,* caffeine), or other recreational substances (*e.g.,* methamphetamine, fentanyl, fentanyl analogues, carfentanil, benzodiazepines (*e.g.,* alprazolam), heroin, cocaine, synthetic cannabinoids, fluoroamphetamine, MDMA). Multiple drug use and potential co-ingestions are confirmed by forensic analysis of seized and purchased synthetic cathinone products.

Factor 5. Scope, Duration and Significance of Abuse

Since 2009, the popularity of synthetic cathinones and their associated products has continued, as evidenced by law enforcement seizures, public health information, and media reports. As one synthetic cathinone is controlled, another unscheduled synthetic cathinone appears in the recreational drug market. *N*-Ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are synthetic cathinones that have been identified in the United States' illicit drug market (*see* DEA 3-Factor Analysis for a full discussion).

Law enforcement data indicate that *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are being abused in the United States as recreational drugs. While law enforcement data are not direct evidence of abuse, the data can infer that a drug has been diverted and abused.[4] Forensic laboratories have confirmed the presence of these substances in drug exhibits received from state, local, and federal law enforcement agencies. From January 2012 to September 24, 2018, there were 1,131 exhibits reported to NFLIS databases (federal, state, and local forensic laboratories) pertaining to the trafficking, distribution and abuse of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP. These exhibits had a net weight of approximately 18.7 kilograms. These data also indicated that the abuse of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP is widespread and has been encountered in many states since 2012 in the United States.

The following information details data obtained from the NFLIS database (queried on September 24, 2018), including dates of first encounter, exhibits/reports, and locations.

N-ethylhexedrone: NFLIS—233 reports, first encountered in August 2016, locations include: Arizona, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and Wyoming.

α-*PHP:* NFLIS—395 reports, first encountered in May 2014, locations include: Arkansas, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New Jersey, New York, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming.

4–MEAP: NFLIS—105 reports, first encountered in August 2013, locations include: Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Kansas, Louisiana, Maryland, Minnesota, New Hampshire, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, and Texas.

MPHP: NFLIS—71 reports, first encountered in June 2012, locations include: California, Connecticut, Florida, Georgia, Indiana, Kansas, Kentucky, Maine, Minnesota, Missouri, Nebraska, Nevada, New Jersey, Ohio, Pennsylvania, and Texas.

PV8: NFLIS—166 reports, first encountered in December 2013, locations include: Arizona, Connecticut, District of Columbia, Florida, Georgia, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and Wisconsin.

4-Chloro-α-PVP: NFLIS—160 reports, first encountered in December 2015, locations include: California, District of Columbia, Louisiana, Maryland, Arizona, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Massachusetts, Minnesota, Missouri, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, and Washington.

Additionally, encounters/seizures of these substances have occurred by the CBP at United States ports of entry. As observed by the DEA and CBP, synthetic cathinones originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. From 2014 to 2017, CBP encountered 73 shipments of products containing *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, or 4-chloro-α-PVP. Additional evidence indicates that some of these synthetic cathinones have been seized abroad. *N*-Ethylhexedrone and 4-chloro-α-PVP have been identified in seized materials in China and Poland, respectively. These data demonstrate that these substances are being trafficked and abused in the United States and abroad.

Concerns over the abuse of synthetic cathinone substances have led to the control of many synthetic cathinones. The DEA controlled 13 synthetic cathinones: methylone, mephedrone, MDPV, 4-methyl-*N*-ethylcathinone (4-MEC), 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP), *alpha*-pyrrolidinopentiophenone (α-PVP), butylone (1-(1,3-benzodioxol-5-

and high school graduates into adulthood by conducting national surveys.

[4] *See* 76 FR 77330, 77332, Dec. 12, 2011.

yl)-2-(methylamino)butan-1-one), pentedrone (2-(methylamino)-1-phenylpentan-1-one), pentylone, 4-fluoro-*N*-methylcathinone (4-FMC), 3-fluoro-*N*-methylcathinone (3-FMC), naphyrone (1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one), and *alpha*-pyrrolidinobutiophenone (α-PBP) from 2011 to 2014 (October 21, 2011; 76 FR 65371 and March 7, 2014; 79 FR 12938). Recently, the DEA controlled another synthetic cathinone, *N*-ethylpentylone (August, 31, 2018; 83 FR 44474), as a schedule I substance.

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

Available evidence on the overall public health risks associated with the use of synthetic cathinones suggests that *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP can cause acute health problems leading to emergency department (ED) admissions, violent behaviors causing harm to self or others, or death. Acute adverse effects of synthetic cathinone substances are those typical of sympathomimetic agents (*e.g.,* cocaine, methamphetamine, amphetamine) and include among other effects tachycardia, headache, palpitations, agitation, anxiety, mydriasis, tremor, fever or sweating, and hypertension. Other effects, with possible public health risk implications, that have been reported from the use of synthetic cathinone substances include psychological effects such as psychosis, paranoia, hallucinations, and agitation.

α-PHP, 4-MEAP, MPHP, and PV8 have been associated with the overdoses or deaths of individuals. There have been documented reports of ED admissions or deaths associated with the abuse of α-PHP, 4-MEAP, MPHP, and PV8. Individuals under the influence of 4-MEAP and MPHP have acted violently or unpredictably causing harm, or even death, to themselves or others. Adverse effects associated with α-PHP, 4-MEAP, MPHP, and PV8 abuse included vomiting, agitation, paranoia, hypertension, unconsciousness, tachycardia, seizures, cardiac arrest, rhabdomyolysis, or death. No overdose information is currently available for *N*-ethylhexedrone and 4-chloro-α-PVP, but the pharmacological similarity of these substances to other currently controlled schedule I synthetic cathinones (*e.g.,* methcathinone, mephedrone, methylone, pentylone, MDPV) suggests that these substances can also pose an imminent hazard to public safety.

It remains highly likely that additional cases of adverse health effects involving α-PHP, 4-MEAP, MPHP, and PV8 in the United States may have occurred and will continue to be under-reported as these substances, as well as *N*-ethylhexedrone and 4-chloro-α-PVP, are not part of standard panels for biological specimens. The pharmacological data for *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP alone or combined with documented case reports, if any, demonstrate that the potential for fatal and non-fatal overdoses exists for *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP; thus, these substances pose an imminent hazard to the public health and safety.

As found with other synthetic cathinone substances, products containing synthetic cathinones often do not bear labeling information regarding the ingredients or the health risks and potential hazards associated with these products. The limited knowledge about product content and its purity, as well as lack of information about its effects, pose additional risks for significant adverse health effects to the users.

Based on pharmacological data or documented case reports of overdose fatalities, the misuse and abuse of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP leads to the same qualitative public health risks as schedule I and II substances such as cathinone, methcathinone, mephedrone, methylone, pentylone, MDPV, methamphetamine, cocaine, and MDMA. α-PHP, MPHP, and PV8 have been associated with fatalities. As the data demonstrates, the potential for fatal and non-fatal overdoses exists for *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP; thus, *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP pose an imminent hazard to the public safety.

N-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP are being encountered on the illicit drug market in the United States and have no accepted medical use in the United States. Regardless, these products continue to be easily available and abused by diverse populations.

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

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and/or abuse of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP, resulting from the lack of control of these substances, pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP 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 a lack of accepted safety for use under medical supervision. Available data and information for *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP indicate that these synthetic cathinones have 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. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated March 9, 2018, notified the Acting Assistant Secretary of the DEA's intention to temporarily place *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I.

Conclusion

This notice of intent provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h), of the DEA's intent to issue a temporary scheduling order. In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Acting Administrator considered available data and information, herein set forth the grounds for his determination to temporarily schedule *N*-ethylhexedrone; alpha-pyrrolidinohexanophenone (trivial name: α-PHP); 4-methyl-alpha-ethylaminopentiophenone (trivial name: 4-MEAP); 4′-methyl-alpha-pyrrolidinohexiophenone (trivial name: MPHP); alpha-pyrrolidinoheptaphenone (trivial name: PV8); and 4-chloro-alpha-pyrrolidinovalerophenone (trivial name: 4-chloro-α-PVP) in schedule I of the CSA, and finds that placement of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I of the CSA on a temporary basis is necessary to avoid an imminent hazard to the public safety.

The temporary placement of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before May 31, 2019. Because the Acting Administrator hereby finds that it is necessary to temporarily place *N*-

ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling these substances will be effective on the date that the order is published in the **Federal Register** and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Acting Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this notice. Upon publication of the temporary order, *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. 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. 21 U.S.C. 811. 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 that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this notice of intent. The APA expressly differentiates between an order and a rule, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*'' 5 U.S.C. 551(6) (emphasis added). The specific language chosen by Congress indicates an intention for the DEA to proceed through the issuance of an *order* instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for *other* kinds of scheduling actions, *see* section 201(a) of the CSA, 21 U.S.C. 811(a), it is noteworthy that, in section 201(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Acting Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to section 811(h)(4).

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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, the DEA proposes to amend 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), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(42) through (47) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(42) *N*-Ethylhexedrone, its optical, positional, and geometric isomers, salts and salts of isomers ..	(7246)
(43) *alpha*-Pyrrolidinohexanophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: α-PHP)	(7544)
(44) 4-Methyl-*alpha*-ethylaminopentiophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4-MEAP)	(7245)
(45) 4′-Methyl-*alpha*-pyrrolidinohexiophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MPHP)	(7446)
(46) *alpha*-Pyrrolidinoheptaphenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: PV8)	(7548)
(47) 4-Chloro-*alpha*-pyrrolidinovalerophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4-chloro-α-PVP)	(7443)

Dated: April 22, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–08704 Filed 4–30–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SATS No. IL–109–FOR; Docket ID: OSM–2019–0003 S1D1S SS08011000 SX064A000 190S180110; S2D2S SS08011000 SX064A000 19XS501520]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Illinois regulatory program (Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Illinois proposes revisions to its regulations, including allowing the extraction of coal as an incidental part of a government-financed construction project, revising its Ownership and Control rules, and clarifying land use changes requiring a significant permit revision. Illinois intends to revise its program to be as effective as the Federal regulations. This document gives the times and locations where the Illinois program documents and this proposed amendment to that program are available for your inspection, establishes the comment period during which you may submit written comments on the amendment, and describes the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., CST, May 31, 2019. If requested, we will hold a public hearing on the amendment on May 28, 2019. We will accept requests to speak at a hearing until 4:00 p.m., CST on May 16, 2019.

ADDRESSES: You may submit comments, identified by SATS No. IL–109–FOR, by any of the following methods:

- *Mail/Hand Delivery:* Paul Ehret, Acting Chief, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169.
- *Fax:* (618) 463–6470
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID OSM–2019–0003. If you would like to submit comments go to *http://www.regulations.gov*. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Illinois program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Alton Field Division, or the full text of the program amendment is available for you to review at *www.regulations.gov*. Paul J. Ehret, Acting Chief, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169, Telephone: (618) 463–6463, Email: *pehret@osmre.gov*.

In addition, you may review a copy of the amendment during regular business hours at the following location: Office of Mines and Minerals, Illinois Department of Natural Resources, One Natural Resources Way, Springfield, IL 62702–1271, Telephone: (618) 439–9111.

FOR FURTHER INFORMATION CONTACT: Paul Ehret, Acting Chief, Alton Field Division, Telephone: (618) 463–6463, Email: *pehret@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Illinois program effective June 1, 1982. You can find background information on the Illinois program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Illinois program in the June 1, 1982, **Federal Register** (47 FR 23858). You can also find later actions concerning the Illinois program and program amendments at 30 CFR 913.10, 913.15, and 913.17.

II. Description of the Proposed Amendment

By letter dated December 5, 2018 (Administrative Record No. IL–5100), Illinois sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) at its own initiative. By email dated December 11, 2018, Illinois requested that OSMRE's review be put on hold until they could resubmit the proposed amendment due to editorial changes requested by the Illinois Joint Committee on Administrative Rules. Illinois resubmitted the proposed amendment to OSMRE on February 20, 2019. OSMRE will use this date for its review. Below is a summary of the changes proposed by Illinois. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

Illinois proposes to revise the Illinois Surface Coal Mining Land Conservation and Reclamation Act (225 ILCS 720), Section 1.06, ''Scope of the Act,'' by adding language allowing coal extraction as an incidental part of a government-financed project. The language added is nearly identical to that found in Section 528 of SMCRA (30 U.S.C. 1278).

Illinois also proposes to revise the following Parts of Title 62 of the Illinois Administrative Code:

Section 1701 Appendix A. Definitions

Illinois proposes to revise its regulation at section 1701 Appendix A, amending a number of its definitions, including those for ''ownership,'' ''control,'' and ''violations,'' to conform with the Federal definitions at 30 CFR 701.5 and 707.5.

Section 1703 Exemption for Coal Extraction Incident to Government-Financed Highway or Other Construction

Illinois proposes adding a new section 1703 to allow the extraction of coal as an incidental part of a government-financed construction project, which incorporates language identical to the Federal regulations at 30 CFR part 707.