on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Analysis of Environmental Impact

We have tentatively determined under 21 CFR part 25.32(a) that this action, if finalized, is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. French Dressing; Proposed Revocation of a Standard of Identity: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, available at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 169

Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that 21 CFR part 169 be amended as follows:

PART 169—FOOD DRESSINGS AND FLAVORINGS

■ 1. The authority citation for 21 CFR part 169 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§ 169.115 [Removed]

■ 2. Remove § 169.115.

Dated: December 2, 2020

Stephen M. Hahn,

Commissioner of Food and Drugs.

Dated: December 14, 2020

Alex M. Azar II,

Secretary,Department of Health and Human Services.

[FR Doc. 2020–27822 Filed 12–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–542]

Designation of 3,4-MDP-2-P Methyl Glycidate (PMK Glycidate), 3,4-MDP-2-P Methyl Glycidic Acid (PMK Glycidic Acid), and Alpha-Phenylacetoacetamide (APAA) as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing to designate 3,4-MDP-2-P methyl glycidate (PMK glycidate), including its optical and geometric isomers; 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), including its salts, optical and geometric isomers, and salts of isomers; and *alpha*-phenylacetoacetamide (APAA), including its optical isomers, as list I chemicals under the Controlled Substances Act (CSA). PMK glycidate and PMK glycidic acid are used in and are important to the manufacture of the schedule I controlled substance 3,4-methylenedioxymethamphetamine (MDMA) and other ''ecstasy''-type substances. APAA is used in and is important to the manufacture of the schedule II controlled substances amphetamine and methamphetamine. If finalized, this action would subject handlers (manufacturers, distributors, importers, and exporters) of PMK glycidate, PMK glycidic acid, and APAA to the chemical regulatory provisions of the CSA and its implementing regulations. This action does not propose the establishment of a threshold for domestic and international transactions of these chemicals. As such, all transactions involving any of these chemicals, regardless of size, would be regulated. In addition, this action proposes that chemical mixtures containing any of these three chemicals would not be exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of PMK glycidate, PMK glycidic acid, or APAA would be regulated.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before February 19, 2021. 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.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–542'' on all correspondence, including any attachments.

Electronic comments: The Drug Enforcement Administration (DEA) encourages 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 *http://www.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 and are discouraged. 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.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received 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 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 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 generally 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.

Legal Authority

The Controlled Substances Act (CSA) gives the Attorney General the authority to specify, by regulation, a chemical as a ''list I chemical;'' this term refers to a chemical that is used in manufacturing a controlled substance in violation of subchapter I (Control and Enforcement) of the CSA and is important to the manufacture of the controlled substance.[1] Pursuant to 28 CFR 0.100(b), the Attorney General has delegated his authority to so designate list I chemicals to the Administrator of DEA (Administrator). CSA regulations permit the Administrator to add a substance as a listed chemical by publishing a final rule in the **Federal Register** following the publication of a notice of proposed rulemaking that has provided at least 30 days for public comments.[2] The current list of all list I chemicals is available in 21 CFR 1310.02(a).

In addition, the United States is a Party to the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), December 20, 1988, 1582 U.N.T.S. 95. Under Article 12 of the 1988 Convention, when the United States receives notification that a chemical has been added to Table I or Table II (tables annexed to such Convention), the United States must take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion, including measures related to international trade.

Background

With the growing problem of illicit drug production, the issue of precursor chemical control has gained global attention. International efforts to prevent the illicit production of controlled substances and international control of precursors have made significant progress with this problem. Article 12 of the 1988 Convention established International controls on precursors. This Convention established two categories of controlled illicit drug precursor substances: Table I and Table II.[3] Two international entities have played a crucial role in this effort: The United Nations Commission on Narcotic Drugs (CND) and the International Narcotics Control Board (INCB).

In response to domestic and international controls on precursors to the schedule I substance 3,4-methylenedioxymethamphetamine (MDMA), and schedule II substances amphetamine and methamphetamine, clandestine laboratory operators have continued to explore alternate methods to produce these illicit drugs, including the development of their own immediate precursors (''designer precursors'') and diversion of other precursors (pre-precursors) to produce these designer precursors. These clandestine laboratory operators often use 3,4-MDP-2-P methyl glycidate (PMK glycidate) and 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) as precursors to MDMA, and other ''ecstasy''-type substances, and *alpha*-phenylacetoacetamide (APAA) as a precursor to amphetamine and methamphetamine.

''Precursor chemicals'' are generally defined as chemical substances that become incorporated, at the molecular level, into a final product (including a controlled substance); it is a building block used to manufacture the final product/controlled substance. PMK glycidate and PMK glycidic acid are building blocks for the manufacture of the schedule I controlled substance MDMA, while APAA serves as a building block for the manufacture of the schedule II substance Phenyl-2-propanone (P2P), and subsequent final manufacture of the schedule II substances amphetamine and methamphetamine. All these chemicals meet the definition of list I chemicals since they are important to the manufacture of these controlled substances.

In a letter dated May 23, 2019, the Secretary-General of the United Nations, in accordance with Article 12, paragraph 6 of the 1988 Convention, informed the United States Secretary of State that the CND voted to place the chemicals PMK glycidate (and all stereoisomers), PMK glycidic acid (and all stereoisomers), and APAA (and all optical isomers) in Table I of the 1988 Convention (CND Decisions 62/10, 62/11, and 62/12, respectively) at its 62nd Session on March 19, 2019. As a Party to the 1988 Convention, the United States is obligated to control these substances pursuant to Article 12 of the 1988 Convention, as described in the above Legal Authority section. By designating PMK glycidate (and its optical and geometric isomers), PMK glycidic acid (and its salts, optical and geometric isomers, and salts of isomers), and APAA (and its optical isomers) as list I chemicals, the United States will fulfill its obligations under the 1988 Convention.[4]

PMK glycidate, PMK glycidic acid, and APAA are close chemical relatives of controlled list I precursor 3,4 methylenedioxyphenyl-2-propanone (3,4-MDP-2-P), and have been made specifically to circumvent existing precursor controls. DEA has not identified any known legitimate uses for these chemicals, other than possible research purposes. The first two substances, PMK glycidate and PMK glycidic acid, are closely related in chemical structure to precursors of MDMA (schedule I) and other ''ecstasy''-type substances in schedule I. APAA is a precursor of schedule II controlled substances amphetamine and methamphetamine. All three chemicals are used for the illicit manufacture of two precursors listed in Table I of the 1988 Convention (3,4-MDP-2-P and 1-phenyl-2-propanone (P-2-P)). For years, countries have reported the illicit trafficking and use of these chemicals in manufacturing controlled substances,

[1] 21 U.S.C. 802(34) and 871(b).

[2] 21 CFR 1310.02(c).

[3] Table I and Table II are amended from time to time in accordance with Article 12 of the 1988 Convention.

[4] With this scheduling action, if finalized, DEA would control the same set of chemicals specified by the CND. However, DEA uses more precise terms that relate to the specific chemical and variations that can actually exist.

with increasing frequency and amounts reported in recent years.[5]

In making its assessments pursuant to Article 12, paragraph 4, of the 1988 Convention, the CND found that there was no known legitimate manufacture of, and trade in, any of the three substances, and that their use was limited in small amounts to research, development, and laboratory analytical purposes. The inclusion of these substances in Table I would require Governments, as parties to the 1988 Convention, to establish pre-export notifications as a means of monitoring shipments entering their territories. Therefore, the CND voted to include PMK glycidate (all four stereoisomers), PMK glycidic acid (all four stereoisomers), and APAA (including its optical isomers) in Table I of the 1988 Convention.

Proposed Designation of PMK Glycidate, PMK Glycidic Acid, and APAA as List I Chemicals

For the reasons discussed above, the Acting Administrator of DEA finds that PMK glycidate, PMK glycidic acid, and APAA are used in the manufacture of a controlled substance in violation of the CSA, and are important to the manufacture of these controlled substances. Therefore, the Acting Administrator proposes the designation of PMK glycidate, PMK glycidic acid, and APAA as list I chemicals.

If finalized, handlers (manufacturers, distributors, importers, and exporters) of these chemicals would become subject to the chemical regulatory provisions of the CSA, including 21 CFR parts 1309, 1310, 1313, and 1316. Since even a small amount of these chemicals can potentially yield a significant amount of controlled substances, this action does not propose the establishment of a threshold for domestic, import, or export transactions in accordance with the provisions of 21 CFR 1310.04(g). Rather, DEA is proposing that all transactions, regardless of size, will be regulated transactions as defined in 21 CFR 1300.02(b). As such, if finalized, all PMK glycidate, PMK glycidic acid, and APAA transactions will be subject to recordkeeping, reporting, import and export controls, and other CSA chemical regulatory requirements. In addition, each regulated bulk manufacturer must submit manufacturing, inventory, and use data to DEA's Diversion Control Division, Drug and Chemical Evaluation section on an annual basis, in accordance with 21 CFR 1310.05(d).

Chemical Mixtures of PMK Glycidate, PMK Glycidic Acid or APAA

This rulemaking also proposes that chemical mixtures containing any of these three chemicals are subject to regulatory requirements at any concentration unless a manufacturer submits to DEA an application for exemption of a chemical mixture, DEA accepts the application for filing, and DEA exempts the chemical mixture in accordance with 21 CFR 1310.13 (Exemption of chemical mixtures; application). Since even a small amount of these three chemicals can potentially yield a significant amount of controlled substances, DEA believes that regulation of chemical mixtures containing any amount of these three chemicals is necessary to prevent their illicit extraction, isolation, and use. Therefore, all chemical mixtures containing any quantity of these three chemicals would be subject to CSA control. This rule proposes modification of the ''Table of Concentration Limits'' in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of these three chemicals are subject to CSA chemical control provisions.

Application Process for Exemption of Chemical Mixtures

DEA has implemented an application process to exempt certain chemical mixtures from the requirements of the CSA and its implementing regulations.[6] Manufacturers may submit an application for exemption for those mixtures that do not meet the criteria set forth in 21 CFR 1310.12(d) for an automatic exemption. Pursuant to 21 CFR 1310.12(a), DEA may grant an exemption of a chemical mixture, by publishing a final rule in the **Federal Register**, if DEA determines that: (1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and (2) the listed chemical or chemicals cannot be readily recovered.

Requirements for Handling List I Chemicals

If finalized as proposed, the designation of these three chemicals as list I chemicals will subject handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all of the regulatory controls and administrative, civil, and criminal actions applicable to the manufacture, distribution, importation, and exportation of a list I chemical. Upon publication of a final rule, persons potentially handling these three chemicals, including regulated chemical mixtures containing any of these three chemicals, would be required to comply with the following list I chemical regulations:

1. *Registration.* Any person who handles (manufactures, distributes, imports, or exports), or proposes to engage in such handling of, any of these three chemicals or a chemical mixture containing any of these three chemicals must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309. DEA regulations require separate registrations for manufacturing, distributing, importing, and exporting of any of these three chemicals.[7] Further, a separate registration is required for each principal place of business at one general physical location where list I chemicals are manufactured, distributed, imported, or exported by a person.[8]

DEA notes that under the CSA, ''warehousemen'' are not required to register and may lawfully possess list I chemicals, if the possession of those chemicals is in the usual course of business or employment.[9] Under DEA implementing regulations, the warehouse in question must receive the list I chemical from a DEA registrant, shall only distribute the list I chemical back to the DEA registrant, and registered location from which it was received.[10] A warehouse that distributes list I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register as such.

Upon publication of a final rule, any person manufacturing, distributing, importing, or exporting any of these three chemicals or a chemical mixture containing any of these three chemicals will become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons subject to the registration requirement to immediately complete and submit an application for

[5] Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances: Report of the International Narcotics Control Board for 2018 on the Implementation of Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (E/INCB/2018/4, Released March 5, 2019)

[6] 21 CFR 1310.13 specifies that this chemical mixture is a chemical mixture consisting of two or more chemical components, at least one of which is a list I or list II chemical..

[7] 21 CFR 1309.21.

[8] 21 CFR 1309.23(a). See also 21 U.S.C. 822(e)(1) with separate registration requirements pertaining to manufacturing or distributing a list I chemical.

[9] 21 U.S.C. 822(c)(2) and 21 U.S.C. 957(b)(1)(B).

[10] See 21 CFR 1309.23(b)(1).

registration and for DEA to immediately issue registrations for those activities. Therefore, to allow continued legitimate commerce in these three chemicals, DEA is proposing to establish in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with any of these three chemicals, provided that DEA receives a properly completed application for registration on or before 30 days after publication of a final rule implementing regulations regarding these three chemicals. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, would become effective on the effective date of the final rule. Therefore, all transactions of these three chemicals and chemical mixtures containing any of these three chemicals will be regulated while an application for registration or exemption is pending. This is necessary because failing to regulate these transactions could result in increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to these three chemicals, nor does it supersede State or local laws or regulations. All handlers of any of these three chemicals must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports to DEA with respect to these three chemicals pursuant to 21 U.S.C. 830(a) and (b)(1) and (2) and in accordance with 21 CFR 1310.04 and 1310.05. Pursuant to 21 CFR 1310.04(a), a record must be made and maintained for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical is required to submit manufacturing, inventory, and use data on an annual basis.[11] Existing standard industry reports containing the required information will be acceptable, provided the information is separate or readily retrievable from the report.

The CSA and its implementing regulations require that each regulated person must report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of subchapter I of the CSA. In addition, regulated persons must report any proposed regulated transaction with a person whose description or other identifying characteristics DEA has previously furnished to the regulated person, any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier.[12]

3. *Importation and Exportation.* All importation and exportation of these three chemicals would need to be in compliance with 21 U.S.C. 957, 958, and 971 and in accordance with 21 CFR part 1313.

4. *Security.* All applicants and registrants would be required to provide effective controls against theft and diversion in accordance with 21 CFR 1309.71–1309.73.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A. 21 U.S.C. 88).

6. *Liability.* Any activity involving these three chemicals not authorized by, or in violation of, the CSA would be unlawful, and may subject the person to administrative, civil, and/or criminal action.

Regulatory Analyses

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

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 13771. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. DEA has determined that this proposed rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f).

E.O. 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation.[13] In furtherance of this requirement, E.O. 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.[14] According to guidance provided by OMB, the requirements of E.O. 13771 only apply to each new ''significant regulatory action that . . . imposes costs.'' [15] This proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under E.O. 12866.

If finalized as proposed, PMK glycidate, PMK glycidic acid, and APAA will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. The first two chemicals, PMK glycidate and PMK glycidic acid, are closely related in chemical structure to precursors of MDMA and other ''ecstasy''-type substances, as discussed in the above background section. APAA is a

[11] 21 CFR 1310.05(d).

[12] 21 U.S.C. 830(b) and 21 CFR 1310.05(a) and (b).

[13] Sec. 2(a).

[14] Sec. 2(c).

[15] OMB Guidance Implementing Executive Order 13771 titled ''Reducing Regulation and Controlling Regulatory Costs'' (April 5, 2017).

precursor of amphetamine and methamphetamine. All three chemicals are highly suitable for the illicit manufacture of precursors listed in Table I of the 1988 Convention (3,4-methylenedioxyphenyl-2-propanone (3,4-MDP-2-P) and 1-phenyl-2-propanone (P-2-P)). As noted earlier, incidents of illicit manufacture and tracking of these three chemicals have been reported for many years to the INCB, with an increase in the frequency and amounts reported in recent years.

In making its assessment pursuant to Article 12, paragraph 4 of the 1988 Convention, the CND found that there was no known legitimate manufacture of and trade in any of the three chemicals and that their use was limited, in small amounts, to research, development, laboratory, and analytical purposes. DEA also searched information in the public domain for legitimate uses of these three chemicals, and likewise, did not identify any known legitimate use for any of these chemicals, other than possibly for research purposes. DEA evaluated the costs and benefits of this proposed action.

DEA cannot rule out the possibility that minimal quantities of PMK glycidate, PMK glycidic, or APAA are used for the manufacturing of legitimate pharmaceutical substances. DEA welcomes any public comment on these quantities and their economic significance.

Costs

As stated above, the only use for PMK glycidate and PMK glycidic acid is as intermediaries for the manufacturing of MDMA and other ''ecstasy''-type substances. Similarly, the only use for APAA is as a precursor for amphetamine and methamphetamine. Any manufacturer, distributor, importer, or exporter of any of these three chemicals for legitimate pharmaceutical commerce, if they exist at all, would incur costs if this proposed rule were finalized. The primary costs associated with this proposed rule are the annual registration fees ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters). Additionally, any manufacturer that uses any of these three chemicals for legitimate pharmaceutical purposes is likely to already be registered with DEA and have all security and other handling processes in place, resulting in minimal cost.

DEA has identified ten domestic suppliers of one or more of these chemicals, PMK glycidate, PMK glycidic acid, and APAA; nine of these suppliers are not currently registered with DEA to handle list I chemicals. The amount of these three chemicals distributed by these suppliers is unknown. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the discussion above, DEA believes any quantity of sales from these distributors for legitimate pharmaceutical purposes is minimal. If this proposed rule is finalized, suppliers for the legitimate use of PMK glycidate, PMK glycidic acid, and APAA are expected to choose the least-cost option, and stop selling the minimal quantities, if any, of PMK glycidate, PMK glycidic acid, and APAA, rather than incur the registration cost. Therefore, DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this proposed rule is minimal. DEA welcomes any public comment regarding this estimate.

This analysis excludes consideration of any economic impact to those businesses that facilitate the manufacturing and distribution of PMK glycidate, PMK glycidic acid, or APAA for the illicit production of amphetamine, methamphetamine, MDMA, or other ''ecstasy''-type substances.

Benefits

Controlling PMK glycidate, PMK glycidic acid, and APAA is expected to prevent, curtail, and limit the unlawful manufacture and distribution of amphetamine, methamphetamine, and MDMA and other ''ecstasy''-type substances. This action is also expected to assist in the prevention of possible theft or diversion of PMK glycidate, PMK glycidic acid, and APAA from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing PMK glycidate, PMK glycidic acid, and APAA and selling it (as an unregulated material) through the internet and other channels to individuals who may wish to acquire unregulated intermediary chemicals for the purpose of manufacturing illicit amphetamine, methamphetamine, or MDMA or other ''ecstasy''-type substances.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this proposed action, if finalized, will minimize the diversion of PMK glycidate, PMK glycidic acid, and APAA. DEA believes the market for PMK glycidate, PMK glycidic acid, and APAA for the legitimate pharmaceutical purposes is minimal. Thus, any potential cost resulting from this regulation is minimal. Therefore, the estimated economic impact of this proposed rule is less than $100 million in any given year.

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 (RFA)

The Acting Administrator, in accordance with the RFA,[16] 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. As discussed above, if finalized as proposed, PMK glycidate, PMK glycidic acid, and APAA will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, and exportation of list I chemicals. PMK glycidate and PMK glycidic acid are closely related in chemical structure to precursors of MDMA and other ''ecstasy''-type substances. APAA is a precursor of amphetamine and methamphetamine. All three chemicals are highly suitable for the illicit manufacture of precursors listed in Table I of the 1988 Convention (3,4-methylenedioxyphenyl-2-propanone (3,4-MDP-2-P) and 1-phenyl-2-propanone (P-2-P)). DEA has not

[16] 5 U.S.C. 601–612.

identified any legitimate industrial use for PMK glycidate, PMK glycidic acid, or APAA, other than as intermediary chemicals in the production of amphetamine, methamphetamine, and MDMA or other ''ecstasy''-type substances. Therefore, DEA believes the vast majority, if not all, of PMK glycidate, PMK glycidic acid, and APAA is used for the illicit manufacturing of amphetamine, methamphetamine, and MDMA or other ''ecstasy''-type substances. The primary costs associated with this proposed rule are the annual registration fees ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters). Additionally, any manufacturer that uses PMK glycidate, PMK glycidic acid, or APAA for legitimate pharmaceutical purposes is likely to be already registered with DEA and have all security and other handling processes in place, resulting in minimal cost.

DEA has identified ten domestic suppliers of one or more of the chemicals, PMK glycidate, PMK glycidic acid, and APAA; nine of these suppliers are currently not registered with DEA to handle list I chemicals. All nine non-registered domestic suppliers are affected, and all nine (94.5 percent, based on Small Business Administration size standard for chemical distributors and Statistics of U.S. Businesses data) are estimated to be small entities. The quantity of these three chemicals distributed by these suppliers is unknown. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the discussion above, DEA believes any quantity of sales from these distributors for legitimate pharmaceutical purposes is minimal. DEA estimates that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. DEA welcomes any public comment regarding this estimate.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this proposed rule 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 the UMRA.

Paperwork Reduction Act

The proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This proposed 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 21 CFR Part 1310

Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, DEA proposes to amend 21 CFR part 1310 as follows:

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

■ 1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

■ 2. In § 1310.02 add paragraphs (a)(34) through (36) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

(34) 3,4-MDP-2-P methyl glycidate (PMK glycidate) and its optical and geometric isomers 8535

(35) 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) and its salts, optical and geometric isomers, and salts of isomers 8525

(36) *alpha*-phenylacetoacetamide (APAA) and its optical isomers 8515

■ 3. In § 1310.04:

■ a. Redesignate paragraphs (g)(1)(vii) through (xiii) as paragraphs (g)(1)(x) through (xvi), respectively;

■ b. Redesignate paragraphs (g)(1)(i) through (vi) as paragraphs (g)(1)(ii) through (vii), respectively; and

■ c. Add new paragraphs (g)(1)(i), (viii), and (ix).

The additions read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(i) *alpha*-phenylacetoacetamide (APAA) and its optical isomers

* * * * *

(viii) 3,4-MDP-2-P methyl glycidate (PMK glycidate) and its optical and geometric isomers

(ix) 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) and its salts, optical and geometric isomers, and salts of isomers

* * * * *

■ 4. Amend § 1310.09 by adding paragraph (q) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(q)(1) Each person required under 21 U.S.C. 822 and 957 to obtain a registration to manufacture, distribute, import, or export regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidate (PMK glycidate), and *alpha*-phenylacetoacetamide (APAA), including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), or *alpha*-phenylacetoacetamide (APAA) pursuant to § 1310.13 on or before (30 days after publication of a rule implementing regulations regarding these three chemicals). The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a chemical mixture containing regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), or *alpha*-phenylacetoacetamide (APAA) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

■ 5. Amend § 1310.12(c) by adding in alphabetical order entries for 3,4-MDP-

2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), and *alpha*-phenylacetoacetamide (APAA) in the table ''Table of Concentration Limits'' to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code No.	Concentration	Special conditions
* * *	*	*	* * *
3,4-MDP-2-P methyl glycidate (PMK glycidate) and its optical and geometric isomers.	8535	Not exempt at any concentration.	Chemical mixtures containing any amount of this chemical are not exempt.
3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) and its salts, optical and geometric isomers, and salts of isomers.	8525	Not exempt at any concentration.	Chemical mixtures containing any amount of this chemical are not exempt.
alpha-phenylacetoacetamide (APAA) and its optical isomers.	8515	Not exempt at any concentration.	Chemical mixtures containing any amount of this chemical are not exempt.
* * *	*	*	* * *

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Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–26813 Filed 12–18–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 1270

[Docket No. FDA–2020–N–1519]

RIN 0910–AI41

Revocation of the Regulations for Human Tissue Intended for Transplantation and Human Dura Mater

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to revoke the regulations for human tissue intended for transplantation and human dura mater recovered prior to May 25, 2005. The proposed revocation does not affect the regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps) recovered on or after May 25, 2005. FDA is proposing this action because these regulations are obsolete or no longer necessary to achieve public health goals. This action is part of FDA's implementation of Executive Orders 13771 and 13777. Under these Executive Orders, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

DATES: Submit either electronic or written comments on the proposed rule by March 8, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 8, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 8, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1519 for ''Revocation of the Regulations for Human Tissue Intended for Transplantation.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS