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Board:
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Jim Creel, Jr.

**South Carolina Board of Health and Environmental Control
Agenda
September 27, 2018**

***Call to Order – 8:30 a.m., Board Room (#3420)
South Carolina Department of Health and Environmental Control,
2600 Bull Street, Columbia, S.C.***

1. Placement of N-Ethylpentylone in Schedule I for Controlled Substances
2. Executive Session for discussion of a personnel matter

Live Stream will not be available for this meeting since the Board will be in Executive Session for the majority of the time, and no business will be held after the Executive Session.

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Summary Sheet
September 27, 2018

Action

Information

I. SUBJECT: Placement of N-Ethylpentylone in Schedule I for Controlled Substances

II. FACTS: Controlled substances are governed by the S.C. Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Schedule I substances are listed in S.C. Code Ann. Section 44-53-190. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by DHEC. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated.

Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The Acting Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic cathinone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one (N-ethylpentylone, ephylone) and its 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 N-ethylpentylone in schedule I of the Controlled Substances Act (CSA) 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, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle N-ethylpentylone. The federal final order became effective August 31, 2018 <https://www.gpo.gov/fdsys/pkg/FR-2018-08-31/pdf/2018-18988.pdf>

III. ANALYSIS:

Around 2014, the synthetic cathinone, N-ethylpentylone, emerged in the United States' illicit drug market after the scheduling of other popular synthetic cathinones (e.g., ethylone, 4-methyl-N-ethylcathinone (4-MEC), mephedrone, methylone, pentylone, and 3,4-methylenedioxypropylone (MDPV)). The identification of N-ethylpentylone in forensic evidence and overdose deaths indicates that this substance is being misused and abused. N-Ethylpentylone, like other synthetic cathinones, is a designer drug of the phenethylamine class and it is pharmacologically similar to schedule I synthetic cathinones (e.g., cathinone, methcathinone, mephedrone, methylone, pentylone, and MDPV) and well-known schedule I and II sympathomimetic agents (e.g., methamphetamine, 3,4-methylenedioxymethamphetamine (MDMA), and cocaine). N-ethylpentylone, similar to these substances, causes stimulant related psychological and somatic effects. Consequently, there have been documented reports of emergency room admissions and numerous deaths associated with the abuse of N-ethylpentylone. No approved medical use has been identified for this substance, nor has it been approved by the FDA for human consumption. N-ethylpentylone is most likely ingested by swallowing capsules or tablets or snorted by nasal insufflation of the powder tablets. Products containing N-ethylpentylone, similar to schedule I synthetic cathinones, are likely to be falsely marketed as "research chemicals," "jewelry cleaner," "stain remover," "plant food or fertilizer," "insect repellants" or "bath salts," sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations, and purchased on the internet.

The identification of N-ethylpentylone in toxicological samples associated with fatal and non-fatal overdoses have been reported in medical and scientific literature, forensic laboratory reports, and public health documents. Like schedule I synthetic cathinones, N-ethylpentylone has caused acute health problems leading to emergency department (ED) admissions, violent behaviors causing harm to self or others, and/or death. Adverse health effects associated with the abuse of N-ethylpentylone include a number of stimulant-like adverse health effects such as diaphoresis, insomnia, mydriasis, hyperthermia, vomiting, agitation, disorientation, paranoia, abdominal pain, cardiac arrest, respiratory failure, and coma. In addition, N-ethylpentylone has been involved in deaths of many individuals. The DEA is aware of approximately 151 overdose deaths involving N-ethylpentylone abuse reported in the United States between 2014 and 2018. Thus, the abuse of N-ethylpentylone, like that of the abuse of schedule I synthetic cathinones and stimulant drugs, poses significant adverse health risks. Furthermore, because abusers of synthetic cathinones obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent. These unknown factors pose an additional risk for significant adverse health effects to the end user.

Based on information received by the DEA, the misuse and abuse of N-ethylpentylone has led to, at least, the same qualitative public health risks as schedule I synthetic cathinones, MDMA, and methamphetamine. The public health risks attendant to the abuse of synthetic cathinones, including N-ethylpentylone, are well established and have resulted in large numbers of ED visits and fatal overdoses.

This temporary order places N-ethylpentylone in schedule I of the CSA for two years. DEA may extend the temporary scheduling for an additional year (a total of three years) if proceedings to permanently schedule the substances are pending.

When determining whether a substance should be placed into Schedule I of the S.C. Controlled Substances Act, Section 44-53-180 of the S.C. Code of Laws requires the Department place a substance in Schedule I if it meets the following criteria:

- (a) A high potential for abuse;
- (b) No accepted medical use in treatment in the United States; and
- (c) A lack of accepted safety for use in treatment under medical supervision.

S.C. Code Ann. § 44-53-180.

As indicated, the Acting Administrator considered available data and information, and herein sets forth the grounds for his determination that it is necessary to temporarily schedule N-ethylpentylone in schedule I of the CSA to avoid an imminent hazard to the public safety.

IV. RECOMMENDATION:

As DEA has determined it is necessary, based on their required procedures, to temporarily schedule N-ethylpentylone into Schedule I of the CSA, and finds that placement of this substance into schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety; therefore, the Department recommends the Board adopt the scheduling of N-ethylpentylone into Schedule I for Controlled Substances permanently as set forth below and amend SC Code Section 44-53-190(F)(4) to include :

N-Ethylpentylone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one)

Submitted by:



for Lisa Thomson

Lisa Thomson
Chief, Bureau of Drug Control



Shelly Kelly
Deputy Director of Health Regulations

Attachments: Federal Register Vol. 83, No. 170, Friday, August 31, 2018

readily visible part of the outside of the floating cabin.

* * * * *

(c) A floating cabin moored at a location approved pursuant to the regulations in this subpart shall not be relocated and moored at a different location without prior approval by TVA, except for movement to a new location within the designated harbor limits of the same commercial dock or marina.

§ 1304.103 [Removed and Reserved]

■ 7. Remove and reserve § 1304.103.

■ 8. Amend § 1304.204 by revising paragraphs (a), (b), and (n) to read as follows:

§ 1304.204 Docks, piers, and boathouses.

* * * * *

(a) Docks, piers, boathouses, and all other residential water-use facilities shall not exceed a total footprint area of greater than 1,000 square feet, unless the proposed water-use facility will be located in an area of preexisting development. For the purpose of this regulation, “preexisting development” means either: The water-use facility will be located in a subdivision recorded before November 1, 1999, and TVA permitted at least one water-use facility in the subdivision prior to November 1, 1999; or if there is no subdivision, where the water-use facility will be located within a quarter-mile radius of another water-use facility that TVA permitted prior to November 1, 1999. TVA may allow even larger facilities where an applicant requests and justifies a waiver or variance, set forth in §§ 1304.212 and 1304.408 respectively, but such waivers or variances shall be made in TVA’s discretion and on a case-by-case basis.

(b) Docks, boatlips, piers, and fixed or floating boathouses are allowable. These and other water-use facilities associated with a lot must be sited within a 1,000- or 1,800-square-foot rectangular or square area as required by § 1304.204(a) at the lakeward end of the access walkway that extends from the shore to the structure. Access walkways to the water-use structure are not included in calculating the 1,000- or 1,800-square foot area.

* * * * *

(n) Except for floating cabins approved in accordance with subpart B of this part, toilets and sinks are not permitted on water-use facilities.

* * * * *

§ 1304.406 [Amended]

■ 9. Amend § 1304.406 in the first sentence by removing the words “nonnavigable houseboat” and adding

in their place the words “floating cabin”.

- 10. Amend § 1304.412 by:
 - a. Adding in alphabetical order definitions for “Existing floating cabin” and “New floating cabin”;
 - b. Removing the definition of “Nonnavigable houseboat”; and
 - c. Adding in alphabetical order definitions for “Rebuilding” and “Tennessee River System”.

The additions read as follows:

§ 1304.412 Definitions.

* * * * *

Existing floating cabin means a floating cabin that was located or moored on the Tennessee River System on or before December 16, 2016.

* * * * *

New floating cabin means a floating cabin that was not located or moored on the Tennessee River System on or before December 16, 2016.

* * * * *

Rebuilding means replacement of all or a significant portion of an approved obstruction to the same configuration, total footprint, and dimensions (length, width, and height) as the approved plans, standards, and conditions of the Section 26a permit.

* * * * *

Tennessee River System means TVA reservoirs, the Tennessee River or any of the Tennessee River’s tributaries.

* * * * *

David L. Bowling,
Vice President, Land & River Management.
[FR Doc. 2018–18887 Filed 8–30–18; 8:45 am]
BILLING CODE 8120–08–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–482]

Schedules of Controlled Substances: Temporary Placement of *N*-Ethylpentylone 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 is issuing this temporary scheduling order to schedule the synthetic cathinone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one (*N*-ethylpentylone, ephylone) and its 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 *N*-ethylpentylone in schedule I of the Controlled Substances Act (CSA) 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, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle *N*-ethylpentylone.

DATES: This temporary scheduling order is effective August 31, 2018, until August 31, 2020. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Thomas D. Sonnen, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–2896.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the 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 scheduling¹ 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). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

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.

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*-ethylpentylone in schedule I on a temporary basis to the Acting Assistant Secretary for Health of HHS by letter dated November 22, 2017. The Acting Assistant Secretary responded to this notice of intent by letter dated December 13, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no active investigational new drug applications or approved new drug applications for *N*-ethylpentylone. The Acting Assistant Secretary also stated that HHS has no objection to the temporary placement of *N*-ethylpentylone 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*-Ethylpentylone is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for this substance under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of *N*-ethylpentylone in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule *N*-ethylpentylone was published in the **Federal Register** on June 13, 2018. 83 FR 27520.

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).

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.

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*-ethylpentylone, summarized below, indicate that this synthetic cathinone has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis and the Assistant Secretary's December 13, 2017 letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at www.regulations.gov under FDMS Docket ID: DEA-2018-0011 (Docket Number DEA-482).

N-Ethylpentylone

Around 2014, the synthetic cathinone, *N*-ethylpentylone, emerged in the United States' illicit drug market after the scheduling of other popular synthetic cathinones (e.g., ethylone, 4-methyl-*N*-ethylcathinone (4-MEC), mephedrone, methylone, pentylone, and 3,4-methylenedioxypyrovalerone (MDPV)). The identification of *N*-ethylpentylone in forensic evidence and overdose deaths indicates that this substance is being misused and abused. 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, the System to Retrieve Information from Drug Evidence (STRIDE), a federal database for the drug samples analyzed by DEA forensic laboratories, and STARLiMS (a web-based, commercial laboratory information management system that replaced STRIDE in 2014). Forensic laboratories have analyzed drug exhibits received from Federal, State, or local, law enforcement agencies that were found to contain *N*-ethylpentylone.³ NFLIS registered over 6,000 reports from state and local forensic laboratories identifying this substance in drug-related exhibits for a period from January 2013 to December 2017 from 41 states. There were no occurrences of *N*-

³ NFLIS and STRIDE/STARLiMS databases were queried on February 8, 2018.

ethylpentylone reported in NFLIS for 2013. *N*-Ethylpentylone was first identified in NFLIS in May 2014. STRIDE/STARLiMS registered over 300 reports from DEA forensic laboratories from January 2013 to December 2017. There were no occurrences of *N*-ethylpentylone reported in STRIDE/STARLiMS for 2013. *N*-Ethylpentylone was first reported to STRIDE/STARLiMS in December 2015. Additionally, U.S. Customs and Border Protection (CBP) encounters of *N*-ethylpentylone have occurred.

N-Ethylpentylone, like other synthetic cathinones, is a designer drug of the phenethylamine class and it is pharmacologically similar to schedule I synthetic cathinones (e.g., cathinone, methcathinone, mephedrone, methylone, pentylone, and MDPV) and well-known schedule I and II sympathomimetic agents (e.g., methamphetamine, 3,4-methylenedioxymethamphetamine (MDMA), and cocaine). *N*-ethylpentylone, similar to these substances, causes stimulant related psychological and somatic effects. Consequently, there have been documented reports of emergency room admissions and numerous deaths associated with the abuse of *N*-ethylpentylone. No approved medical use has been identified for this substance, nor has it been approved by the FDA for human consumption.

Factor 4. History and Current Pattern of Abuse

N-Ethylpentylone is a synthetic cathinone of the phenethylamine class and it is structurally and pharmacologically similar to cathinone, methcathinone, mephedrone, methylone, pentylone, MDPV, methamphetamine, MDMA, and other schedule I and II substances. Thus, it is highly likely that *N*-ethylpentylone is abused in the same manner and by the same users as these substances. That is, *N*-ethylpentylone, like these substances, is most likely ingested by swallowing capsules or tablets or snorted by nasal insufflation of the powder tablets. Products containing *N*-ethylpentylone, similar to schedule I synthetic cathinones, are likely to be falsely marketed as "research chemicals," "jewelry cleaner," "stain remover," "plant food or fertilizer," "insect repellants" or "bath salts," sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations, and purchased on the internet. Like those seen with commercial products that contain synthetic cathinones, the packages of products that contain *N*-ethylpentylone also

probably contain the warning “not for human consumption,” most likely in an effort to circumvent statutory restrictions for these substances. Demographic data collected from published reports and mortality records suggest that the main users of *N*-ethylpentylone, similar to schedule I synthetic cathinones and MDMA, are young adults.

Available evidence suggests that the history and pattern of abuse of *N*-ethylpentylone parallels that of MDMA, methamphetamine, or cocaine and that *N*-ethylpentylone has been marketed as a replacement for these substances. *N*-Ethylpentylone has been identified in law enforcement seizures that were initially suspected to be MDMA. In addition, there are reports that abusers of *N*-ethylpentylone thought they were using

MDMA or another illicit substance but toxicological analysis revealed that the psychoactive substance was *N*-ethylpentylone. Toxicology reports also revealed that *N*-ethylpentylone is being ingested with other substances including other synthetic cathinones, common cutting agents, or other recreational substances. Consequently, products containing synthetic cathinones, including *N*-ethylpentylone, are distributed to users, often with unpredictable outcomes. Thus, the recreational abuse of synthetic cathinones, including *N*-ethylpentylone, is a significant concern.

Factor 5. Scope, Duration and Significance of Abuse

N-Ethylpentylone is a popular recreational drug that emerged on the United States' illicit drug market after the scheduling of other popular synthetic cathinones (e.g., ethylone, mephedrone, methylone, pentylone, and MDPV) (see DEA 3-Factor Analysis for a full discussion). Forensic laboratories have confirmed the presence of *N*-ethylpentylone in drug exhibits received from state, local, and federal law enforcement agencies. Law enforcement data show that *N*-ethylpentylone first appeared in the illicit drug market in 2014 with one encounter and began increasing thereafter.⁴ In 2015, NFLIS registered five reports from three states regarding *N*-ethylpentylone. However, in 2016, there were 2,074 reports from 39 states and, in 2017, there were 3,955 reports from 39 states related to this substance registered in NFLIS. *N*-Ethylpentylone represented 60% of all synthetic cathinones encountered by local law enforcement agencies and

reported to NFLIS in 2017. From January 2013 to December 2017, NFLIS registered 6,035 reports from state and local forensic laboratories identifying this substance in drug-related exhibits from 41 states. STRIDE/STARLiMS registered over 338 reports from DEA forensic laboratories during January 2013 to December 2017. There were no occurrences of *N*-ethylpentylone reported in NFLIS or STRIDE/STARLiMS for 2013. Additionally, seizures of *N*-ethylpentylone have occurred by the U.S. Customs and Border Protection (CBP) beginning in 2016. Concerns over the continuing abuse of synthetic cathinones have led to the control of many synthetic cathinones.

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

The identification of *N*-ethylpentylone in toxicological samples associated with fatal and non-fatal overdoses have been reported in medical and scientific literature, forensic laboratory reports, and public health documents. Like schedule I synthetic cathinones, *N*-ethylpentylone has caused acute health problems leading to emergency department (ED) admissions, violent behaviors causing harm to self or others, and/or death. Adverse health effects associated with the abuse of *N*-ethylpentylone include a number of stimulant-like adverse health effects such as diaphoresis, insomnia, mydriasis, hyperthermia, vomiting, agitation, disorientation, paranoia, abdominal pain, cardiac arrest, respiratory failure, and coma. In addition, *N*-ethylpentylone has been involved in deaths of many individuals. The DEA is aware of approximately 151 overdose deaths involving *N*-ethylpentylone abuse reported in the United States between 2014 and 2018. Thus, the abuse of *N*-ethylpentylone, like that of the abuse of schedule I synthetic cathinones and stimulant drugs, poses significant adverse health risks. Furthermore, because abusers of synthetic cathinones obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent. These unknown factors pose an additional risk for significant adverse health effects to the end user.

Based on information received by the DEA, the misuse and abuse of *N*-ethylpentylone has led to, at least, the same qualitative public health risks as schedule I synthetic cathinones, MDMA, and methamphetamine. The public health risks attendant to the abuse of synthetic cathinones, including *N*-ethylpentylone, are well established

and have resulted in large numbers of ED visits and fatal overdoses.

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

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information, summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and/or abuse of *N*-ethylpentylone poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance 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*-ethylpentylone indicate that this synthetic cathinone has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated November 22, 2017, notified the Acting Assistant Secretary of the DEA's intention to temporarily place this substance in schedule I. A notice of intent was subsequently published in the **Federal Register** on June 13, 2018, 83 FR 27520.

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, herein set forth the grounds for his determination that it is necessary to temporarily schedule *N*-ethylpentylone in schedule I of the CSA, and finds that placement of *N*-ethylpentylone in schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

Because the Acting Administrator hereby finds that it is necessary to temporarily place *N*-ethylpentylone in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling this substance 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

⁴ NFLIS and STRIDE/STARLiMS databases were queried on February 8, 2018.

(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*-ethylpentylone 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*-ethylpentylone 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 August 31, 2018. Any person who currently handles *N*-ethylpentylone, and is not registered with the DEA, must submit an application for registration and may not continue to handle *N*-ethylpentylone as of August 31, 2018, 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 this substance in a manner not authorized by the CSA on or after August 31, 2018 is unlawful and those in possession of any quantity of this substance 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*-ethylpentylone must surrender all currently held quantities of *N*-ethylpentylone.

3. *Security.* *N*-ethylpentylone is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of August 31, 2018.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-ethylpentylone must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from August 31, 2018, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of *N*-ethylpentylone on the effective date of this order must take an inventory of all stocks of this substance 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*-ethylpentylone) 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*-ethylpentylone 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*-ethylpentylone 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*-ethylpentylone must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of August 31, 2018.

8. *Order Forms.* All DEA registrants who distribute *N*-ethylpentylone must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of August 31, 2018.

9. *Importation and Exportation.* All importation and exportation of *N*-ethylpentylone must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of August 31, 2018.

10. *Quota.* Only DEA registered manufacturers may manufacture *N*-

ethylpentylone in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of August 31, 2018.

11. *Liability.* Any activity involving *N*-ethylpentylone not authorized by, or in violation of the CSA, occurring as of August 31, 2018, 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 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, do not apply to this notice of intent. 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.

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 this substance 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 this substance in schedule I because it poses 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 paragraph (h)(36) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *
(36) N-Ethylpentylone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one).....(7543)

Dated: August 24, 2018.
Uttam Dhillon,
Acting Administrator.
[FR Doc. 2018-18988 Filed 8-30-18; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0841]

Drawbridge Operation Regulation; Trent River, New Bern, NC

AGENCY: Coast Guard, DHS.
ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the U.S. 70 (Alfred A. Cunningham) Bridge across the Trent River, mile 0.0, at New Bern, NC. The deviation is necessary to accommodate the 30th Annual Bike MS: Historic New Bern Ride. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 8:00 a.m. on September 8, 2018 to 9:30 a.m. on September 9, 2018.

ADDRESSES: The docket for this deviation, [USCG-2018-0841], is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Ms. Kashanda Booker, Bridge Administration Branch Fifth District, Coast Guard, telephone (757) 398-6227, email kashanda.l.booker@uscg.mil.

SUPPLEMENTARY INFORMATION: The event director, Game On Inc., with approval from the North Carolina Department of Transportation, who owns and operates the U.S. 70 (Alfred A. Cunningham) Bridge across the Trent River, mile 0.0, at New Bern, NC, has requested a temporary deviation from the current operating regulations. This temporary deviation is necessary to accommodate participation by cyclists during the 30th Annual Bike MS: Historic New Bern Ride. The bridge is a double bascule bridge and has a vertical clearance in the closed position of 14 feet above mean high water.

The current operating schedule is set out in 33 CFR 117.843(a). Under this temporary deviation, the bridge will be maintained in the closed-to-navigation position from 8:00 a.m. to 9:30 a.m. on September 8th and September 9th 2018. The Trent River is used by a variety of vessels including small commercial vessels and recreational vessels. The Coast Guard has carefully coordinated the restrictions with waterway users in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed position may do so at anytime. There is no immediate alternate route for vessels unable to pass through the bridge in the closed position but the bridge will be able to open for emergencies. The Coast Guard will also inform users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impacts caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 27, 2018.
Hal R. Pitts,
Bridge Program Manager, Fifth Coast Guard District.
[FR Doc. 2018-18929 Filed 8-30-18; 8:45 am]
BILLING CODE 9110-04-P

