BIS does not seek to expand jurisdiction over technologies that are not currently subject to the EAR, such as ''fundamental research'' described in § 734.8 of the EAR.

BIS will review public comments submitted in response to this ANPRM to help inform BIS and its interagency partners' efforts to identify, reevaluate and subsequently control foundational technologies. This interagency process is expected to result in rules and comment periods with new control levels for items currently controlled for AT reasons on the CCL or new ECCNs on the CCL for technologies currently classified as EAR99.

OMB has determined that this action is significant under Executive Order 12866.

Submission of Comments

Comments should be submitted to BIS as described in the **ADDRESSES** section of this ANPRM by October 26, 2020.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–18910 Filed 8–26–20; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–482]

Schedules of Controlled Substances: Placement of N-Ethylpentylone in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 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 whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances 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: Comments must be submitted electronically or postmarked on or before September 28, 2020.

Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for a hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before September 28, 2020.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–482'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/ALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–8209.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this

proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for a hearing and waivers of participation must be sent to DEA using the address information provided above.

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary for Health of the HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent [2] the imposition of regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle *N*-ethylpentylone.

Background

On August 31, 2018, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one (*N*-ethylpentylone, ephylone) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 83 FR 44474. That temporary scheduling order was effective on the date of publication, and was based on findings by the former Acting Administrator of DEA that the temporary scheduling of this synthetic cathinone was necessary to avoid an imminent hazard to the public safety pursuant to section 811(h)(1). Section 811(h)(2) provides that the temporary control of this substance expire two years from the effective date of the scheduling order, which was August 31, 2020. However, this same provision also provides that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) for the permanent scheduling of the substance, the temporary scheduling of that substance can be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of HHS,[3] or on the petition of any interested party. An extension of the existing temporary order is being ordered by the Acting Administrator of DEA (Acting Administrator) in a separate action, and is being simultaneously published elsewhere in this issue of the **Federal Register**.

The Acting Administrator, on his own motion, is initiating proceedings under 21 U.S.C. 811(a)(1) to permanently schedule *N*-ethylpentylone. DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for this synthetic cathinone. On September 25, 2019, the former Acting Administrator submitted a request to the Assistant Secretary to provide DEA with a scientific and medical evaluation of available information and a scheduling recommendation for *N*-ethylpentylone, in accordance with 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, on July 15, 2020, the Assistant Secretary submitted to the Acting Administrator HHS's scientific and medical evaluations for this substance. Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of *N*-ethylpentylone in accordance with 21 U.S.C. 811(c).

Proposed Determination To Schedule N-Ethylpentylone

As discussed in the background section, the Acting Administrator is initiating proceedings, pursuant to 21 U.S.C. 811(a)(1), to add *N*-ethylpentylone permanently to schedule I. DEA has reviewed the scientific and medical evaluation and scheduling recommendation, received from HHS, and all other relevant data and conducted its own eight-factor analysis of the abuse potential of *N*-ethylpentylone pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both the DEA and the HHS 8-Factor analyses and the Assistant Secretary's July 15, 2020, letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this rulemaking action at *http://www.regulations.gov,* under Docket Number ''DEA–482.''

1. *The Drug's Actual or Relative Potential for Abuse:* Both the DEA and the HHS 8-factor analyses found that *N*-ethylpentylone has abuse potential associated with its abilities to produce psychoactive effects that are similar to those produced by schedule I synthetic cathinones such as pentylone, mephedrone, methylone, and 3,4-methylenedioxypyrovalerone (MDPV) and schedule II stimulants such as methamphetamine and cocaine that have a high potential for abuse. In particular, the responses in humans to N-ethylpentylone are stimulant-like and include paranoia, agitation, palpitations, tachycardia, hypertension, and hyperthermia.

N-Ethylpentylone has no approved medical uses in the United States [4] and has been encountered on the illicit market with adverse outcomes on the public health and safety. Because this substance is not an approved drug product, a practitioner may not legally

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within 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 HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[2] *N*-ethylpentylone is currently subject to schedule I controls on a temporary basis, pursuant to a temporary scheduling order issued by DEA under authority of 21 U.S.C. 811(h). 83 FR 44474, Aug. 31, 2018.

[3] Because the Secretary of HHS has delegated to the Assistant Secretary for Health the authority to make domestic drug scheduling recommendations, for purposes of this proposed rulemaking, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

[4] There are no legitimate drug channels for *N*-ethylpentylone as a marketed drug, but DEA notes that this synthetic cathinone has been used in scientific research.

prescribe it, and it cannot be dispensed to an individual. The use of this substance without medical advice leads to the conclusion that this synthetic cathinone is being abused for its psychoactive properties.

Reports from public health and law enforcement state that this substance is being abused and taken in amounts sufficient to create a hazard to an individual's health. This hazard is evidenced by emergency department admissions and deaths, representing a significant safety issue for those in the community. Further, from January 2014 through December 2019 (query date: July 10, 2020), the System to Retrieve Information from Drug Evidence (STRIDE), STARLiMS, and the National Forensic Laboratory Information System (NFLIS) databases registered a total of 20,502 reports by participating DEA, State, local, and other forensic laboratories, as applicable, pertaining to *N*-ethylpentylone.[5] NFLIS registered more than 19,000 reports from state and local forensic laboratories identifying this substance in drug-related exhibits for a period from January 2014 to December 2019 from 46 states. There were no occurrences of *N*-ethylpentylone reported in NFLIS for 2013. *N*-Ethylpentylone was first identified in NFLIS in May 2014. STRIDE/STARLiMS registered more than 700 reports from DEA forensic laboratories from January 2015 to December 2019. There were no occurrences of *N*-ethylpentylone reported in STRIDE/STARLiMS for 2013 and 2014. *N*-Ethylpentylone was first reported to STRIDE/STARLiMS in December 2015. Consequently, the data indicate that *N*-ethylpentylone is being abused, and it presents safety hazards to the health of individuals who consume it due to its stimulant properties, making it a hazard to the safety of the community.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* As described by HHS, studies show that *N*-ethylpentylone produces pharmacological effects that are similar to those produced by schedule I and II substances such as methamphetamine (II), cocaine (II), MDMA (I), mephedrone (I), MDPV (I), and methylone (I). Similar to these schedule I and II substances, *N*-ethylpentylone binds to monoamine transporters for dopamine, serotonin, or norepinephrine, and blocks the uptake of these neurotransmitters at their transporters, but does not promote the release of these monoamines. Additionally, behavioral studies in animals demonstrate that *N*-ethylpentylone produces locomotor behavior and discriminative stimulus effects that are similar to those of MDMA, methamphetamine, and cocaine. Overall, these data indicate that *N*-ethylpentylone produces pharmacological effects and stimulant-like behaviors that are similar to those of schedule I substances MDMA, mephedrone, MDPV, and methylone, as well as schedule II stimulants methamphetamine and cocaine.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance: N*-Ethylpentylone, like other synthetic cathinones, is a designer drug of the phenethylamine class and it is structurally similar to schedule I substances pentylone, mephedrone, methylone, MDMA, and MDPV, as well as schedule II substance methamphetamine. *N*-Ethylpentylone has an ethyl carbon chain ($-CH_2CH_3$) on the nitrogen (N) atom, a propyl group ($-CH_2CH_2CH_3$) on the α-carbon, and a methylenedioxy group ($-OCH_2O-$) on the phenyl ring.

Pharmacokinetic studies show that *N*-ethylpentylone is rapidly absorbed and enters the brain within 20 minutes after intraperitoneal administration, and at approximately 40 minutes reaches its maximum concentration. *N*-Ethylpentylone was found to undergo hydrogenation, deethylation, demethylation, and hydroxylation in human liver microsomes resulting in four different metabolites. These four metabolites of *N*-ethylpentylone have been identified in blood and oral fluid specimens in humans.

Neither DEA nor HHS is aware of any currently accepted medical use for *N*-ethylpentylone. According to HHS's July 2020 scientific and medical evaluation and scheduling recommendation, FDA has not approved a marketing application for a drug product containing N-ethylpentylone for any therapeutic indication, nor is HHS aware of any reports of clinical studies or claims of an accepted medical use for *N*-ethylpentylone in the United States.

A drug has a ''currently accepted medical use'' if DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, all of the following must be demonstrated: The drug's chemistry is known and reproducible; there are adequate safety studies; there are adequate and well-controlled studies proving efficacy; the drug is accepted by qualified experts; and the scientific evidence is widely available. 57 FR 10499 (1992). Based on this analysis, *N*-ethylpentylone has no currently accepted medical use in the United States. Furthermore, DEA has not found any references regarding clinical testing of *N*-ethylpentylone in the scientific and medical literature. Although the chemistry of synthetic cathinones, in general, is known and has been reproduced, as mentioned above there are no clinical studies involving *N*-ethylpentylone. Taken together with the HHS's conclusion, DEA finds that there is no legitimate medical use for *N*-ethylpentylone in the United States.

4. *History and Current Pattern of Abuse:* As described by DEA and HHS, *N*-ethylpentylone is a synthetic cathinone of the phenethylamine class and it is structurally and pharmacologically similar to schedule I and II substances such as pentylone (I), mephedrone (I), methylone (I), MDPV (I), methamphetamine (II), MDMA (I). Thus, it is 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

[5] STRIDE is a database of drug exhibits sent to DEA laboratories. Exhibits from the database are from DEA, other federal agencies, and some local law enforcement agencies. STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by DEA laboratories, and it replaced STRIDE in 2014. NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country. The NFLIS participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is over 97 percent. NFLIS includes drug chemistry results from completed analyses only. NFLIS and STRIDE/STARLiMS databases were queried on July 10, 2020.

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 *N*-ethylpentylone is a significant concern.

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's Eight 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.[6] In 2015, NFLIS registered 6 reports from 4 states regarding *N*-ethylpentylone. However, in 2016, there were 2,252 reports from 40 states and, in 2017, there were 6,242 reports from 44 states related to this substance registered in NFLIS. *N*-Ethylpentylone represented 61 percent of all synthetic cathinones encountered by local law enforcement agencies and reported to NFLIS in 2017. In 2018, there were 9,680 reports from 41 states related to this substance registered in NFLIS, and in 2019, there were 1,598 reports from 25 states. At its peak in 2018, *N*-ethylpentylone represented 79 percent of all synthetic cathinones encountered by local law enforcement agencies and reported to NFLIS. Overall, from January 2014 to December 2019, NFLIS registered 19,779 reports from state and local forensic laboratories identifying this substance in drug-related exhibits from 46 states. STRIDE/STARLiMS registered more than 700 reports from DEA forensic laboratories during January 2015 to December 2019. There were no occurrences of *N*-ethylpentylone reported to STRIDE/STARLiMS for 2014. Concerns over the continuing abuse of synthetic cathinones have led to the control of many synthetic cathinones.

6. *What, if Any, Risk There Is to the Public Health:* HHS reported that the public health risks of *N*-ethylpentylone result from its ability to induce stimulant-like responses, which may lead to adverse events that include cognitive impairment and even 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. DEA is aware of approximately 154 overdose deaths involving *N*-ethylpentylone abuse reported in the United States between 2014 and 2018. Some of these deaths occurred in Alabama, Maryland, and Florida. Furthermore, the identification of *N*-ethylpentylone in toxicological samples associated with fatal and non-fatal overdoses as reported in the medical and scientific literature, forensic laboratory reports, and public health documents confirms these adverse effects of *N*-ethylpentylone. Like schedule I synthetic cathinones, *N*-ethylpentylone has caused acute health problems leading to emergency department admissions, violent behaviors causing harm to self or others, and/or death. Thus, the abuse of *N*-ethylpentylone, like that of the abuse of schedule I synthetic cathinones and stimulant drugs, poses significant adverse health risks including death.

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 DEA, the abuse of *N*-ethylpentylone has led to, at least, the same qualitative public health risks as schedule I synthetic cathinones and MDMA, and schedule II 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 emergency department visits and fatal overdoses.

7. *Its Psychic or Physiological Dependence Liability:* According to HHS, the psychic or physiological dependence liability of *N*-ethylpentylone is demonstrated by its positive abuse-related studies in animals and reported stimulant effects in humans. The results from two behavioral studies (drug discrimination and locomotor studies) demonstrate that *N*-ethylpentylone produced behavioral effects that are similar to those of substances with stimulant effects such as the schedule I cathinones pentylone and MDPV. Furthermore, *N*-ethylpentylone has been reported to be abused for its stimulant properties. In addition, DEA notes that because *N*-ethylpentylone shares pharmacological properties with substances that have stimulant properties, it is probable that *N*-ethylpentylone has a dependence profile similar to these substances which are known to cause substance dependence.

In summary, data suggests that *N*-ethylpentylone produces behavioral effects in animals and humans that are similar to those of schedule I and II stimulants. Although there are no clinical studies evaluating dependence liabilities specific for *N*-ethylpentylone, the pharmacological profile of this substance strongly suggests that it possesses dependence liabilities that are qualitatively similar to schedule I or II substances such as pentylone (I), MDMA (I), methamphetamine (II), and cocaine (II).

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA: N*-Ethylpentylone is not an immediate precursor of any controlled substance under the CSA as defined by 21 U.S.C 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's scheduling recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of *N*-ethylpentylone. As such, DEA hereby proposes to permanently schedule *N*-ethylpentylone as a controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Acting

[6] NFLIS and STRIDE/STARLiMS databases were queried on July 10, 2020.

Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. *N*-Ethylpentylone has a high potential for abuse;

2. *N*-Ethylpentylone has no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of *N*-ethylpentylone under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one (*N*-ethylpentylone, ephylone) including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrants continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling N-Ethylpentylone

If this rule is finalized as proposed, *N*-ethylpentylone would continue [7] to be subject to the CSA's schedule I 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) *N*-ethylpentylone, or who desires to handle *N*-ethylpentylone, is required to be registered with 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.

2. *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. Non-practitioners handling N-ethylpentylone must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-ethylpentylone must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture *N*-ethylpentylone in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle *N*-ethylpentylone must have an initial inventory of all stocks of controlled substances (including *N*-ethylpentylone) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including *N*-ethylpentylone) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to *N*-ethylpentylone pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes *N*-ethylpentylone is required to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

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

9. *Liability.* Any activity involving *N*-ethylpentylone not authorized by, or in violation of the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order (E.O.) 13563.

This proposed rule does not meet the definition of an E.O. 13771 regulatory action, and the repeal and cost offset requirements of E.O. 13771 have not been triggered. OMB has previously determined that formal rulemaking actions concerning the scheduling of controlled substances, such as this rule, are not significant regulatory actions under Section 3(f) of E.O. 12866.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On August 31, 2018, DEA published an order to temporarily place *N*-ethylpentylone in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle this substance have already established and implemented the systems and processes required to handle *N*-ethylpentylone. There are

[7] *N*-Ethylpentylone is currently subject to schedule I controls on a temporary basis, pursuant to the temporary scheduling order issued by DEA under the authority of 21 U.S.C. 811(h). 83 FR 44474, August 31, 2018. An order extending the temporary scheduling of *N*-ethylpentylone for one year is published elsewhere in this issue of the **Federal Register**, on the same day as this notice of proposed rulemaking.

currently 20 unique registrations authorized to handle *N*-ethylpentylone specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. From review of entity names, DEA estimates these 20 registrations represent 16 entities. Some of these entities are likely to be small entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 16 entities are small entities. Therefore, DEA conservatively estimates as many as 16 small entities are affected by this proposed rule.

A review of the 20 registrations indicates that all entities that currently handle *N*-ethylpentylone also handle other schedule I controlled substances, and thus they have established and implemented (or maintain) the systems and processes required to handle *N*-ethylpentylone as a schedule I substance. Therefore, DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities, and, thus, will not have a significant economic impact on any of the 16 affected small entities. Therefore, DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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, 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 (d)(86) and remove and reserve paragraph (h)(36).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(86) *N*-Ethylpentylone (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one)	7543

* * * * *

Dated: August 24, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–19007 Filed 8–26–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS–1720–RCN]

RIN 0938–AT64

Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations Extension of Timeline for Publication of Final Rule

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Extension of timeline for publication of final rule.

SUMMARY: This notice announces an extension of the timeline for publication of a Medicare final rule in accordance with the Social Security Act, which allows us to extend the timeline for publication of the final rule.

DATES: As of August 26, 2020, the timeline for publication of the final rule to finalize the provisions of the October 17, 2019 proposed rule (84 FR 55766) is extended until August 31, 2021.

FOR FURTHER INFORMATION CONTACT: Lisa O. Wilson, (410) 786–8852.

SUPPLEMENTARY INFORMATION: In the October 17, 2019 **Federal Register** (84 FR 55766), we published a proposed rule that addressed undue regulatory impact and burden of the physician self-referral law. The proposed rule was issued in conjunction with the Centers for Medicare & Medicaid Services' (CMS) Patients over Paperwork initiative and the Department of Health and Human Services' (the Department or HHS) Regulatory Sprint to Coordinated Care. In the proposed rule, we proposed exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers; a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; a new exception for donations of cybersecurity technology and related services; and amendments to the existing exception for electronic health records (EHR) items and services. The proposed rule also provides critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations. This notice announces an extension of the timeline for publication of the final rule and the continuation of effectiveness of the proposed rule.

Section 1871(a)(3)(A) of the Social Security Act (the Act) requires us to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation. In accordance with section 1871(a)(3)(B) of the Act, the timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but may not be longer than 3 years except under exceptional circumstances. In addition, in accordance with section 1871(a)(3)(B) of the Act, the Secretary may extend the initial targeted publication date of the final regulation if the Secretary, no later than the regulation's previously established proposed publication date, publishes a notice with the new target date, and such notice includes a brief explanation of the justification for the variation.

We announced in the Spring 2020 Unified Agenda (June 30, 2020, *www.reginfo.gov*) that we would issue the final rule in August 2020. However, we are still working through the