DATES: The due date of comments requested in the document published on March 23, 2020 (85 FR 16278) is extended. Comments should be filed no later than July 22, 2020. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date. The NRC staff will continue to monitor the COVID–19 PHE to determine if an additional extension may be warranted.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0142. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Tim Reed, telephone: 301–415–1462, email: *Timothy.Reed@nrc.gov;* or Audrey Klett, telephone: 301–415–0489, email: *Audrey.Klett@nrc.gov.* Both are staff of the Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0142 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0142.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

B. Submitting Comments

Please include Docket ID NRC–2018–0142 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

On March 23, 2020, the NRC issued for public comment draft NUREG–1409, ''Backfitting Guidelines,'' Revision 1 (ADAMS Accession No. ML18109A498). This draft NUREG provides guidance on the implementation of the backfitting and issue finality provisions of the NRC's regulations and the NRC's forward fitting policy in accordance with Management Directive and Handbook 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests'' dated September 20, 2019 (ADAMS Accession No. ML18093B087). The public comment period was originally scheduled to close on May 22, 2020. In recognition of the impacts of the current COVID–19 PHE across the nation, the NRC has decided to extend the public comment period on this document until July 22, 2020, to allow more time for members of the public to develop and submit comments.

Dated: April 30, 2020.

For the Nuclear Regulatory Commission.

Jennifer L. Dixon-Herrity,

Chief, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–09654 Filed 5–14–20; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL TRADE COMMISSION

16 CFR Chapter I

Semiannual Regulatory Agenda; Withdrawal

AGENCY: Federal Trade Commission.

ACTION: Proposed rule; Withdrawal.

SUMMARY: The Federal Trade Commission (FTC or Commission) is withdrawing the proposed rule titled, ''Semiannual Regulatory Agenda,'' published on May 7, 2020. This agenda will be incorporated in the upcoming government-wide Unified Agenda of Federal Regulatory and Deregulatory Actions.

DATES: The FTC is withdrawing the proposed rule published May 7, 2020 (85 FR 27191) as of May 15, 2020.

ADDRESSES: Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: G. Richard Gold, Attorney, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580; telephone number: (202) 326–3355; email address: *rgold@ftc.gov.*

SUPPLEMENTARY INFORMATION: None.

Dated: May 8, 2020.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020–10301 Filed 5–14–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–509]

Schedules of Controlled Substances: Placement of para-Methoxymethamphetamine (PMMA) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine *(para-*

methoxymethamphetamine, PMMA), including its salts, isomers, 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. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle PMMA.

DATES: Comments must be submitted electronically or postmarked on or before June 15, 2020.

Interested persons may file a request for 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 hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before June 15, 2020.

ADDRESSES: 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. To ensure proper handling of comments, please reference ''Docket No. DEA–509'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* 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 to 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/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for 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 be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 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 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 confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying 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 a 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 (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the person's interests in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

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

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543 as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2–4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[1] after

[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

consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance. 21 U.S.C. 811(d)(3). If such requirements are not met by existing controls and the Secretary of HHS concurs in the scheduling decision, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to 21 U.S.C. 811(a) and (b). 21 U.S.C. 811(d)(3)(B).

In the event that the Secretary of HHS did not consult with the Attorney General, as provided under 21 U.S.C. 811(d)(3), and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of DEA (Administrator). 28 CFR 0.100.

Background

para-Methoxymethamphetamine (PMMA) is a substituted phenethylamine and shares structural similarity to methamphetamine (schedule II) and *para*-methoxyamphetamine (PMA), schedule I. PMMA shares a similar pharmacological profile with 3,4-methylenedioxymethamphetamine (MDMA or ecstasy), a schedule I substance with high potential for abuse. Similar to MDMA, data obtained from preclinical studies show that PMMA's effects are mediated by monoaminergic (dopamine, norepinephrine, and serotonin) transmission, mostly via activation of the serotonergic system. In animals, PMMA mimics MDMA in producing discriminative stimulus effect, indicative of similar subjective effects. Law enforcement has encountered PMMA on the recreational drug market. In this market, PMMA is available and sold as ''ecstasy'' either alone or in combination with MDMA or PMA for oral consumption. For many years, there has been worldwide (mostly in Europe) reporting of non-fatal and fatal cases of overdoses involving PMMA. PMMA has no accepted medical use in treatment in the United States.

Proposed Determination To Schedule PMMA

On March 18, 2016, the Commission on Narcotic Drugs (CND) voted to place PMMA in Schedule I of the 1971 Convention (CND Dec/59/3) during its 59th Session due to its dependence and abuse potential. The United States is a member of the 1971 Convention, and in accordance with 21 U.S.C. 811(b), on April 7, 2017, DEA, after gathering the necessary data, requested from HHS [2] a scientific and medical evaluation and a scheduling recommendation for PMMA. On December 18, 2018, pursuant to 21 U.S.C. 811(b), HHS provided DEA with a scheduling recommendation entitled ''Basis for the Recommendation to Place 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine (para-methoxymethamphetamine, PMMA) in Schedule I of the Controlled Substances Act.''

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 8-Factor analysis in accordance with 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 the scheduling decision. Please note that both DEA and HHS 8-Factor analyses are available in their entirety under the tab ''Supporting Documents'' of the public docket for this action at *http://www.regulations.gov* under Docket Number ''DEA–509.''

1. *The Drug's Actual or Relative Potential for Abuse:* The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests that DEA consider the following criteria when determining whether a particular drug or substance has a potential for abuse: [3]

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

According to HHS, there is currently no approved medical use in treatment for PMMA anywhere in the world, and there is no Food and Drug Administration (FDA)-approved drug product containing PMMA used in treatment in the United States. Evidence demonstrates that PMMA, similar to MDMA, is abused for its stimulant, psychedelic, and empathogenic effects. Over a period of approximately 30 years starting in the 1990s, PMMA has been associated with numerous cases of non-fatal intoxications (n = 31) and fatal intoxications (n = 131) in three continents. PMMA and its metabolites have been positively identified in blood, urine, and hair samples of individuals with a substance use disorder. Evidence posits that PMMA is abused knowingly and/or unknowingly as an MDMA (ecstasy) substitute.

Law enforcement seizure [4] data indicate that individuals have abused and are continuing to abuse PMMA. According to the National Forensic Laboratory Information System (NFLIS) [5] database, which collects drug identification results from drug cases

scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, March 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] Administrative responsibilities for evaluating a substance for control under the CSA are performed for HHS by FDA, with the concurrence of NIDA, according to a Memorandum of Understanding. 50 FR 9518, March 8, 1985.

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); *reprinted in* 1970 U.S.C.C.A.N. 4566, 4603.

[4] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, December 12, 2011.

[5] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the Nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5%. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, December 12, 2011. NFLIS data were queried October 23, 2019.

submitted to and analyzed by some Federal, State, and local forensic laboratories, there have been 39 reports for PMMA between January 2002 and October 2019, and no reports for PMMA from January 2003 to December 2010, January 2013 to December 2013, and January 2017 to December 2017 (query date: October 23, 2019).[6] The identification of this substance on the illicit drug market is an indication that individuals are taking PMMA in amounts sufficient to create a hazard to public health. In the United States, PMMA is not an approved drug product, and there appears to be no legitimate source for this substance as a marketed drug product.

Based on available data, PMMA is related in its effects to the actions of other substances such as PMA (schedule I) and MDMA (schedule I) that are already listed as having potential for abuse. According to HHS, PMMA has similar pharmacological effects to MDMA, and thus is expected to have a high potential for abuse and high risk to public health.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* According to HHS, PMMA is an empathogenic drug that produces mild stimulant and psychedelic effects. Data obtained from *in vitro* studies show that similar to MDMA, PMMA significantly increased dopamine (DA) and serotonin (5-HT) levels in brain regions associated with abuse liability. Data obtained from an enzymatic assay demonstrate that PMMA inhibited monoamine oxidase A and B. According to HHS, results from the enzymatic study may partially explain the higher levels of monoamines seen with PMMA administration in brain microdialysis studies. High levels of monoamines, especially 5-HT, can lead to a serious medical condition referred to as serotonin syndrome. High doses of PMMA have been associated with symptoms of serotonin syndrome, including increased body temperature (hyperthermia), tremor, and agitation, which can lead to death.

In preclinical studies, high doses of PMMA transiently increased locomotor activity. HHS stated that PMMA's locomotor stimulatory effects are not as robust as that of amphetamine or methamphetamine. In drug discrimination studies, using a test to determine physical or behavioral effects (an interoceptive response) of an unknown drug, the effects of PMMA are different from structural analogs, amphetamine or 2,5-dimethoxy-4-methylamphetamine (DOM). However, in rats trained to discriminate between MDMA or PMMA, MDMA and PMMA cross-substitute for one another. Based on these and additional data, HHS stated that PMMA likely has similar psychoactive effects as MDMA.

There are no clinical studies conducted with PMMA. However, according to HHS, an article described that a self-administered 110 milligram (mg) dose of PMMA resulted in compulsive yawning and increased pulse one hour post-administration. The described effects returned ''back to baseline'' four hours post-administration. A study examined the psychoactive effects of individuals who had taken ''ecstasy.'' The study followed 5,786 individuals who provided the tablets for a chemical analysis and reported on their subjective effects. Out of this sample set, 70 (1.2 percent) ''ecstasy'' tablets were identified as containing PMMA and MDMA together, with PMMA concentrations in a range of 5.0 to 128.0 mg/tablet. It was noted that abusers of the PMMA and MDMA combination experienced hyperthermic seizures, palpitations, agitation, hallucinations, abdominal cramps, nausea, dizziness, and headache.

In summary, PMMA is a psychoactive substance with a mechanism of action similar to that of MDMA. Data from *in vitro* studies show that PMMA increases serotonin levels more than dopamine levels in the brain reward circuitry. In addition, PMMA has an inhibitory effect on monoamine oxidase-A enzyme that further increases monoamine levels and can lead to serotonin syndrome, a dangerous medical condition. Data from animal studies demonstrate that PMMA produced locomotor stimulant effects at high doses with potency of about six times less than that of (+)-amphetamine. In drug discrimination studies, PMMA produces stimulus effect similar to MDMA in rats. Both PMMA and MDMA cross-substitute for one another. There are currently no controlled clinical studies that have evaluated the effects of PMMA in humans. However, anecdotal reports show that similar to MDMA, PMMA produces adverse health effects, such as hyperthermia, seizures, hallucinations, and nausea. Taken together, these data demonstrate that PMMA shares a mechanism of action and discriminative stimulus effects similar to the schedule I substance, MDMA.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* PMMA is a substituted phenethylamine and is a methoxy-derivative of methamphetamine. PMMA is also related to PMA and MDMA, which are schedule I substances.

As stated by HHS, there are several sources describing the synthesis of PMMA either directly or through alternate route by conversion of PMA to PMMA. The precursor substances that can be used for the synthesis of PMMA include methylamine, 4-methoxyphenyacetone, and cyanoborohydride. Additional chemicals and solvents required for PMMA synthesis include methanol, dichloromethane, isopropanol, hydrochloric acid, ethyl chloroformate, trimethylamine, carbamate, formamide, and lithium aluminum hydride.

Pharmacokinetic studies of PMMA in rats showed that after subcutaneous administration, peak PMMA concentration was detected in the plasma within 30 minutes. Brain levels of PMMA were delayed behind the plasma levels for several hours. HHS states that this delay supports user comments that PMMA has a longer onset of effect than MDMA. Most of PMMA and its metabolites were excreted within the first 24-hours post-administration. Metabolites detected were products of *O*-demethylation or *N*-demethylation of PMMA to 4-methoxyamphetamine (PMA), 4-hydroxymethamphetamine (OH-MAM), 4-hydroxyamphetamine (OH-AM), 4-hydroxy-3′-methoxymethamphetamine (HM-MAM), and 4′-hydroxy-3′-methoxyamphetamine (HM-AM). The cytochrome P450 enzyme CYP2D6 was identified as being the only enzyme capable of demethylating PMMA.

PMMA toxicity data in animals demonstrate that toxicity occurs at early stages of administration. In PMMA-dosed animals, prior to lethality, hyperactivity, increased respiration, salivation, and tremor were observed.

4. *Its History and Current Pattern of Abuse:* Abuse of PMMA was first documented in the late 1980s and associated with ''ecstasy'' tablets as this drug was often substituted for MDMA. Abuse of PMMA has been documented worldwide with usage particularly extensive in Europe, Asia, and Canada. PMMA was originally used as a powder with doses ranging around 100 mg or less. PMMA is now most commonly encountered in a tablet form, and PMMA tablets have been seized in Europe, Asia, and the United States.

PMMA tablets are primarily sold as ''ecstasy'' and are sometimes encountered along with amphetamine, methamphetamine, or ephedrine. PMMA tablets may be marked with different logos, including ''E,'' ''Mitsubishi,'' ''Jumbo,'' or ''Superman.'' Street names for PMMA tablets include ''Dr. Death,'' ''Death,'' or ''Killer.'' According to a review of PMMA by the

[6] NFLIS is still reporting data for October–December 2018, due to normal lag time in reporting.

European Monitoring Centre for Drugs and Drug Addition (EMCDDA) in 2003, tablets were reported to contain between 20 and 97 mg of PMMA. PMMA is primarily administered orally in a tablet form. Data indicate that MDMA is often mixed with other substances, one of which is PMMA. It was observed that MDMA mixed with PMMA led to a higher number of adverse events than other MDMA combinations. According to HHS, there is little anecdotal information on the use of PMMA most likely because individuals ingesting this substance in the context of abuse believe they are taking MDMA rather than a mixture of drugs that may include PMMA thus attributing its effects to MDMA.

DEA conducted a search of NFLIS and the System to Retrieve Information from Drug Evidence (STRIDE)/STARLiMS for law enforcement encounters of PMMA. Prior to October 1, 2014, STRIDE collected the analytical results of drug evidence submitted by DEA, other Federal law enforcement agencies, and some local law enforcement agencies to DEA forensic laboratories. Since October 1, 2014, STARLiMS (a web-based, commercial laboratory information management system) has replaced STRIDE as DEA laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. According to data from STRIDE [7] and STARLiMS [8] between January 2000 and December 2018, DEA laboratories analyzed 41 drug exhibits containing PMMA. NFLIS is a DEA program that collects drug identification results from drug cases analyzed by other Federal, State, and local forensic laboratories. Within the NFLIS database, there have been 39 reports [9] for PMMA between January 2002 and October 2019, and no reports from January 2003 to December 2010, January 2013 to December 2013, and January 2017 to December 2017 from state and local laboratories. The NFLIS database shows there were two reports in 2002 from one state; three reports from two states in 2011; three reports from three states in 2012; 21 reports from one state in 2014; three reports from two states in 2015; two reports from one state in 2016; four reports from two states in 2018; and one report from one state in 2019.

5. *The Scope, Duration, and Significance of Abuse:* PMMA abuse has been associated with ''ecstasy'' tablets and is used as a substitute for MDMA. As a result, most users think they are taking ''ecstasy'' with MDMA and are not intentionally purchasing PMMA on the illicit market. One study reported that tablets containing a combination of MDMA and PMMA resulted in adverse effects, such as hyperthermic seizures, palpitations, agitation, nausea, and hallucinations. Most abusers of PMMA take the drug in combination with other drugs as noted in the PMMA-associated deaths (see Factor 6). Furthermore, there is evidence of PMMA drug seizures or confiscation in the United States, as reported by DEA's STRIDE/STARLiMS or NFLIS databases.

Numerous deaths and overdoses associated with PMMA usage demonstrate that there is a considerable population abusing PMMA, and its abuse is a significant public health concern. Prior to death, individuals exhibit high temperatures, seizures, coma, and respiratory distress. The PMMA-related public health risks, such as deaths and overdoses, led the European Union Member States to control PMMA in 2002.

6. *What, if Any, Risk There is to the Public Health:* According to HHS, there are several risk factors associated with the use of PMMA. The first risk is that individuals inadvertently use PMMA because it is sold as MDMA and such products may contain other drugs. This risk can lead to poly-drug use, which is inherently more dangerous to the individuals who consume such products. The second risk described by HHS is the slow onset of action of PMMA compared to MDMA. The delay in onset of effect for PMMA can make individuals consume more PMMA, and such action can lead to overdose or death. Thirdly, HHS described that the pharmacological actions of PMMA, such as increase in monoamine levels (DA and 5-HT) combined with inhibition of monoamine oxidase-A, an enzyme responsible for degradation of these monoamines, can lead to a serious medical condition known as serotonin syndrome. The symptoms of serotonin syndrome are similar to those seen when high doses of PMMA are used. These include hyperthermia, tremor, agitation, and can result in death.

Over a period of approximately 30 years starting in the 1990s, a total of 131 analytically confirmed PMMA (detected in either blood and/or urine)-associated deaths in Europe (69 deaths), Israel (27 deaths), Canada (27 deaths), and Taiwan (8 deaths) has been reported. Published case reports on PMMA-related deaths occurred mostly in males and ages ranged from 14–59 years with the majority of them under the age of 30. Common symptoms that were observed prior to death were hyperthermia, decreased respiratory rate, seizures, and cardiac arrest. In most of the PMMA-related fatalities, other drugs were detected in the blood or urine.

7. *Its Psychic or Physiological Dependence Liability:* According to HHS, abuse liability of PMMA has only been characterized through drug discrimination studies. The drug discrimination studies do not provide information that can be used to assess the psychic or physiological dependence liability of PMMA, although they provide information on the subjective effects of the drug. Data from drug discrimination studies showed that both PMMA and MDMA share discriminative stimulus effects. Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, indicated that there is evidence of a withdrawal syndrome from MDMA with observations of both psychological and physical dependence. Similarities in the drug discriminative stimulus properties of PMMA and MDMA indicate that the subjective effects of PMMA are similar to that of the schedule I substance, MDMA. As stated by HHS, both PMMA and MDMA also largely share a common mechanism of action. Thus, it is plausible to extrapolate that PMMA has a dependence liability similar to that of MDMA. HHS states some individuals have become tolerant to MDMA resulting in taking high doses of the drug, and these individuals have reported undergoing a withdrawal syndrome, although it is unclear whether they were undergoing withdrawal or adverse effects from high doses of MDMA. Thus, evidence suggests that MDMA causes psychological dependence and may be associated with physical dependence, although not to the same extent as that of cocaine.

HHS concludes that PMMA most likely has a psychic dependence liability similar to that of MDMA, though not as strong as that of cocaine. The use of PMMA may be associated with physical dependence.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* PMMA is not an immediate precursor to any substance already controlled in 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 8-Factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for

[7] STRIDE data were queried through September 30, 2014, by the date of collection for DEA forensic laboratories.

[8] STRIDE/STARLIMS was queried October 23, 2019, by the date of collection.

[9] NFLIS is still reporting data for October–December 2018, due to normal lag time in reporting.

abuse of PMMA. As such, DEA hereby proposes to schedule PMMA as a schedule I 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 Health of HHS and review of all available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(c) and 812(b)(1), finds the following:

(1) The Drug or Substance Has a High Potential for Abuse

PMMA has a mechanism of action similar to that of the schedule I substance MDMA. Similar to MDMA, PMMA increases levels of monoamines, specifically DA and 5-HT, in the brain reward circuitry. Data from animal studies demonstrate that PMMA fully substitutes for the discriminative stimulus effect of MDMA, indicative of similar subjective effects. Although there is currently no data that has directly assessed the psychological or physiological dependence liability of PMMA, its pharmacological similarities to MDMA suggest it likely has low physical dependence liability similar to that of MDMA. Evidence demonstrates that users of PMMA seem to be seeking MDMA, which may be mixed with PMMA. Because PMMA shares a pharmacological mechanism of action and psychoactive effects similar to the schedule 1 substance MDMA, PMMA has a high potential for abuse.

(2) The Drug or Substance Has No Currently Accepted Medical Use in Treatment in the United States

According to HHS, FDA has not approved any marketing application for a drug product containing PMMA for any indication. In addition, there are no clinical studies or petitioners that have claimed an accepted medical use of PMMA in the United States. Thus, PMMA has no currently accepted medical use in treatment in the United States.[10]

(3) There Is a Lack of Accepted Safety for Use of the Drug or Substance Under Medical Supervision

Because PMMA has no approved medical use in treatment in the United States and has not been investigated as a new drug, its safety for use under medical supervision has not been determined. Therefore, there is a lack of accepted safety for use of PMMA under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that PMMA warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1). More precisely, because PMMA shares a pharmacological mechanism of action and psychoactive effects similar to the schedule 1 substance MDMA, DEA is proposing to place PMMA in 21 CFR 1308.11(d) (the hallucinogenic category of schedule I). As such, the proposed control of PMMA includes the substance, as well as its salts, isomers, and salts of isomers whenever the existence of such isomers and salts is possible, within the specific chemical designation.

Requirements for Handling PMMA

If this rule is finalized as proposed, PMMA would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, 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) PMMA, or who desires to handle PMMA, would need to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312, as of the effective date of a final scheduling action. Any person who currently handles PMMA, and is not registered with DEA, would need to submit an application for registration and may not continue to handle PMMA after the effective date of a final scheduling action unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration would be required to surrender all quantities of currently held PMMA or transfer all quantities of currently held PMMA to a person registered with DEA before the effective date of a final scheduling action, in accordance with all applicable Federal, State, local, and tribal laws. As of the effective date of a final scheduling action, PMMA would be required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* PMMA would be subject to schedule I security requirements and would need to be handled and stored in accordance with 21 CFR 1301.71–1301.93 as of the effective date of a final scheduling action.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of PMMA would need to be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302, as of the effective date of a final scheduling action.

5. *Quota.* Only registered manufacturers would be permitted to manufacture PMMA in accordance with a quota assigned, pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of the effective date of a final scheduling action.

6. *Inventory.* Every DEA registrant who possesses any quantity of PMMA on the effective date of a final scheduling action would be required to take an inventory of PMMA on hand at that time, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who becomes registered with DEA on or after the effective date of the final scheduling action would be required to take an initial inventory of all stocks of controlled substances (including PMMA) 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(a) and (b).

After the initial inventory, every DEA registrant would be required to take an inventory of all controlled substances (including PMMA) 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.

[10] Although there is no evidence suggesting that PMMA has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. The drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992).

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports for PMMA, or products containing PMMA, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, and 1317, as of the effective date of a final scheduling action. Manufacturers and distributors would be required to submit reports regarding PMMA to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312, as of the effective date of a final scheduling action.

8. *Order Forms.* Every DEA registrant who distributes PMMA would be required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305, as of the effective date of a final scheduling action.

9. *Importation and Exportation.* All importation and exportation of PMMA would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312, as of the effective date of a final scheduling action.

10. *Liability.* Any activity involving PMMA not authorized by, or in violation of, the CSA or its implementing regulations, would be unlawful, and may 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 procedures and 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 13563.

This rulemaking is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 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 Executive Order 12988, Civil Justice Reform, 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 Executive Order 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 Executive Order 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, 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.

DEA proposes placing the substance PMMA (chemical name: 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would impose the 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 with, or possess), or propose to handle PMMA.

According to HHS, PMMA has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for PMMA in the United States. Therefore, DEA estimates that no United States entity currently handles PMMA and does not expect any United States entity to handle PMMA in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule if finalized. As such, the proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with 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 million 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, 21 CFR part 1308 is proposed to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR 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)(80) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(79)	1-(4-methoxyphenyl)-*N*-methylpropan-2-amine (other names: *para*-methoxymethamphetamine, PMMA), ...	(1245)

* * * * *

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–09599 Filed 5–14–20; 8:45 am]

BILLING CODE 4410–09–P

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy

21 CFR Part 1401

RIN 3201–AA02

Criteria for Designation of Emerging Drug Threats in the United States

AGENCY: Office of National Drug Control Policy.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Office of National Drug Control Policy is announcing this Advance Notice of Proposed Rulemaking (ANPRM) and requests information relevant to criteria for designating and terminating the designation of emerging drug threats in the United States pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). This ANPRM briefly summarizes the White House Office of National Drug Control Policy's (ONDCP) ongoing work in this area and describes the criteria that ONDCP is considering to monitor and identify emerging drug threats. The ANPRM invites interested parties to submit comments, data, and other pertinent information concerning ONDCP's development of proposed criteria for designating emerging drug threats and terminating such designations.

DATES: Send comments on or before June 30, 2020.

ADDRESSES: You may send comments, identified by RIN number 3201–AA02 and/or docket number ONDCP–2020–0001, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing.
- *Email: OGC@ondcp.eop.gov,* Include docket number ONDCP–2020–0001 and/or RIN number 3201–AA02 in the subject line of the message.
- *Mail:* Executive Office of the President, Office of National Drug Control Policy, 1800 G Street NW, 9th Floor, Washington, DC 20006, Attn: Office of General Counsel.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Questions concerning this ANPRM should be directed to Michael J. Passante, Acting General Counsel, Office of General Counsel, Office of National Drug Control Policy, Executive Office of the President, at *OGC@ondcp.eop.gov* (email) or (202) 395–6622 (voice).

SUPPLEMENTARY INFORMATION:

I. Public Participation

ONDCP strongly recommends using electronic means for submitting comments. Due to COVID–19, comments submitted through conventional mail delivery services may not be received in a timely manner. To ensure proper handling, please reference RIN 3201–AA02 on your correspondence. The mailing address may be used for paper, disk, or CD–ROM submissions.

Interested persons are invited to submit written data, views, or arguments on all aspects of this ANPRM. All comments must be submitted in English, or accompanied by an English translation. Please note that all comments received are considered part of the public record and made available for public inspection at *www.regulations.gov.* Such information includes personally identifiable information (such as a person's name, address, or any other data that might personally identify that individual) that the commenter voluntarily submits.

If you want to submit personally identifiable information as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONALLY IDENTIFIABLE INFORMATION'' in the first paragraph of your comment and precisely and prominently identify the information for which you seek redaction.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment and precisely and prominently identify the confidential business information for which you seek redaction. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.* Personally identifiable information and confidential business information provided as set forth above will be placed in the agency's public docket file, but not posted online. To inspect the agency's public docket file in person, you must make an appointment with agency counsel. Please see the **FOR FURTHER INFORMATION CONTACT** paragraph above for the agency counsel's contact information specific to this rulemaking.

II. Introduction

Through enacting Section 8218 of the SUPPORT Act, 21 U.S.C. 1708, Congress codified its intention for the Federal government to closely monitor emerging drug threats and to take action at the outset of a trend to prevent such threats from reaching levels seen during the opioid crisis. The SUPPORT Act requires ONDCP to promulgate standards for designating an emerging drug threat and terminating such a designation. 21 U.S.C. 1708(c). The SUPPORT Act created the Emerging Threats Committee consisting of representatives from National Drug Control Program Agencies and other agencies, representatives from State, local and Tribal governments, and representatives from other entities designated by the ONDCP Director. 21 U.S.C. 1708(b). The Emerging Threats Committee is responsible for, among other matters, monitoring evolving and emerging drug threats in the United States. One of the Committee's principal responsibilities is to develop and recommend criteria that ONDCP may use to designate and terminate the designation of emerging drug threats. 21 U.S.C. 1708(b)(6).

How best to monitor and identify emerging drug threats in the United States is a question with broad public health implications. Before proceeding, ONDCP intends to benefit from a full airing of the issues through the public comment process. ONDCP's objective is to develop criteria that will enable the United States to be proactive in identifying emerging drug threats and taking action to prevent such drug threats from becoming public health emergencies.