

(5) *Forest Service*. (i) Civil penalty for willful disregard of the prohibition against the export of unprocessed timber originating from Federal lands, codified at 16 U.S.C. 620d(c)(1)(A), has a maximum of \$975,230 per violation or three times the gross value of the unprocessed timber, whichever is greater.

(ii) Civil penalty for a violation in disregard of the Forest Resources Conservation and Shortage Relief Act or the regulations that implement such Act regardless of whether such violation caused the export of unprocessed timber originating from Federal lands, codified in 16 U.S.C. 620d(c)(2)(A)(i), has a maximum of \$146,285 per violation.

(iii) Civil penalty for a person that should have known that an action was a violation of the Forest Resources Conservation and Shortage Relief Act or the regulations that implement such Act regardless of whether such violation caused the export of unprocessed timber originating from Federal lands, codified at 16 U.S.C. 620d(c)(2)(A)(ii), has a maximum of \$97,523 per violation.

(iv) Civil penalty for a willful violation of the Forest Resources Conservation and Shortage Relief Act or the regulations that implement such Act regardless of whether such violation caused the export of unprocessed timber originating from Federal lands, codified in 16 U.S.C. 620d(c)(2)(A)(iii), has a maximum of \$975,230.

(v) Civil penalty for a violation involving protections of caves, codified at 16 U.S.C. 4307(a)(2), has a maximum of \$21,314.

(6) [Reserved]

(7) *Federal Crop Insurance Corporation*.

(i) Civil penalty for any person who willfully and intentionally provides any false or inaccurate information to the Federal Crop Insurance Corporation or to an approved insurance provider with respect to any insurance plan or policy that is offered under the authority of the Federal Crop Insurance Act, or who fails to comply with a requirement of the Federal Crop Insurance Corporation, codified in 7 U.S.C. 1515(h)(3)(A), has a maximum of the greater of: The amount of the pecuniary gain obtained as a result of the false or inaccurate information or the noncompliance; or \$12,650.

(ii) [Reserved]

(8) *Rural Housing Service*. (i) Civil penalty for a violation of section 536 of Title V of the Housing Act of 1949, codified in 42 U.S.C. 1490p(e)(2), has a maximum of \$207,313 in the case of an individual, and a maximum of \$2,073,133 in the case of an applicant other than an individual.

(ii) Civil penalty for equity skimming under section 543(a) of the Housing Act of 1949, codified in 42 U.S.C. 1490s(a)(2), has a maximum of \$37,412.

(iii) Civil penalty under section 543b of the Housing Act of 1949 for a violation of regulations or agreements made in accordance with Title V of the Housing Act of 1949, by submitting false information, submitting false certifications, failing to timely submit information, failing to maintain real property in good repair and condition, failing to provide acceptable management for a project, or failing to comply with applicable civil rights laws and regulations, codified in 42 U.S.C. 1490s(b)(3)(A), has a maximum of the greater of: Twice the damages USDA, guaranteed lender, or project that is secured for a loan under Title V suffered or would have suffered as a result of the violation; or \$74,824 per violation.

(9) [Reserved]

(10) *Commodity Credit Corporation*.

(i) Civil penalty for willful failure or refusal to furnish information, or willful furnishing of false information under of section 156 of the Federal Agricultural Improvement and Reform Act of 1996, codified at 7 U.S.C. 7272(g)(5), has a maximum of \$16,449 for each violation.

(ii) Civil penalty for willful failure or refusal to furnish information or willful furnishing of false data by a processor, refiner, or importer of sugar, syrup and molasses under section 156 of the Federal Agriculture Improvement and Reform Act of 1996, codified at 7 U.S.C. 7272(g)(5), has a maximum of \$16,449 for each violation.

(iii) Civil penalty for filing a false acreage report that exceeds tolerance under section 156 of the Federal Agriculture Improvement and Reform Act of 1996, codified at 7 U.S.C. 7272(g)(5), has a maximum of \$16,449 for each violation.

(iv) Civil penalty for knowingly violating any regulation of the Secretary of the Commodity Credit Corporation pertaining to flexible marketing allotments for sugar under section 359h(b) of the Agricultural Adjustment Act of 1938, codified at 7 U.S.C. 1359hh(b), has a maximum of \$12,023 for each violation.

(v) Civil penalty for knowing violation of regulations promulgated by the Secretary pertaining to cotton insect eradication under section 104(d) of the Agricultural Act of 1949, codified at 7 U.S.C. 1444a(d), has a maximum of \$14,811 for each offense.

(11) *Office of the Secretary*. (i) Civil penalty for making, presenting, submitting or causing to be made, presented or submitted, a false, fictitious, or fraudulent claim as defined

under the Program Fraud Civil Remedies Act of 1986, codified at 31 U.S.C. 3802(a)(1), has a maximum of \$11,804.

(ii) Civil penalty for making, presenting, submitting or causing to be made, presented or submitted, a false, fictitious, or fraudulent written statement as defined under the Program Fraud Civil Remedies Act of 1986, codified at 31 U.S.C. 3802(a)(2), has a maximum of \$11,804.

John Rapp,

Acting Director, Office of Budget and Program Analysis.

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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-phenylacetamide (APAA) as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration is finalizing a December 21, 2020, notice of proposed rulemaking to designate three chemicals, known as PMK glycidate, PMK glycidic acid, and APAA, 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, and APAA is used in and is important to the manufacture of the schedule II controlled substances amphetamine and methamphetamine. This final rulemaking subjects 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.

DATES: Effective June 9, 2021.

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

SUPPLEMENTARY INFORMATION: This final rule designates the following chemicals as list I chemicals and subjects them to the regulatory requirements applicable to list I chemicals:

- 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*-phenylacetamide (APAA), including its optical isomers,.

Legal Authority

The Controlled Substances Act (CSA) and the Drug Enforcement Administration's (DEA) implementing regulations give the Attorney General, as delegated to the Administrator of DEA, the authority to specify, by regulation, a chemical as a "list I chemical."¹ 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.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

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 Commission on Narcotic Drugs (CND) voted to place the chemicals 3,4-MDP-2-P methyl glycidate (PMK glycidate) (and all stereoisomers), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) (and all stereoisomers), and *alpha*-phenylacetamide (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.

On December 21, 2020, DEA published a notice of proposed rulemaking (NPRM) [85 FR 82984] 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*-phenylacetamide (APAA), including its optical isomers, as list I chemicals under the CSA.³

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 3,4-methylenedioxymethamphetamine (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 to the International Narcotics Control Board (INCB) the illicit trafficking and use of these chemicals in manufacturing controlled substances, with increasing frequency and amounts reported in 2018 and 2019.⁴

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

In response to the December 21, 2020, NPRM, DEA received one anonymous comment expressing general opposition to the "war on drugs" and to the addition of more substances to the list

³ DEA proposed to control the same set of chemicals specified by the CND. However, DEA used more precise terms that relate to the specific chemical and variations that can actually exist.

⁴ 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) and Report of the International Narcotics Control Board for 2019 on the Implementation of Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (E/INCB/2019/1, Released February 27, 2020)

and under CSA control. DEA considers the general comment about the war on drugs to be outside the scope of this rulemaking.

Regarding the general opposition to listing more substances, DEA notes that it proposed to designate and add these three specific chemicals to the list as they met the statutory and regulatory definition of a list I chemical, and DEA is using its legal authority to so designate these chemicals as list I chemicals.

Therefore, for the reasons discussed in the NPRM, and reiterated in the above background section, the Acting Administrator of DEA finds that PMK glycidate, PMK glycidic acid, and APAA are used in the manufacture of controlled substances in violation of the CSA, and are important to the manufacture of these controlled substances. Therefore, the Acting Administrator designates PMK glycidate, PMK glycidic acid, and APAA as list I chemicals.

Chemical Mixtures of PMK Glycidate, PMK Glycidic Acid or APAA

Pursuant to this final rulemaking, 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. This rule modifies 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, including 21 CFR parts 1309, 1310, 1313, and 1316.

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.⁵ Manufacturers may submit an

⁵ 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 not a list I or list II chemical, and the mixture and its listed chemical(s) must meet certain other conditions.

¹ 21 U.S.C. 802(34) and 871(b) and 21 CFR 1310.02(c).

² 21 U.S.C. 802(34) and 21 CFR 1300.02(b).

application for exemption for those mixtures that do not meet the category criteria set forth in 21 CFR 1310.12(d) for an automatic exemption. DEA may grant an exemption of a chemical mixture if the Administrator determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and the listed chemical or chemicals contained in the chemical mixture cannot be readily recovered (*i.e.*, the chemical mixture meets the conditions set forth in 21 U.S.C. 802(39)(A)(vi) and 21 CFR 1310.13(a)(1)–(2)).

Requirements for Handling List I Chemicals

The designation of these three chemicals as list I chemicals subjects 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 the effective date of this final rulemaking, persons potentially handling these three chemicals, including regulated chemical mixtures containing any of these three chemicals, are 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 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.⁶ 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.⁷

DEA notes that under the CSA, a “warehouseman” is not required to register and may lawfully possess a list I chemical, if the possession of the chemical is in the usual course of business or employment.⁸ Under DEA implementing regulations, the warehouse in question must receive the list I chemical from a DEA registrant,

and shall only distribute the list I chemical back to the DEA registrant and registered location from which it was received.⁹ 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 the effective date of this final rulemaking, any person manufacturing, distributing, importing, or exporting 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 registration and for DEA to immediately issue registrations for those activities. Therefore, to allow continued legitimate commerce in these three chemicals, DEA is establishing 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 or application for exemption of chemical mixtures on or before June 9, 2021. 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, will 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 must 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 must submit to DEA manufacturing, inventory, and use data on an annual basis.¹⁰ Existing standard industry reports containing the required information are 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 or 21 CFR part 1310. 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.¹¹

3. *Importation and Exportation.* All importation and exportation of these three chemicals must be done 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 must 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. 880(b).

⁶ 21 CFR 1309.21.

⁷ 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.

⁸ 21 U.S.C. 822(c)(2) and 21 U.S.C. 957(b)(1)(B).

⁹ See 21 CFR 1309.23(b)(1).

¹⁰ 21 CFR 1310.05(d). See also 21 U.S.C. 830(b)(2).

¹¹ 21 U.S.C. 830(b)(1)(A)–(C) and 21 CFR 1310.05(a) and (b)(1).

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

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review and Improving Regulation and Regulatory Review

This rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. 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 rule is not a “significant regulatory action” under E.O. 12866, section 3(f).

As finalized, PMK glycidate, PMK glycidic acid, and APAA are 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 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 2018 and 2019.

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 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. However, DEA did not receive any public comments to that effect in response to the NPRM.

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, will incur costs if they are not already registered for handling List I chemicals. The primary costs associated with this rule are the annual registration fees (\$3,047 for manufacturers and \$1,523 for distributors, importers, and exporters). Moreover, 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. As finalized, suppliers for the legitimate use of PMK glycidate, PMK glycidic acid, and APAA are expected to choose the least-cost option, which in many cases may lead them to 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 rule is minimal.

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 them (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 action will minimize the diversion of PMK glycidate, PMK glycidic acid, and APAA. DEA believes the legitimate market for PMK glycidate, PMK glycidic acid, and APAA for legitimate pharmaceutical purposes is minimal. Thus, any potential cost resulting from this regulation is minimal.

Executive Order 12988, Civil Justice Reform

This 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The 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 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,¹² has reviewed this 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, PMK glycidate, PMK glycidic acid, and APAA will now become 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 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 rule are the annual

registration fees (\$3,047 for manufacturers and \$1,523 for distributors, importers, and exporters), but only if they are not already registered to handle any list I chemicals.

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 did not receive any comments to the contrary in response to the NPRM. DEA estimates that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995 (UMRA)

In accordance with the UMRA, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this rule will 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 action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action will 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.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses

of Congress and to the Comptroller General.

List of Subjects 21 CFR Part 1310

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

Accordingly, for the reasons set forth in the preamble, DEA amends 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. In § 1310.09, add paragraph (q) to read as follows:

¹² 5 U.S.C. 601–612.

§ 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 glycidic acid (PMK glycidic acid), 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. In § 1310.12, in paragraph (c), add in alphanumerical 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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D. Christopher Evans,
Acting Administrator.

[FR Doc. 2021-09697 Filed 5-7-21; 8:45 am]

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AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 228

[AID-2020-0004]

RIN 0412-AB09

Procurement of Certain Essential Medical Supplies To Address the COVID-19 Pandemic

AGENCY: Agency for International Development.

ACTION: Final rule; technical amendments.

SUMMARY: On October 23, 2020, the United States Agency for International

Development (USAID) issued a Temporary Final Rule (TFR) amending our regulations to allow USAID to waive “Source and Nationality” rules to provide for increased flexibility, targeting, and speed of procurement of Essential Medical Supplies required to address the COVID-19 pandemic worldwide. The TFR was effective through April 30, 2021. This document reverts the amended sections to the text of those sections as they existed prior to the issuance of the TFR, with minor technical updates. This reversion to the original text is applicable upon the expiration of the TFR.

DATES: This rule is effective May 10, 2021. As stated in the October 23, 2020, final rule, the TFR was effective from October 23, 2020, through April 30, 2021. The amendments in this rule are applicable beginning May 1, 2021, after the expiration of the TFR.

ADDRESSES: You may review the docket by searching for Docket ID [AID-2020-

0004], via the Federal eRulemaking Portal: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Greg Marchand, Assistant General Counsel, Office of the General Counsel, USAID, 1300 Pennsylvania Ave. NW, Washington, DC 20523, 202-215-3409, GCFEDREGMailbox@usaid.gov.

SUPPLEMENTARY INFORMATION: This document affects 22 CFR 228.01, which was amended by the TFR published in the **Federal Register** on October 23, 2020 (85 FR 67443) and subsequently corrected on December 16, 2020 (85 FR 81390). The TFR and its subsequent correction revised the definitions in § 228.01 by adding a new definition for “Essential medical supplies.” This document reinstates the definitions in § 228.01 exactly as they existed prior to the issuance of the TFR. This document also reverts 22 CFR 228.11 and 228.30, which were also amended by the TFR published in the **Federal Register** on October 23, 2020 (85 FR 67443). The TFR amended these sections to create a