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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-379]

RIN 1117-ZA04

Designation of Alpha-Phenylacetonitrile (APAAN), a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing to designate the chemical alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, as a list I chemical under the Controlled Substances Act. APAAN is used in clandestine laboratories to illicitly manufacture the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone or P2P), methamphetamine, and amphetamine and is important to the manufacture of these controlled substances. This action does not propose the establishment of a threshold for domestic and international transactions of APAAN. As such, all transactions involving APAAN, regardless of size, would be regulated. In addition, this action proposes that chemical mixtures containing APAAN would not be exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures

containing any quantity of APAAN would be regulated pursuant to the Controlled Substances Act.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. 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-379” on all correspondence, including any attachments.

The Drug Enforcement Administration 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 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/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

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

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 (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your

comment. You must also prominently identify 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 proposed rule is available at <http://www.regulations.gov> for easy reference.

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the

illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

The CSA gives the Attorney General the authority to specify, by regulation, chemicals as list I or list II chemicals. 21 USC 802 (34) and (35). A “list I chemical” is a chemical that is used in manufacturing a controlled substance in violation of title II of the CSA and is important to the manufacture of the controlled substance. 21 U.S.C. 802(34). A “list II chemical” is a chemical (other than a list I chemical) that is used in manufacturing a controlled substance in violation of title II of the CSA. 21 U.S.C. 802(35). The current list of all listed chemicals is published at 21 CFR 1310.02. Pursuant to 28 CFR 0.100(b), the Attorney General has delegated her authority to designate list I and list II chemicals to the Administrator of the Drug Enforcement Administration.

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). When the United States receives notification that a chemical has been added to Table I or Table II of the 1988 Convention pursuant to article 12, the United States is required to take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion. In addition, the 1988 Convention requires the United States to take other specified measures related to that chemical, including measures related to its international trade.

Background

By a letter dated April 9, 2014, the Secretary-General of the United Nations informed the United States Government that the chemical alpha-phenylacetoacetonitrile (APAAN) was added to Table I of the 1988 Convention. This letter was prompted by a March 19, 2014, decision at the 57th Session of the United Nations Commission on Narcotic Drugs (CND) to add APAAN to Table I. As a Party to the 1988 Convention, the United States is obligated, pursuant to article 12, to take measures it deems appropriate to monitor the manufacture and distribution of APAAN within the United States and to prevent its diversion. Article 12 also obligates the United States to take other specified measures related to APAAN, including measures related to its international trade. By designating APAAN as a list I chemical, the United States will fulfill its obligations under the 1988 Convention.

APAAN is a primary precursor for the manufacture of phenylacetone (also known as phenyl-2-propanone (P2P) or benzyl methyl ketone), methamphetamine, and amphetamine. Throughout the 1970s, methamphetamine was illicitly produced in the United States, primarily with the precursor chemical P2P. In response to the illicit use of P2P, the DEA controlled P2P as a schedule II controlled substance in 1980 pursuant to the “immediate precursor” provisions of the CSA, specifically 21 U.S.C. 811(e). Clandestine laboratory operators responded by developing a variety of synthetic methods for producing P2P.

Congress and the DEA responded with the implementation of controls on P2P precursor chemicals such as phenylacetic acid (and its salts and esters), acetic anhydride, benzyl cyanide, benzaldehyde, and nitroethane, all of which are controlled as listed chemicals. 21 CFR 1310.02 (a)–(b). However, clandestine laboratory operators soon adjusted to these controls on P2P (and its precursors). As an alternative for methamphetamine production, clandestine laboratory operators used the precursors ephedrine and pseudoephedrine, and as an alternative for amphetamine production, they used the precursor phenylpropanolamine.

This led Congress and the DEA to implement stringent controls on the manufacture, distribution, importation, and exportation of ephedrine (its salts, optical isomers, and salts of optical isomers), pseudoephedrine, and phenylpropanolamine (controlled as list I chemicals), and pharmaceutical products containing these chemicals. The international community soon took similar measures.

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 amphetamine-type stimulants (including amphetamine and methamphetamine), and international control of precursors, have made significant progress. International controls on precursors were established under article 12 of the 1988 Convention.¹ The 1988 Convention established two categories of controlled illicit drug precursor substances:

¹ Dec. 20, 1988, 1582 U.N.T.S. 95.

Table I and Table II.² 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.

In response to domestic and international controls on amphetamine and methamphetamine precursors, clandestine laboratory operators have continued to explore alternate methods of making these illicit drugs, including developing techniques to manufacture their own precursors and diverting other precursors to produce these precursors. This has led clandestine laboratory operators to utilize the P2P precursor APAAN. Clandestine laboratory operators currently use APAAN to manufacture P2P, which they then convert to methamphetamine and amphetamine.

APAAN

APAAN also goes by the names: 1-cyano-1-phenylpropan-2-one; 2-phenylacetonitrile; 2-acetyl-2-phenylacetonitrile; alpha-acetyl-benzene acetonitrile; phenyl aceto-acetonitrile; α -acetylphenylacetonitrile; 3-oxo-2-phenylbutanenitrile; CAS Number: 4468-48-8; and Identification Number: UN3439.

The DEA has long been aware of APAAN's potential illicit use as a primary precursor for the production of P2P. The synthesis of P2P from benzyl cyanide involves the manufacture of APAAN prior to the final synthesis of P2P. Therefore, benzyl cyanide and APAAN share the same synthetic pathway in the production of P2P. In the

² Table I and Table II are annexed to the Convention.

late 1980's the DEA advocated for the Congressional control of the P2P precursor benzyl cyanide as a list I chemical.

Due to the lack of industrial uses of APAAN, there has historically been a lack of available product for potential diversion. In recent years, however, large international seizures of APAAN have been made, primarily in Europe, which suggest there is a ready supply of APAAN from international chemical manufacturers.

While the DEA has encountered one clandestine laboratory in the United States utilizing this synthetic pathway in recent years, the DEA's European counterparts have made a large number of APAAN seizures. For calendar years 2009 through 2014, the European Commission has documented at least 113 seizures and stop shipments, involving over 80 metric tons of APAAN. Many of these seizures were associated with seizures of P2P and amphetamine. Many of these APAAN seizures originated from chemical suppliers based in Asia.

The DEA has determined that APAAN is now readily available from commercial chemical suppliers and has identified 34 potential suppliers in China, 6 potential suppliers in the United States, 2 in Russia, and 1 each in Bulgaria, Cameroon, the Czech Republic, France, and Germany.

The DEA is concerned about the ease with which APAAN serves as a precursor chemical for illicit controlled substance production and with the international trafficking in this chemical. The international community echoes this concern. As noted above, the

CND has added APAAN to Table I of the 1988 Convention. Therefore, the DEA is proposing the designation of APAAN as a list I chemical.

Proposed Designation of APAAN and its Salts, Optical Isomers, and Salts of Optical Isomers as a List I Chemical

The CSA, specifically 21 U.S.C. 802(34), and its implementing regulations at 21 CFR 1310.02(c), provides the Attorney General with the authority to specify, by regulation, a chemical as a “list I chemical” if the chemical is used in the manufacture of a controlled substance in violation of the CSA and is important to the manufacture of these controlled substances. Clandestine laboratory operators are using APAAN as the precursor material for the illicit manufacture of P2P, methamphetamine, and amphetamine. These three substances are all controlled substances under the CSA. APAAN is a primary precursor for P2P, for subsequent conversion to methamphetamine or amphetamine. Therefore, APAAN is important to the manufacture of a controlled substance. This action proposes the designation of APAAN as a list I chemical because the DEA finds that APAAN is used in the illicit manufacture of these controlled substances and is important to the illicit manufacture of these controlled substances.

If finalized, handlers of APAAN 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 APAAN can make a significant amount of P2P, this action does not propose the establishment of a threshold for domestic and import transactions of APAAN in accordance with the provisions of 21 CFR 1310.04(g). Therefore, the DEA is

proposing that all APAAN transactions, regardless of size, will be regulated transactions as defined in 21 CFR 1300.02(b). As such, if finalized, all APAAN transactions will be subject to recordkeeping, reporting, import and export controls, and other CSA chemical regulatory requirements. In addition, each regulated bulk manufacturer shall submit manufacturing, inventory, and use data on an annual basis.

Chemical Mixtures of APAAN

This rulemaking also proposes that chemical mixtures containing APAAN would not be exempt from regulatory requirements at any concentration unless an application for exemption of a chemical mixture is submitted by an APAAN manufacturer and the application is reviewed and accepted and the mixture exempted by the DEA under 21 CFR 1310.13 (Exemption by Application Process). Since even a small amount of APAAN yields a significant amount of P2P, the DEA believes that regulation of chemical mixtures containing any amount of APAAN is necessary to prevent the illicit extraction, isolation, and use of the APAAN. Therefore, all chemical mixtures containing any quantity of APAAN would be subject to CSA control, unless the APAAN manufacturer is granted an exemption by the application process in accordance with 21 CFR 1310.13. This rule proposes the modification of the “Table of Concentration Limits” in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of APAAN are subject to CSA chemical control provisions.

Exemption by Application Process

The DEA has implemented an application process to exempt certain chemical mixtures from the requirements of the CSA and its implementing regulations. 21 CFR 1310.13. Manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status may be granted if the DEA 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 that the listed chemical or chemicals cannot be readily recovered. 21 CFR 1310.13(a) (1)–(2).

Requirements for Handling List I Chemicals

If finalized as proposed, the designation of APAAN as a list I chemical will subject APAAN 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, importing, and exporting of a list I chemical. Upon publication of a final rule, persons potentially handling APAAN, including regulated chemical mixtures containing APAAN, would be required to comply with the following list I chemical regulations:

1. *Registration.* Any person who manufactures, distributes, imports, or exports APAAN, or proposes to engage in the manufacture, distribution, importation, or exportation of APAAN, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309. Consistent with 21 CFR Parts 1309 and 1310, separate registrations will

be required for manufacturing, distribution, importing, and exporting of APAAN.

Different locations operated by a single entity require separate registration if any location is involved with the manufacture, distribution, importation, or exportation of APAAN.

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. 21 CFR 1309.23. Any person manufacturing, distributing, importing, or exporting an APAAN chemical mixture will be subject to the registration requirement under the CSA as well.

The DEA notes that warehouses are exempt from the requirement of registration and may lawfully possess list I chemicals, if the possession of those chemicals is in the usual course of business or employment. 21 U.S.C. 822(c)(2), 21 U.S.C. 957(b)(1)(B). For purposes of this exemption, the warehouse 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. All other activities conducted by a warehouse do not fall under this exemption; 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. 21 CFR 1309.23(b)(1).

Upon publication of a final rule, any person manufacturing, distributing, importing, or exporting APAAN or a chemical mixture containing APAAN will become subject to the registration requirement under the CSA. The DEA recognizes, however, that it is not

possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for the DEA to immediately issue registrations for those activities. Therefore, to allow continued legitimate commerce in APAAN, the 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 APAAN, provided that the DEA receives a properly completed application for registration on or before 30 days after publication of a final rule implementing regulations regarding APAAN. The temporary exemption for such persons will remain in effect until the 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 APAAN and chemical mixtures containing APAAN will be regulated while an application for registration or exemption is pending. This is necessary because not regulating 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 APAAN, nor does it supersede State or local laws or regulations. All handlers of APAAN 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 reports with respect to APAAN pursuant to 21 U.S.C. 830 and in accordance with 21 CFR part 1310. Pursuant to 21 CFR 1310.04, 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 will be required to submit manufacturing, inventory, and use data on an annual basis. 21 CFR 1310.05(d). Existing standard industry reports containing the required information will be acceptable, provided the information is separate or readily retrievable from the report.

21 CFR 1310.05(a) requires that each regulated person shall report to the 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 the CSA and its corresponding regulations. Regulated persons are also required to report any proposed regulated transaction with a person whose description or other identifying characteristics the Administration 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; any in-transit loss in which the regulated person is the supplier; and any domestic regulated transaction in a tableting or encapsulating machine.

3. *Importation and Exportation.* All importation and exportation of APAAN 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 (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.

6. *Liability.* Any activity involving APAAN 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 and 13563

This notice of proposed rulemaking, which proposes the designation of APAAN as a list I chemical, has been developed in accordance with the principles of Executive Orders 12866 and 13563. The DEA followed the principles of these Executive Orders, even though it has been determined that this action is not a significant regulatory action.

To determine whether this action is a significant regulatory action, the DEA utilized a least cost option analysis. At the outset, the DEA determined that the primary costs of this rule would come from complying with the registration, recordkeeping, reporting, and export and import requirements set forth in the CSA. Therefore, under the least cost option, an entity would choose to discontinue the sale of APAAN if proceeds from the sale are less than the cost of complying with the rule.

The DEA has not identified any industrial uses of APAAN by domestic entities and its potential usage appears to be limited to research. Based on independent research following a 2013 United Nations Questionnaire/Survey on APAAN, the DEA identified three entities that have each imported APAAN. Two of the three entities had average annual sales of APAAN totaling \$13 during the analysis period. The third entity had average annual sales of APAAN totaling \$1,440 during the same period. Other chemical distributors list APAAN in their chemical catalogs. However, these entities do not manufacture APAAN, instead opting to purchase APAAN from international sources to fill special orders. These entities do not stock APAAN in inventory and the vast majority had no previous sales of APAAN.

The registration fee to import a list I chemical is \$1,523 per year. Based on the least cost option, these three entities would choose to discontinue the sale of APAAN because complying with the rule is more costly. Thus, the annual economic impact of the rule is \$1,467 (total annual sales of APAAN from the three affected entities). Therefore, this is

evidence that this proposed rule would not have an annual effect on the economy of \$100 million or more and is not a significant regulatory action.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 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

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

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 (RFA), 5 U.S.C. 601–612, 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. The purpose of this proposed rule is to designate APAAN as a list I chemical under the CSA. No less restrictive measures (i.e., non-control or control in list II) would enable the DEA to meet its statutory obligation under the CSA and its international obligations of the 1988 Convention. The DEA estimates that this rule affects three small entities. As discussed above, the DEA compared the dollar value of APAAN sales to the cost of registration. Further, the DEA assumed that if the cost of registration is more than the dollar value of APAAN sales, then each entity would discontinue the sale of APAAN.

Two entities earned \$13 in annual sales of APAAN while the third entity earned \$1,440 in annual sales of APAAN. The cost of registration alone is \$1,523 for each entity. Therefore, the DEA anticipates that each entity will discontinue the sale of APAAN because the cost of compliance is greater than the annual sales. As a result, the annual economic impact of the rule is \$1,467.

Using 1% of annual revenue as the criteria for significant economic impact, the DEA estimates that none of the three small entities will experience a significant economic impact if the proposed rule is finalized. The cost of the rule as a percentage of annual revenue for the three entities is, 0.00044%, 0.00036%, and 0.038%, respectively, which is

less than 1% of the entities' annual income. Therefore, the proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. The DEA does not anticipate that it will receive new registration applications for the purpose of engaging in transactions involving this chemical. The transactions in this chemical of which the DEA is aware are very small, and it does not appear to the DEA that it would be economically justifiable because DEA believes there is no legitimate market for manufacturing or engaging in commercial transactions in this chemical. 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 21 CFR Part 1310

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

Accordingly, for the reasons set forth in the preamble, part 1310 of title 21 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1310-- RECORDS AND REPORTS OF LISTED CHEMICALS AND 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. Amend § 1310.02 by redesignating paragraphs (a)(1) through (a)(30) as paragraphs (a)(2) through (a)(31), respectively, and adding a new paragraph (a)(1) in the table “List I chemicals” to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

(1) Alpha-phenylacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN).....8512

* * * * *

3. Amend § 1310.04 by redesignating paragraphs (g)(1)(i) through (g)(1)(x) as paragraphs (g)(1)(ii) through (g)(1)(xi), respectively, and adding a new paragraph (g)(1)(i) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(i) Alpha-phenylacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN)

* * * * *

4. Amend § 1310.09 by adding new paragraph (n) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(n)(1) Each person required under Sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, including regulated chemical mixtures pursuant to Section 1310.12 of this part, is temporarily exempted from the registration requirement, provided that the DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, pursuant to Section 1310.13 of this part on

or before (30 days after publication of a Final Rule implementing regulations regarding APAAN). 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 alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers whose application for exemption is subsequently denied by the DEA must obtain a registration with the DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that the 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 the DEA takes final action on their registration application.

5. Amend § 1310.12 paragraph (c) by adding in alphabetical order an entry “Alpha-phenylacetonitrile, and its salts, optical isomers, and salts of optical isomers. (APAAN)” 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

Alpha-phenylacetonitrile, and its salts, optical isomers, and salts of optical isomers. (APAAN).....	8512	Not exempt at any concentration. Chemical mixtures containing any amount of APAAN are not exempt.

* * * * *

Dated: December 2, 2016

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016-29523 Filed: 12/9/2016 8:45 am; Publication Date: 12/12/2016]