Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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: Proposed amendment; notice of intent.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is publishing this notice of intent to issue an order temporarily scheduling *N*-1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (*N*-ethylpentylone, ephylone) in schedule I. This action is based on a finding by the Acting Administrator that the placement of *N*-ethylpentylone in schedule I is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose regulatory requirements under the Controlled Substances Act (CSA) on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of *N*-ethylpentylone, as well as administrative, civil, and criminal remedies with respect to persons who fail to comply with such requirements or otherwise violate the CSA with respect to *N*-ethylpentylone.

DATES: June 13, 2018.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: This notice of intent is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary order (in the form of a temporary amendment) placing *N*-ethylpentylone in schedule I of the Controlled Substances Act (CSA).[1] The temporary scheduling order will be published in the **Federal Register** on or after July 13, 2018.

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 scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place *N*-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 the HHS has no objection to the temporary placement of *N*-ethylpentylone in schedule I of the CSA. *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.

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).

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-methylenedioxymethamphetamine (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

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

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

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 State, local, or Federal 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. *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. *N*-Ethylpentylone was first reported to STRIDE/STARLiMS in December 2015. Additionally, encounters of *N*-ethylpentylone have occurred by the U.S. Customs and Border Protection (CBP).

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.

Available data and information for *N*-ethylpentylone, summarized below, indicate that this substance 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 is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–482.

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. 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 the 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

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

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

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 resulting from the lack of control of this substance 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 substance 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 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.

Conclusion

This notice of intent provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h), of DEA's intent to issue a temporary scheduling order. In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Acting Administrator considered available data and information, herein set forth the grounds for his determination 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 on a temporary basis is necessary in order to avoid an imminent hazard to the public safety.

The temporary placement of *N*-ethylpentylone in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before July 13, 2018. 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, the temporary order scheduling this substance will be effective on the date that order is published in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Acting Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this notice. Upon publication of the temporary order, *N*-ethylpentylone will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

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

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order 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 Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

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

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

of the APA or any other law to publish a general notice of proposed rulemaking.

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

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

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add 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, *N*-1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone)	(7543)

* * * * *

Dated: June 6, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018–12669 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2018–6; Order No. 4635]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is noticing a recent filing requesting that the Commission initiate an informal rulemaking proceeding to consider changes to an analytical method for use in periodic reporting (Proposal Three). This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 29, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On June 1, 2018, the Postal Service filed a petition pursuant to 39 CFR 3050.11, requesting that the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports.[1] The Petition identifies the proposed analytical changes filed in this docket as Proposal Three.

II. Proposal Three

Background. The Commission adopted the use of incremental costs as the basis for class-level and product-level attributable costs in September of 2016.[2] In FY 2017, the methodology was fully applied for the first time.[3] Proposal Three seeks to revise two incremental costing procedures in accordance with this methodological change.

The first proposed revision concerns the Postal Service's method for calculating incremental costs for competitive products collectively. Under current analytical principles, the Postal Service calculates these costs using a so-called ''hybrid'' approach. The Postal Service first calculates the incremental costs of competitive domestic products (including group specific costs for these products) and then adds it to the volume variable and product specific costs of competitive international products. This ''hybrid'' approach blends an estimate of competitive domestic incremental costs with a proxy estimate of competitive international incremental costs.

The second proposed revision relates to estimating inframarginal costs for products with insufficient data at the cost pool level. The Postal Service states that this revision primarily concerns negotiated service agreements (NSAs), because NSAs are classified as independent products, which can have low volumes. Petition, Proposal Three at 1. Furthermore, the Postal Service contends that NSAs create practical issues in calculating incremental costs, in part because the Postal Service's data systems do not distinguish between NSA and non-NSA mailpieces. *Id.* at 13. This prevents the Postal Service from creating the standard cost drivers for NSAs (*e.g.* volume, weight, cubic volume), which are necessary for calculating incremental costs. *Id.*

Proposal. As discussed above, the Postal Service proposes two procedures to revise its calculation of incremental costs.

Under procedure one, the Postal Service seeks to replace the ''hybrid'' approach to calculating aggregate incremental costs, which relies on a proxy for international costs, with a direct estimation of those costs. *Id.* at 4. Due to improvements suggested in the FY 2016 Annual Compliance Determination, in conjunction with corresponding analytical improvements, the Postal Service states that it can now directly estimate the actual incremental costs of international mail. *Id.* at 6.

Under procedure two, the Postal Service proposes thresholds for calculating inframarginal costs and an alternative methodology for approximating the appropriate cost driver ratios for NSAs. *Id.* at 8. Specifically, the Postal Service suggests that it should not have to calculate the incremental costs if an NSA has less than 0.3 percent of the product type's (*e.g.* Priority Mail, Parcel Select) volume variable cost or less than $8 million in volume variable cost. *Id.* at 11. The Postal Service also seeks to use the ratio of NSA volume variable costs to product type volume variable costs as a proxy cost driver to calculate the incremental cost of NSA products. *Id.* at 12–20.

Rationale and impact. The Postal Service contends that procedure one will allow it ''to rely upon the best available information'' because the

[1] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Three), June 1, 2018 (Petition).

[2] Docket No. ACR2017, Annual Compliance Report, December 29, 2017, at 4–6.

[3] Docket No. ACR2017, Annual Compliance Determination, March 29, 2018, at 8.