Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97:

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC on June 28, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 15 August 2019

Soldotna, AK, Soldotna, VOR–A, Amdt 8
Hot Springs, AR, Memorial Field, ILS OR LOC RWY 5, Amdt 16
Hot Springs, AR, Memorial Field, RNAV (GPS) RWY 5, Amdt 2
Hot Springs, AR, Memorial Field, Takeoff Minimums and Obstacle DP, Amdt 7
Hot Springs, AR, Memorial Field, VOR RWY 5, Amdt 5
Madera, CA, Madera Muni, RNAV (GPS) RWY 12, Amdt 2
Madera, CA, Madera Muni, RNAV (GPS) RWY 30, Amdt 2
Madera, CA, Madera Muni, Takeoff Minimums and Obstacle DP, Amdt 5
Madera, CA, Madera Muni, VOR RWY 30, Amdt 10, CANCELLED
South Lake Tahoe, CA, Lake Tahoe, LDA RWY 18, Amdt 8
South Lake Tahoe, CA, Lake Tahoe, RNAV (GPS) RWY 18, Amdt 1
Visalia, CA, Visalia Muni, ILS OR LOC RWY 30, Amdt 8
Visalia, CA, Visalia Muni, RNAV (GPS) RWY 12, Amdt 2
Visalia, CA, Visalia Muni, RNAV (GPS) RWY 30, Amdt 2
Visalia, CA, Visalia Muni, Takeoff Minimums and Obstacle DP, Amdt 4
Visalia, CA, Visalia Muni, VOR RWY 12, Amdt 7
Brooksville, FL, Brooksville-Tampa Bay Rgnl, ILS OR LOC RWY 9, Amdt 3
Mount Carmel, IL, Mount Carmel Muni, RNAV (GPS) RWY 4, Orig–B
Mount Carmel, IL, Mount Carmel Muni, RNAV (GPS) RWY 22, Orig–A
Johnson, KS, Stanton County Muni, RNAV (GPS) RWY 17, Amdt 2
Johnson, KS, Stanton County Muni, RNAV (GPS) RWY 35, Amdt 2
Austin, MN, Austin Muni, RNAV (GPS) RWY 17, Amdt 2
Austin, MN, Austin Muni, RNAV (GPS) RWY 35, Amdt 2
Bemidji, MN, Bemidji Rgnl, ILS OR LOC RWY 31, Amdt 6A

[FR Doc. 2019–15126 Filed 7–17–19; 8:45 am]

BILLING CODE 4910–13–P

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: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration (DEA) is issuing this temporary scheduling order to schedule the synthetic cathinones, *N*-ethylhexedrone (2-(ethylamino)-1-phenylhexan-1-one); *alpha*-pyrrolidinohexanophenone (1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one; *alpha*-pyrrolidinohexiophenone; trivial name: α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (2-(ethylamino)-1-(4-methylphenyl)pentan-1-one; trivial name: 4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one; 4′-methyl-*alpha*-pyrrolidinohexanophenone; trivial name: MPHP); *alpha*-pyrrolidinoheptaphenone (1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one; trivial name: PV8); and 4′-chloro-*alpha*-pyrrolidinovalerophenone (1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one; 4′-chloro-*alpha*-pyrrolidinopentiophenone; trivial name: 4-chloro-α-PVP), and their optical, positional, and geometric isomers, salts, and salts of isomers in schedule I. This action is based on a finding by the Acting Administrator that the placement of these synthetic cathinones in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, possess, import, export, research, or conduct instructional activities or chemical analysis), or propose to handle, *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP.

DATES: This temporary scheduling order is effective July 18, 2019, until July 18, 2021. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, 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:

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 [1] 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; *alpha*-pyrrolidinohexanophenone (α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (MPHP); *alpha*-pyrrolidinoheptaphenone (PV8); and 4-chloro-*alpha*-pyrrolidinovalerophenone (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 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 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.

The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). *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. The DEA has found that the control of *N*-ethylhexedrone (2-(ethylamino)-1-phenylhexan-1-one); *alpha*-pyrrolidinohexanophenone (1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one; *alpha*-pyrrolidinohexiophenone; trivial name: α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (2-(ethylamino)-1-(4-methylphenyl)pentan-1-one; trivial name: 4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one; 4′-methyl-*alpha*-pyrrolidinohexanophenone; trivial name: MPHP); *alpha*-pyrrolidinoheptaphenone (1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one; trivial name: PV8); and 4′-chloro-*alpha*-pyrrolidinovalerophenone (1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one; 4′-chloro-*alpha*-pyrrolidinopentiophenone; trivial name: 4-chloro-α-PVP) in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent to temporarily schedule *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in the **Federal Register** on May 1, 2019 (84 FR 18423). That notice of intent identified the six substances using the common names; however, in the three-factor analysis, which DEA made available on *www.regulations.gov* contemporaneously with the publication of the notice of intent, these same substances were identified using the International Union of Pure and Applied Chemistry (IUPAC) nomenclature. This temporary scheduling order provides the common names, as well as the IUPAC names, for all six substances.

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

Available data and information for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP, summarized below, 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. The DEA's three-factor analysis and the Assistant Secretary's March 27, 2018 letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov.*

Synthetic Cathinones

Novel synthetic cathinones that mimic the biological effects of substances with stimulant-like effects continue to emerge in 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

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this document 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.

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 several 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 [3] 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. There have been encounters of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP 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,[4] the 2017 annual 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

[3] Not all exhibits had weights recorded in the NFLIS database.

[4] 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 and high school graduates into adulthood by conducting national surveys.

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 substances of abuse (*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.[5] 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.[6] 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. 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-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, DEA controlled another synthetic cathinone, *N*-ethylpentylone (August, 31, 2018; 83 FR 44474), as a schedule I substance.

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

[6] Not all exhibits had weights recorded in the NFLIS database.

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 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. DEA published a notice of intent in the **Federal Register** on May 1, 2019. 84 FR 18423.

Conclusion

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, and herein sets forth the grounds for his determination to temporarily schedule *N*-ethylhexedrone (2-(ethylamino)-1-phenylhexan-1-one); *alpha*-pyrrolidinohexanophenone (1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one; *alpha*-pyrrolidinohexiophenone; trivial name: α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (trivial name: 4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one; 4′-methyl-*alpha*-pyrrolidinohexanophenone; trivial name: MPHP); *alpha*-pyrrolidinoheptaphenone (1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one; trivial name: PV8); and 4′-chloro-*alpha*-pyrrolidinovalerophenone (1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one; 4′-chloro-*alpha*-pyrrolidinopentiophenone; 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 is necessary to avoid an imminent hazard to the public safety.

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, this temporary order scheduling these substances is effective on the date of publication in the **Federal Register**, and is 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).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent 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 permanent 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 permanent 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).

Requirements for Handling

Upon the effective date of this 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, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of July 18, 2019. Any person who currently handles *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP, and is not registered with the DEA, must submit an application for registration and may not continue to handle *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP as of July 18, 2019, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after July 18, 2019 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must surrender all currently held quantities of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP.

3. *Security. N*-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are subject to schedule I security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93, as of July 18, 2019.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from July 18, 2019, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, 1317 and § 1307.11. Current DEA registrants authorized to handle *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of July 18, 2019.

8. *Order Forms.* All DEA registrants who distribute *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 18, 2019.

9. *Importation and Exportation.* All importation and exportation of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of July 18, 2019.

10. *Quota.* Only DEA registered manufacturers may manufacture *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of July 18, 2019.

11. *Liability.* Any activity involving *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, or 4-chloro-α-PVP not authorized by, or in violation of the CSA, occurring as of July 18, 2019, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

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 scheduling order. 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 action 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.

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.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, ''any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.'' 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances in schedule I because they pose an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

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 amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 811, 812, 871(b), 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 (Other name: 2-(ethylamino)-1-phenylhexan-1-one) 7246
(43) *alpha*-Pyrrolidinohexanophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: α-PHP; *alpha*-pyrrolidinohexiophenone; 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one) 7544
(44) 4-Methyl-*alpha*-ethylaminopentiophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4–MEAP; 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one) 7245
(45) 4′-Methyl-*alpha*-pyrrolidinohexiophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MPHP; 4′-methyl-*alpha*-pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one) 7446
(46) *alpha*-Pyrrolidinoheptaphenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one) 7548
(47) 4′-Chloro-*alpha*-pyrrolidinovalerophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4-chloro-α-PVP; 4′-chloro-*alpha*-pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one) 7443

Dated: July 10, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–15184 Filed 7–17–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0577]

RIN 1625–AA00

Safety Zone; Traverse City Ironman Triathlon, Traverse City, Michigan

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the Captain of the Port, Sault Sainte Marie zone. This rule will provide a temporary safety zone to protect 2,400 participating swimmers in the Traverse City Ironman Triathlon. Entry of vessels into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Sault Sainte Marie.

DATES: This rule is effective from 6:15 a.m. through 9:45 a.m. on August 25, 2019.

ADDRESSES: To view documents mentioned in this preamble as being