

Chemical Handler's Manual

A Guide to Chemical Control Regulations

Revised 2022¹

¹ This manual replaces all previous editions of the Chemical Handler's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

DEA Chemical Handler's Manual

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This manual was prepared by the Drug Enforcement Administration (DEA), Diversion Control Division, to assist those persons who handle scheduled listed chemical products and List I and II chemicals in understanding the Federal Controlled Substances Act and its implementing regulations as they pertain to regulated chemicals.

Guidance documents, such as this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement.

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SECTION I - INTRODUCTION

Disclaimer

This Chemical Handler's Manual is intended to summarize and explain the basic requirements for the handling of List I and List II chemicals under the Controlled Substances Act (CSA), [Title 21 United States Code \(U.S.C.\) 801-904](#); the Controlled Substances Import and Export Act (CSIEA), [21 U.S.C. 951-971](#); and DEA regulations, Title 21 Code of Federal Regulations ([CFR](#)), [Parts 1300 to End](#). Pertinent citations to the law and regulations are included in this manual.

This manual is not a legal document. It is a guide to explain select DEA regulations concerning those chemicals regulated by DEA. Readers should refer to the most current copy of the laws (CSA and CSIEA), regulations (CFR), and [Federal Register \(FR\) notices](#) to obtain a complete and accurate representation of regulated chemical laws and regulations.

Printed copies of the complete regulations implementing the CSA (21 CFR Parts 1300 to End) may be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402
1-866-512-1800

Both the CFR and the FR (which includes proposed and final rules implementing the CSA) are available on the Internet through the U.S. Government Printing Office (GPO) website. This website, which provides information by section, citation, and keywords, can be accessed at:

www.govinfo.gov

Unofficial copies of pertinent CFR citations and this chemical handler's manual may be found on the Internet within DEA's Diversion Control Division website:

www.DEAdiversion.usdoj.gov

Should any pertinent provisions of the law or regulations be modified in the future, DEA will issue a revised electronic version of this document, which will be posted on DEA's Diversion Control Division website.

If you encounter errors in this document, please notify the following: ODLP@dea.gov or

Diversion Control Division
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Springfield, VA 22152

Inquiries regarding topics within this document may be addressed with your local [DEA Diversion Field Office](#) (listed in [Appendix P](#)) or the address above.

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Message from the Deputy Assistant Administrator

The DEA Diversion Control Division is pleased to provide you with the 2021 edition of the Chemical Handler's Manual.

The production of illegal drugs such as methamphetamine, cocaine, heroin, and MDMA (ecstasy) requires the utilization of various precursor chemicals. DEA's strategy is to deny these precursor chemicals to drug trafficking organizations and, at the same time, to ensure an adequate supply for commercial licit markets.

The listed chemicals ephedrine, pseudoephedrine, and phenylpropanolamine are used in, and are important to, the illicit manufacture of methamphetamine. Methamphetamine is a highly addictive drug with potent central nervous system stimulant properties. Control as a schedule II substance and the removal of methamphetamine injectable formulations from the United States market, combined with a better appreciation for its high abuse potential, led to a drastic reduction in the abuse of this drug in 1971. However, it is currently considered a major drug of abuse. The widespread availability of methamphetamine today is largely fueled by illicit production in and importation from Mexico with a much smaller amount being manufactured in small capacity production laboratories in the United States.

Since 2004, Congress has passed three laws relating to the regulation of listed chemicals used in the illicit production of methamphetamine and other controlled substances. The Combat Methamphetamine Epidemic Act of 2005 (CMEA) ([Pub. L. 109-177](#)) contained new requirements relating to self-certification for retail sales of scheduled listed chemical products, instituted production quotas for ephedrine, pseudoephedrine, and phenylpropanolamine, and imposed enhanced criminal penalties for methamphetamine production and trafficking.

The Methamphetamine Production Prevention Act of 2008 ([Pub. L. 110-415](#)) facilitated the use of electronic CMEA-mandated logbooks by allowing greater flexibility regarding the capture of logbook information.

The Combat Methamphetamine Enhancement Act of 2010 ([Pub. L. 111-268](#)) extended CMEA's self-certification requirements to include mail-order distributors and made it unlawful to distribute a scheduled listed chemical product to a regulated seller or mail-order distributor who is not currently on the list of self-certified persons maintained by DEA.

I hope that you will find the Chemical Handler's Manual useful and informative. Your role in the proper handling of listed chemicals is critical to protect the public from drug abuse and diversion.

Sincerely,

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

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Preface

In October 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act, better known as the [CSA](#), to consolidate and replace more than 50 pieces of national drug legislation. The CSA went into effect on May 1, 1971. DEA was established in 1973 to serve as the single federal agency to coordinate the Federal Government's drug control activities.

Various quantities of chemicals are required to synthesize, extract, and purify most illicit drugs. DEA has long recognized the need to monitor these chemicals as part of its overall drug control strategy. During the 1980s there was a tremendous increase in the clandestine production of controlled substances, particularly methamphetamine. There was also a proliferation of clandestine laboratories producing controlled substance analogues, very potent and dangerous variations of controlled narcotics, stimulants, and hallucinogens. Furthermore, DEA learned that U.S. firms were exporting large quantities of chemicals, such as acetone, methyl ethyl ketone, and potassium permanganate to cocaine producing countries. Significant amounts of these chemicals ultimately were diverted to clandestine cocaine laboratories. It became clear that mandatory restrictions were needed to control the distribution of these chemicals to have an impact on the clandestine laboratory problem.

DEA embarked upon a broad chemical control program in 1989 that was based on the Chemical Diversion and Trafficking Act (CDTA) of 1988 ([Pub. L. 100-690](#)). The CDTA regulated 12 precursor chemicals (now referred to as List I chemicals), eight essential chemicals (now referred to as List II chemicals), tableting machines, and encapsulating machines by imposing recordkeeping and reporting requirements on certain transactions. The number of chemicals currently controlled under the CSA is 47. These actions resulted in reducing the supply of illicit methamphetamine as evidenced by a reduction in the number of clandestine laboratories seized in the first three years following the law's implementation. Maintaining this success requires continuous effort to thwart traffickers' never-ending search for new methods of diversion. Current List I and List II chemicals can be found at [21 CFR 1310.02](#).

The foundation of the Federal Government's program to prevent chemical diversion includes additional laws such as the Domestic Chemical Diversion Control Act of 1993 (DCDCA) ([Pub. L. 103-200](#)), the Comprehensive Methamphetamine Control Act of 1996 (MCA) ([Pub. L. 104-237](#)), the Methamphetamine Anti-Proliferation Act of 2000 (MAPA) ([Pub. L. 106-310](#)), the CMEA ([Pub. L. 109-177](#)), the Methamphetamine Production Prevention Act of 2008 (MPPA) ([Pub. L. 110-415](#)), and the Combat Methamphetamine Enhancement Act of 2010 (MEA) ([Pub. L. 111-268](#)). Some highlights of the successes of these laws are discussed below.

- When the quantity of U.S. chemicals shipped to cocaine manufacturing countries declined due to CDTA, chemical suppliers from other parts of the world emerged as new sources of supply. The United States government then undertook an aggressive international campaign to educate and elicit the support of other nations in establishing chemical controls. Today, there is a broad level of international agreement regarding the actions that must be taken to achieve chemical control. The cornerstone of international chemical control is the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, also known as the 1988 UN Convention. Many nations have passed laws to prevent the diversion of chemicals.
- As a result of government controls, ephedrine and other chemicals used to manufacture methamphetamine became more difficult to obtain. Traffickers began using over-the-counter

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capsules and tablets that contained ephedrine since these products were not regulated under CDTA requirements. In 1993, the DCDCA closed this loophole and required DEA registration for all manufacturers, distributors, importers, and exporters of List I chemicals. It also established recordkeeping and reporting requirements for transactions of single-entity ephedrine products.

- When single-entity ephedrine products became regulated, drug traffickers turned to pseudoephedrine. This change in strategy was addressed by the MCA by expanding regulatory control of lawfully marketed drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine.
- MAPA focused on the continuing retail level diversion by restricting retail transactions of pseudoephedrine and phenylpropanolamine drug products. It reduced the threshold for such transactions from 24 grams to nine grams of pseudoephedrine base or phenylpropanolamine base in a single transaction and limited package sizes to contain no more than three grams of pseudoephedrine base or phenylpropanolamine base. MAPA also increased penalties for chemical diversion and provided for restitution to the government for clandestine laboratory cleanup costs.

(Due to concerns regarding harmful side effects that phenylpropanolamine can have, on November 6, 2000, the Food and Drug Administration (FDA) issued a public health advisory and requested that all drug companies discontinue marketing products containing phenylpropanolamine.)

- The CMEA further restricted retail level transactions by redefining nonprescription products that contain ephedrine, pseudoephedrine, or phenylpropanolamine as “scheduled listed chemical products (SLCP).” Effective September 30, 2006, the CMEA required all regulated sellers of SLCPs to complete a training and self-certification process. On this date, regulated sellers were mandated to keep all SLCPs behind the counter or in a locked cabinet. Consumers wishing to purchase SLCPs are now required to show identification and sign a logbook for each purchase. The CMEA also established daily sales limits of 3.6 grams per customer for each chemical and limits purchases of these products to nine grams in a 30-day period by any person. Furthermore, mail-order limits were set at 7.5 grams per customer for each chemical in a 30-day period.
- The MPPA amended the existing language of the CMEA to facilitate the creation of electronic logbooks. Several options were provided for obtaining signatures of purchasers and recording transactions at the time of sale.
- The MEA established new requirements for mail-order distributors of SLCPs. Mail-order distributors who sell SLCPs at retail must now train their employees and complete a self-certification process similar to that of a regulated seller.

All these federal laws (CDTA, DCDCA, MCA, MAPA, CMEA, MPPA, and MEA) imposed varying degrees of requirements on the chemical and pharmaceutical industries. Yet, the involvement of private industry as well as the general public should not be limited to the laws enacted by Congress. The voluntary support by industry forms a powerful resource for protecting the health and safety of the nation. DEA encourages each firm to be vigilant and to become a partner in combating the diversion of chemicals and tableting and encapsulating machines used in illegal drug production.

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It is DEA's goal to effectively regulate while maintaining a positive working relationship with the regulated community. DEA seeks to inform and educate industry on the CSA and its implementing regulations. DEA understands that it can best serve the public interest by working in voluntary cooperation with the chemical and pharmaceutical industries to develop programs designed to prevent the diversion of legal pharmaceutical controlled substances and regulated chemicals into the illicit market. For additional information on all the federal Laws and the self-certification process please visit www.DEAdiversion.usdoj.gov.

SECTION II - DEFINITIONS

The official language for the definitions presented in this section can be found at [21 CFR 1300.02](#) or as noted by the specific term.

At Retail

A sale or purchase for personal use of a scheduled listed chemical product.

Broker and Trader

Any individual, corporation, corporate division, partnership, association, or other legal entity, which assists in arranging an international transaction in a listed chemical by:

- Negotiating contracts;
- Serving as an agent or intermediary; or
- Fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

Chemical Exporter

A regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

Chemical Importer

A regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

Chemical Mixture

A combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

Encapsulating Machine

Any manual, semi-automatic, or fully automatic equipment, which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

Established Business Relationship

The regulated person has imported or exported a listed chemical at least once within the past six months, or twice within the past twelve months from or to a foreign manufacturer, distributor, or end user of the chemical that has an established business with a fixed street address. A person or business that functions as a broker or intermediary is not a customer for purposes of this definition.

Established Record as an Importer

The regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months, from a foreign supplier.

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Excluded Transactions

Pursuant to [21 U.S.C. 802\(39\)\(A\)\(iii\)](#), certain transactions have been excluded from the definition of regulated transactions (see [Appendix E](#)).

Exempt Chemical Mixtures

A mixture containing a listed chemical in concentrations equal to or less than those specified in the "Table of Concentration Limits" detailed in [21 CFR 1310.12](#) is exempt from CSA chemical regulatory provisions such as registration, recordkeeping, and import/export notification requirements (see [Appendix F](#)). [Appendix G](#) provides four categories of chemical mixtures that are automatically exempt.

International Transaction

A transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

Listed Chemical

Any List I or List II chemical. A complete list can be found at [21 CFR 1310.02](#).

List I Chemical

A chemical specifically designated in [21 CFR 1310.02\(a\)](#) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of a controlled substance.

List II Chemical

A chemical, other than a List I chemical, specifically designated in [1310.02\(b\)](#) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA.

Mail-Order Sale

A retail sale of scheduled listed chemical products for personal use (a specially defined term, see below in this list) where a regulated person uses or attempts to use the U.S. Postal Service or any private or commercial carrier to deliver the product to the customer. This includes purchase orders submitted by phone, mail, fax, Internet, or any method other than face-to-face transaction. [21 CFR 1314.03](#).

Manufacture

The production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. [21 U.S.C. 802\(15\)](#).

Mobile Retail Vendor

A person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

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Net Disposal

A complete definition can be found at [21 CFR 1315.02](#).

Person

Any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

Readily Retrievable

Certain records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Registrant

Any person registered with DEA.

Regular Customer

A person with whom the regulated person has an established business relationship for a specified listed chemical(s) that has been reported to DEA.

Regular Importer

With respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to DEA.

Regulated Person

Any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or encapsulating machine.

Regulated Seller

A retail distributor, including a pharmacy or a mobile retail vendor. This term does not include an employee or agent of such distributor.

Regulated Transaction

1. A distribution, receipt, sale, importation or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if DEA establishes a threshold amount for a specific listed chemical, a threshold amount as determined by DEA which includes a cumulative threshold amount for multiple transactions of a listed chemical.

A regulated transaction does not include:

- A. A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.
- B. A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the

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lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with [21 CFR Parts 1309, 1310, 1313, and 1315](#).

- C. Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;
 - D. Any transaction in a listed chemical that is contained in a drug other than a scheduled listed chemical product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to paragraph (1)(v) of the definition of regulated transaction found at [21 CFR 1300.02\(b\)](#), unless -
 - (1) The DEA has determined pursuant to the criteria in [21 CFR 1310.10](#) that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and
 - (2) The quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical;
 - E. Any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under [21 CFR 1310.03\(c\)](#); or
 - F. Any transaction in a chemical mixture designated in [21 CFR 1310.12](#) and [1310.13](#) that DEA has exempted from regulation.
2. A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person, in this context, agents or employees means individuals under the direct management and control of the regulated person.

Retail Distributor

A grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

Scheduled Listed Chemical Product (SLCP)

1. A product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.
2. Scheduled listed chemical product does not include any product that is a controlled substance under part 1308 of this chapter. In the absence of such scheduling by the Attorney General, a chemical specified in paragraph (1) of this definition may not be considered to be a controlled substance.

Tableting Machine

Any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

SECTION III - REGISTRATION REQUIREMENTS

Who Must Register

Information regarding general requirements of registration may be found at 21 U.S.C. [822](#), [823](#), [824](#), [957](#), [958](#); and at [21 CFR Part 1309](#) and [21 CFR 1310.12](#) and [1310.13](#).

Pursuant to [21 U.S.C. 822\(a\)](#), [957\(a\)](#), and [958\(c\)](#), the following persons must annually obtain a DEA registration specific to the List I chemicals to be handled:

1. Every person who manufactures or imports or proposes to manufacture* or import a List I chemical or a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine.
2. Every person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under paragraph (iv) of the definition of regulated transaction found at [21 CFR 1300.02\(b\)](#). [21 CFR 1309.21\(a\)](#).

(*See [Section II, Definitions for a complete definition of manufacture.](#))

Only persons actually engaged in the activities are required to obtain a registration; related or affiliated persons who are not engaged in the activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.) [21 CFR 1309.21\(b\)](#).

Persons who handle List II chemicals only are not required to register with DEA; however, they are required to maintain records and file reports equivalent to the requirements explained elsewhere in this manual for List I chemical handlers. [21 CFR 1310.02\(b\)](#); [21 CFR 1310.03](#).

Factors Used by DEA in Determining Approval of List I Chemical Applications

[Title 21 U.S.C. 823\(h\)](#) lists the factors used by DEA in evaluating whether a registration would be inconsistent with the public interest when determining approval of List I chemical applications for manufacturer applicants who will distribute List I chemicals as a coincident activity of manufacturing (see [21 CFR 1309.21\(c\)\(1\)](#)) and applicants who will distribute List I chemicals:

1. Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
2. Compliance by the applicant with applicable Federal, State, and local law;
3. Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
4. Any past experience of the applicant in the manufacture and distribution of chemicals; and
5. Such other factors as are relevant to and consistent with the public health and safety.

The above factors are also used by DEA in evaluating whether a registration would be inconsistent with the public interest when determining approval of List I chemical applications for importer and exporter applicants. [21 U.S.C. 958\(c\)\(2\)\(A\)-\(B\)](#).

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Registration is not required under 21 U.S.C. 823(h) or 958(c)(2) for the distribution, import, or export of a drug product that is exempted under 21 U.S.C. 802(39)(A)(iv). [21 U.S.C. 823\(h\)](#); [21 U.S.C. 958\(c\)\(2\)\(A\)](#).

Exceptions to Registration

There are waivers of registration requirements for certain activities, exemptions for law enforcement officials, an exemption for regulated sellers of SLCP, and an exemption for mail-order distributors of SLCPs. These waivers and exemptions are explained in the following paragraphs. There are also registration exemptions for handlers of certain chemical mixtures. A table of exempt chemical mixtures can be found in [Appendix F](#). [Appendix G](#) provides four categories of chemical mixtures that are automatically exempt. Detailed information on chemical mixtures can be found in [21 CFR 1310.12](#) and [1310.13](#).

Waiver of Registration Requirement for Certain Activities

Information regarding these waivers may be found at [21 CFR 1309.24](#).

Pursuant to [21 CFR 1309.24](#), the following activities are deemed to be waived from the requirement of registration:

1. Any agent or employee of a person who is registered to engage in any group of independent activities, if the agent or employee is acting in the usual course of his or her business or employment.
2. Any person who manufactures or distributes an SLCP or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of "regulated transaction" found at [21 CFR 1300.02](#), if that person is registered with DEA to engage in the same activity with a controlled substance.
3. Any person who imports or exports an SLCP or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of "regulated transaction" found at [21 CFR 1300.02](#), if that person is registered with DEA to engage in the same activity with a controlled substance.
4. Any person who only distributes a prescription drug product containing a List I chemical that is regulated pursuant to paragraph (1)(iv) of the definition of regulated transaction found at [21 CFR 1300.02](#).
5. Any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to another location operated by the same firm solely for internal end-use, or an Environmental Protection Agency (EPA) or state licensed waste treatment or disposal firm for waste disposal.
6. Any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).
7. Any person whose activities with respect to List I chemicals are limited solely to the distribution of Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one fluid ounce (30 ml) or less.
8. Any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

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If any person exempted under paragraphs 2, 3, 4, 5, or 6 above also engages in the distribution, importation, or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for the activities. [21 CFR 1309.24\(i\)](#).

DEA may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a waiver granted under paragraphs 2, 3, 4, 5, or 6 above pursuant to the procedures set forth in [21 CFR 1309.43 - 1309.46](#) and [1309.51 - 1309.55](#). [21 CFR 1309.24\(j\)](#). In considering the revocation or suspension of a person's waiver granted pursuant to paragraph 2 or 3 above, DEA shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to [21 U.S.C. 824](#) is warranted. [21 CFR 1309.24\(j\)](#).

Any person exempted from the registration requirement listed above must comply with the security requirements set forth in [21 CFR 1309.71 - 1309.73](#) and the recordkeeping and reporting requirements set forth under 21 CFR [parts 1310](#), [1313](#), [1314](#), and [1315](#). [21 CFR 1309.24\(k\)](#).

Exemption of Law Enforcement Personnel

Information regarding this waiver can be found at [21 CFR 1309.26](#).

Pursuant to [21 CFR 1309.26](#), the requirement of registration is waived for the following persons:

1. Any officer or employee of the DEA, any officer of U.S. Customs and Border Protection, any officer or employee of the FDA, any other Federal or Insular officer who is lawfully engaged in the enforcement of any Federal law relating to listed chemicals, controlled substances, drugs or customs, and is duly authorized to possess and distribute List I chemicals in the course of official duties; and
2. Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to listed chemicals and controlled substances and is duly authorized to possess and distribute List I chemicals in the course of his official duties.

Any official exempted by this section may, when acting in the course of official duties, possess any List I chemical and distribute any such chemical to any other official who is also exempted by this section and acting in the course of official duties. [21 CFR 1309.26\(b\)](#).

Registration Exemption / Self-Certification for Regulated Sellers of Scheduled Listed Chemical Products

Registration is not required for regulated sellers of SLCPs. *See* [21 U.S.C. 823](#). A regulated seller is a retail distributor (including a pharmacy or a mobile retail vendor). [21 CFR 1300.02](#). Examples of regulated sellers of SLCPs include grocery stores, general merchandise stores, drug stores, or other entities engaged in over-the-counter sales of ephedrine (both single entity and combination products), pseudoephedrine, or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions by direct sales.

Although exempt from registration, regulated sellers must self-certify with DEA pursuant to federal law (see [Section IX, Retail Sales of Scheduled Listed Chemical Products](#)). [21 U.S.C. 830\(e\)\(1\)\(A\)\(vii\)](#), [21 CFR 1314.40\(a\)](#). This self-certification must be renewed annually. [21 CFR 1314.40\(b\)](#). The regulated seller must provide a separate certification for each place of business at which the regulated seller sells scheduled listed chemical products at retail. [21 CFR 1314.40\(c\)](#).

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Registration Exemption / Self-Certification for Mail-Order Distributors of Scheduled Listed Chemical Products (SLCP)

Mail-order distributors of SLCPs to non-regulated parties (a consumer or end-user who does not re-distribute) are exempt from registration. [21 U.S.C. 823](#).

Although exempt from registration, mail-order distributors must self-certify with DEA pursuant to federal law ([Section IX, Retail Sales of Scheduled Listed Chemical Products](#)). [21 U.S.C. 830\(e\)\(2\)\(C\)](#), [21 CFR 1314.102](#). This self-certification must be renewed annually. [21 CFR 1314.102\(b\)](#).

Separate Registration for Independent Activities

Information regarding this subject may be found at [21 CFR 1309.22](#).

Pursuant to [21 CFR 1309.22\(a\)](#), the following groups of activities are independent of each other:

1. Manufacturing List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine;
2. Distributing List I chemicals and SLCPs;
3. Importing List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine; and
4. Exporting List I chemicals and SLCPs.

Pursuant to [21 CFR 1309.22\(b\)](#), except as provided in paragraphs 1 and 2 below, every person who engages in more than one group of independent activities must obtain a separate registration for each group of activities, unless otherwise exempted by the CSA or [21 CFR 1309.24 - 1309.26](#):

1. A person registered to manufacture any List I chemical shall be authorized to distribute that List I chemical after manufacture, but no other chemical that the person is not registered to manufacture. [21 CFR 1309.22\(d\)](#).
2. A person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import. [21 CFR 1309.22\(c\)](#).

Separate Registration for Separate Locations

Information regarding this subject may be found at [21 CFR 1309.23](#).

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\(a\)](#).

Pursuant to [21 CFR 1309.23\(b\)](#), the following locations are exempt from registration:

1. A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered; and

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2. An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

Application Process

Information regarding this subject can be found at 21 CFR 1309.21, [1309.31](#), [1309.32](#), [1309.35](#), [1309.41](#), and [1309.42](#).

Any person wishing to manufacture, distribute, import, or export listed chemicals, who is not exempt from registration, shall obtain a DEA registration annually by filling out the DEA Form 510 (New Application for DEA Registration) which may be completed online at www.DEAdiversion.usdoj.gov/drugreg/index.html. [21 CFR 1309.21](#), [1309.31](#). The application fee is indicated when a business activity is selected.



The screenshot shows the website for the U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control. The page is titled "Registration Applications" and "Office of Diversion Control Web Interactive Forms (ODWIF) NEW APPLICATIONS". It provides contact information for registration help: DEA.Registration.Help@usdoj.gov. A "Begin Application Process" link is highlighted. Below this, a list of eligible entities is provided: Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner, Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter, Narcotic Treatment Program, Domestic Chemical. A section titled "MINIMUM ON-LINE REQUIREMENTS" states that the DEA Forms listed are for those applying to DEA for a controlled substance registration, data will be entered through a secure connection to the ODWIF online web application system, and the web browser must support 128-bit encryption.

A paper copy of the DEA Form 510 may be obtained by downloading the PDF version available online at www.DEAdiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm. The completed paper application should be mailed to the address listed below for processing, along with proper payment.

Drug Enforcement Administration
Attn: Registration Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

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2. Obtain a description of the company's planned activity with the List I chemical(s).
3. Obtain information on the principals of the firm as well as those responsible for handling List I chemicals to include, but not limited to, date of birth, home address, and home phone number.
4. Review of State and Federal licenses and certificates.
5. Obtain supplier list and customer list.
6. Review of the firm's business practices and procedures including procedures for identifying suspicious orders of List I and List II chemicals.
7. Inspection of the firm's physical security and its procedures for employee screening/background checks.

Certificate of Registration

Once DEA has approved the application, DEA mails a DEA Form 511 (Certificate of Registration) to the registered address. [21 CFR 1309.42\(a\)](#). The registrant shall maintain the Certificate of Registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent, or employee of the DEA or any federal, state, or local agency engaged in enforcement of laws relating to List I chemicals or controlled substances. [21 CFR 1309.42\(b\)](#).

If a registrant needs a duplicate DEA Certificate of Registration, they may:

- Download online at www.DEAdiversion.usdoj.gov/webforms/dupeCertLogin.jsp
- Contact the local DEA Field Office (See [Appendix P](#))
- Contact DEA Headquarters at 1-800-882-9539
- E-mail a request to DEA.Registration.Help@dea.gov

Renewal of Chemical Registration

Information regarding this subject may be found at [21 CFR 1309.32](#).

A chemical registration must be renewed every year utilizing DEA Form 510a, Renewal Application for DEA Registration. [21 CFR 1309.21\(a\)](#), [1309.32\(b\)](#). To renew a registration, all information called for in the form must be included unless inapplicable, in which case this fact shall be indicated. [21 CFR 1309.32\(f\)](#). A registrant can apply to renew no more than 60 days prior to the current expiration date. [21 CFR 1309.31\(b\)](#). The DEA Form 510a may be completed online and can be found at www.DEAdiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm. The cost of the application fee is provided on the online form.

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The screenshot shows the website for the U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control. The page is titled "Registration Applications" and "Office of Diversion Control Web Interactive Forms (ODWIF) RENEWAL APPLICATIONS". It includes a navigation menu on the left with options like Home, Registration, Reporting, Info & Legal Resources, and Inside Diversion Control. The main content area features a table with links for "Log in to Begin Renewal Process", "Obtain Receipt", and "Duplicate Certificate". Below the table, there are sections for "MINIMUM ON-LINE REQUIREMENTS" and a list of required information for completing the form, such as Tax ID number, State Controlled Substance Registration Information, and State Medical License Information. A note mentions that the ODWIF system can only process credit card transactions at the time of the screenshot.

DEA Form 510a is mailed to each List I chemical registrant approximately 60 days before the expiration date of their registration. [21 CFR 1309.32\(c\)](#). If the renewal form (DEA Form 510a) is not received within 45 days before the expiration date of the current registration, notice must be promptly given of such fact and DEA Form 510a must be requested by writing the Registration Section of DEA. [21 CFR 1309.32\(c\)](#). The chemical handler may request a renewal form by using one of these options:

- Contact the local DEA Registration Specialist - a current list of Registration Specialists is available at www.DEAdiversion.usdoj.gov/drugreg/offices/index.html
- Call DEA Headquarters at 1-800-882-9539
- Send an e-mail to DEA.Registration.Help@usdoj.gov

Note: Once the expiration date has passed and DEA has not received a renewal application, the chemical handler has no authority to handle List I chemicals. [21 CFR 1309.21](#), [1309.31\(a\)](#), [1309.32\(b\)-\(c\)](#).

Modification of Registration

Information regarding this subject can be found at [21 CFR 1309.61](#).

Any registrant may apply to modify their registration to authorize the handling of additional List I chemicals or to change their name or address by submitting a request online at www.DEAdiversion.usdoj.gov/drugreg/change_requests/index.html.

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A registrant may also submit a request for modification by submitting a letter to:

Drug Enforcement Administration
Attn: Registration Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

The letter shall contain the registrant's name, address, and registration number as printed on the DEA Form 511 (Certificate of Registration). [21 CFR 1309.61](#). The request for modification shall be handled in the same manner as an application for registration. [21 CFR 1309.61](#). There is no fee to modify a registration. [21 CFR 1309.61](#). If the modification is approved, DEA issues a new Certificate of Registration. [21 CFR 1309.61](#). The registrant must maintain the new certificate with the old certificate until expiration. [21 CFR 1309.61](#).

Transfer of Registration

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the DEA Administrator may specifically designate and then only pursuant to the DEA Administrator's written consent. [21 CFR 1309.63](#).

Termination of Registration

Information regarding this subject can be found at [21 CFR 1309.62](#).

The registration of any person shall terminate, without any further action by DEA, if and when such person dies, ceases legal existence, discontinues business or professional practice, or surrenders a registration. [21 CFR 1309.62\(a\)](#). Any registrant who ceases legal existence or discontinues business or professional practice or wishes to surrender a registration shall promptly notify the local Special Agent in Charge in his/her area (see [Appendix P](#)) and seek authority and instructions to dispose of any List I chemicals obtained under the authority of that registration. [21 CFR 1309.62\(a\)](#).

Suspension or Revocation of Registration

Information regarding this subject can be found at 21 U.S.C. [958](#) and [824](#).

Pursuant to [21 U.S.C. 824\(a\)](#) and [958\(d\)](#), DEA has the authority to suspend or revoke a DEA registration upon a finding that the registrant:

1. Has materially falsified any application filed pursuant to or required by the CSA or the CSIEA;
2. Has been convicted of a felony under the CSA or CSIEA or any other law of the United States, or of any State, relating to a controlled substance or a List I chemical;
3. Has had a State license or registration suspended, revoked, or denied by a competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or List I chemicals or has had the suspension, revocation, or denial of a registration recommended by competent State authority;

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4. Has committed such acts as would render his registration inconsistent with the public interest as determined under the CSA. In determining the public interest, the following factors are considered:
 - a. Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
 - b. Compliance by the applicant with applicable Federal, State, and local law;
 - c. Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
 - d. Any past experience of the applicant in the manufacture and distribution of chemicals; and
 - e. Such other factors as are relevant to and consistent with the public health and safety.
5. Has been excluded (or directed to be excluded) from participation in a program pursuant to [Title 42 U.S.C. 1320a-7\(a\)](#).

If a registration is surrendered for cause, DEA's policy is that termination shall occur upon receipt by any DEA employee of a duly-executed Form DEA 104c, *Voluntary Surrender of List I Chemical Privileges*, or any signed writing indicating the desire to surrender a registration. [76 FR 61563](#). If a registrant does not voluntarily surrender for cause by signing this form, DEA may choose to pursue an Order to Show Cause on the registration per [21 CFR 1309.43\(c\)](#).

SECTION IV - SECURITY

Information regarding this subject can be found at [21 CFR 1309.71](#), [1309.72](#), [1309.73](#), [1314.25](#), and [1314.50](#).

Basic Security Requirements

Applicants and registrants are required to provide effective controls and procedures to guard against theft and diversion of List I chemicals. [21 CFR 1309.71\(a\)](#). Regulated sellers of SLCPs should refer to [Section IX, Retail Sales of Scheduled Listed Chemical Products, for SLCP storage requirements](#). Specific attention should be paid to the following areas:

1. Chemicals must be stored in a container sealed in such a way that will reveal any attempts at tampering. [21 CFR 1309.71\(a\)](#). If a chemical cannot be stored in such a sealed container, access to the chemical should be controlled through physical means (e.g., locked in a secure place) or through human or electronic monitoring. [21 CFR 1309.71\(a\)](#).
2. The registrant shall exercise caution in considering the employment of persons who will have access to listed chemicals who have been convicted of a felony offense relating to controlled substances or listed chemicals or who have, at any time, had an application for registration with DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause. [21 CFR 1309.72\(a\)](#). For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances or listed chemicals. [21 CFR 1309.72\(a\)](#). The registrant shall assess the risks involved in employing such persons, including the potential for suspension or revocation of the registrant's DEA registration. [21 CFR 1309.72\(a\)](#).
3. It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer should assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee. [21 CFR 1309.72\(b\)](#).
4. An employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to the employer or a responsible security official of the employer. [21 CFR 1309.73](#). The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. [21 CFR 1309.73](#). A failure to report information of chemical diversion should be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. It is the employer's responsibility to inform employees of this policy. [21 CFR 1309.73](#).

Any person exempted from registration (see [Section III, Waiver of Registration Requirement for Certain Activities](#)) must comply with the security requirements set forth in [21 CFR 1309.71 - 1309.73](#). [21 CFR 1309.24\(k\)](#).

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Pursuant to [21 CFR 1309.71\(b\)](#), in evaluating the effectiveness of security controls and procedures, DEA shall consider the following factors:

1. The type, form, and quantity of List I chemicals handled,
2. The location of the premises and the relationship such location bears on security needs,
3. The type of building construction and the general characteristics of the building,
4. Availability of electronic detection and alarm systems,
5. The extent of unsupervised public access to the facility,
6. The adequacy of supervision over employees who have access to List I chemicals,
7. Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel in areas where List I chemicals are processed and stored, and
8. The adequacy of systems for monitoring receipt, distribution, and disposition of List I chemicals.

As allowed in [21 CFR 1309.71\(c\)](#), any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the local DEA Diversion Field Office, Attn: Special Agent in Charge (see [Appendix P](#)), or to:

Drug Enforcement Administration
Attn: Regulatory Section/DRG
8701 Morrisette Drive
Springfield, VA 22152

“Know Your Customer” Policy

It is fundamental for handlers of listed chemicals to take reasonable measures to verify the identity of their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, detect those transactions that are suspicious in nature. [21 CFR 1310.05\(a\)\(1\)](#), [1310.07](#).

A regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transactions, this is accomplished by having the other party present documents that would verify the identity, or registration status if a registrant, of the other party to the regulated person at the time the order is placed. For export transactions, this is accomplished by good faith inquiry through reasonably available research documents or publicly available information that would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers. [21 CFR 1310.07\(a\)](#). Chemical handlers are cautioned, however, that the granting of a DEA registration is not a confirmation of proper ongoing business practices and does not relieve the chemical handler of the responsibility to evaluate each transaction.

Proof of Identity

Information regarding this subject can be found at [21 U.S.C. 830\(a\)\(3\)](#) and [21 CFR 1310.07](#).

For proof of identity information for retail transactions of SLCPs, see [Section IX, Retail Sales of Scheduled Listed Chemical Products](#).

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Each regulated person engaging in a regulated transaction must identify each other party to the transaction. [21 U.S.C. 830\(a\)\(3\)](#), [21 CFR 1310.07\(a\)](#). It is the duty of such other party to present proof of identity to the regulated person. [21 U.S.C. 830\(a\)\(3\)](#). The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine, or encapsulating machine. [21 CFR 1310.07\(b\)](#).

For a domestic transaction, proof of identity may be accomplished by having the other party present documents to prove their identity to the regulated person at the time the order is placed. [21 CFR 1310.07\(a\)](#). Verification of documents may be accomplished through the following sources, including, but not limited to: telephone directory, local credit bureau, local Chamber of Commerce, or local Better Business Bureau. [21 CFR 1310.07\(b\)](#). Proof of identity may also be verified by a DEA registration status if the ordering party is a registrant. [21 CFR 1310.07\(b\)](#). A DEA registrant can verify the other party's DEA registration by visiting www.DEAdiversion.usdoj.gov/webforms/validateLogin.jsp. When transacting business with a new representative of a firm, the regulated person must verify the claimed agency status of the representative. [21 CFR 1310.07\(c\)](#).

For cash sales or sales to individuals, the proof of identity must consist of at least the signature of the purchaser, a driver's license, and one other form of identification. [21 CFR 1310.07\(d\)](#).

For new customers who are not individuals or cash customers, the regulated person must authenticate the identity of the authorized purchasing agent(s) and have on file that person's signature, electronic password, or other identification. [21 CFR 1310.07\(e\)](#). Once the authorized purchasing agent has been established, the agent list may be updated annually rather than on each order. [21 CFR 1310.07\(e\)](#). The regulated person must ensure that shipments are not made unless the order is placed by an authorized agent of record. [21 CFR 1310.07\(e\)](#).

For electronic orders, the identity of the purchaser shall consist of a computer password, identification number, or some other means of identification consistent with electronic orders, including the information outlined in the above paragraph. [21 CFR 1310.07\(f\)](#).

For an export transaction, proof of identity is to be accompanied by a good faith inquiry to verify the existence and validity of the foreign business entity. [21 CFR 1310.07\(a\)](#). This can be done by verifying the business telephone listing through international telephone information, checking the firm's listing in international or foreign national chemical or commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, or verification through the Commercial Attaché of the embassy of the country of destination. [21 CFR 1310.07\(b\)](#). Official documents provided by the purchaser may confirm the existence and apparent validity of the business entity. [21 CFR 1310.07\(b\)](#).

Any exports to individuals or exports paid in cash are suspect and should be handled as such. [21 CFR 1310.07\(d\)](#). For such exports, the regulated person must obtain from the purchaser or independently seek to confirm clear documentation that proves the person is properly identified such as through foreign identity documents, driver's license, passport information, and photograph. [21 CFR 1310.07\(d\)](#). Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to penalties provided by laws governing regulated transactions of listed chemicals. [21 CFR 1310.07\(d\)](#).

SECTION V - RECORDKEEPING REQUIREMENTS

Recordkeeping requirements for handlers of SLCP can be found in [Section IX, Retail Sales of Scheduled Listed Chemical Products](#).

Persons Required to Keep Records

Information regarding this subject can be found at [21 CFR 1310.03](#).

Each regulated person who engages in a regulated transaction involving a List I or List II chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by 21 CFR 1310.04 and file reports to DEA as outlined in 21 CFR 1310.05. [21 CFR 1310.03\(a\)](#). For those listed chemicals for which thresholds have been established, the quantitative threshold or the cumulative amount for multiple transactions within a *calendar month* is to be utilized in determining whether a receipt, sale, importation, or exportation is a regulated transaction. [21 CFR 1310.04\(f\)](#). Thresholds can be found in [21 CFR 1310.04\(f\)](#) as well as in [Appendix D](#).

Contents of Regulated Transaction Records

Information regarding this subject can be found at [21 CFR 1310.06](#).

Pursuant to [21 CFR 1310.06\(a\)](#), each record required by [21 CFR 1310.03\(a\)](#) must contain the following information:

1. The name, address, and if required, the DEA registration number of each party to the regulated transaction.
2. The date of the regulated transaction.
3. The name, quantity, and, if applicable, National Drug Code (NDC) number. If the NDC number is not applicable, the form of packaging of the listed chemical, or description of the tableting machine or encapsulating machine (including make, model, and serial number, if any, and whether the machine is manual or electric).
4. The method of transfer (company truck, picked up by the customer, etc.).
5. The type of identification used by the purchaser and any unique number of that identification.

Normal business records are considered adequate if they contain the information listed above and are readily retrievable from other business records of the regulated person. [21 CFR 1310.06\(b\)](#).

Location and Availability of Records

Information regarding this subject can be found at [21 CFR 1310.04](#).

A record of a regulated transaction is required to be kept at the regulated person's place of business where the transaction occurred. [21 CFR 1310.04\(c\)](#). Records may be kept at a single, central location of the regulated person if the regulated person has notified DEA of the intention to do so. [21 CFR 1310.04\(c\)](#). Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept (see [Appendix P](#)). [21 CFR 1310.04\(c\)](#).

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A regulated person with more than one place of business where a record is required to be kept must devise a recordkeeping system that detects any party purchasing from several individual locations of the regulated person to circumvent the cumulative threshold or other requirements. [21 CFR 1310.04\(e\)](#).

The records required to be kept shall be readily retrievable and available for inspection and copying by duly authorized DEA officials. [21 CFR 1310.04\(d\)](#).

Maintenance of Records

Information regarding maintenance of records may be found at [21 CFR 1310.04](#) for registrants. Every record required to be kept for a listed chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for two years after the date of the transaction. [21 CFR 1310.04\(a\)-\(b\)](#). However, as with all regulations, regulated persons are advised to also check with other federal, state, and local agencies to verify compliance with regulations regarding record retention periods.

End Use Exception

A non-regulated person who acquires listed chemicals for internal consumption or “end use,” and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals; other records and reports of the infrequent or rare distribution of a listed chemical from inventory would still be required. [21 CFR 1310.03\(a\)](#).

SECTION VI - REPORTS TO THE DRUG ENFORCEMENT ADMINISTRATION

What Must be Reported

Pursuant to [21 U.S.C. 830\(b\)](#) and [21 CFR 1310.05\(a\)-\(b\)](#), each regulated person shall report to the Special Agent in Charge of the local DEA Divisional Office ([Appendix P](#)) for the area in which the regulated person making the report is located, as follows:

1. 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 may be used in violation of the CSA.
2. Any proposed regulated transaction with a person whose description or other identifying characteristic DEA has previously furnished to the regulated person.
3. Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.
4. Any domestic regulated transaction of a tableting machine or an encapsulating machine. The importation and exportation of these machines are addressed in [Section VII](#).

Each report submitted regarding paragraphs 1 through 3 above shall, whenever possible, be made orally to the local DEA office at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible; each report submitted regarding paragraph 4 above must be made when the order is placed with the seller. [21 CFR 1310.05\(a\)\(1\),\(a\)\(2\),\(b\)\(1\),\(b\)\(2\)](#). Written reports of transactions regarding paragraphs 1, 3, and 4 above must be filed within 15 days after the regulated person becomes aware of the circumstances of the event. [21 CFR 1310.05\(a\)\(1\),\(b\)\(1\),\(b\)\(2\)](#). Detailed reporting requirements are found in [21 CFR 1310.06](#).

A transaction may not be completed with a person whose description or identifying characteristic has been previously furnished to the regulated person by DEA unless the transaction is approved by DEA. [21 CFR 1310.05\(a\)\(2\)](#).

Bulk Manufacturers' Reports

Pursuant to [21 CFR 1310.05\(d\)](#), regulated bulk manufacturers of listed chemicals are required to submit manufacturing, inventory, and use data on an annual basis, as set forth in 21 CFR 1310.06(j), to:

Drug Enforcement Administration
Attn: Drug and Chemical Evaluation Section/DPE
8701 Morrisette Drive
Springfield, VA 22152

Reports are due by March 15 of the year immediately following the calendar year for which the report is submitted. [21 CFR 1310.05\(d\)](#).

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Reports of Mail-Order Sales

Information regarding these reports can be found at [21 U.S.C. 830\(b\)\(3\)](#); [21 CFR 1310.03](#), [1310.05](#), and [1310.06](#). Other information regarding mail-order sales can be found in [Section IX, Retail Sales of Scheduled Listed Chemical Products](#).

Each regulated person who engages in a transaction with a non-regulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the U.S. Postal Service or any private or commercial carrier, is required to submit monthly reports of each such transaction. [21 U.S.C. 830\(b\)\(3\)\(B\)](#), [21 CFR 1310.03\(c\)\(1\)](#).

Pursuant to [21 CFR 1314.110\(b\)](#), each monthly report must provide the following information for each distribution:

1. Supplier name and registration number;
2. Purchaser's name and address;
3. Name/address shipped to (if different from purchaser's name/address);
4. Method used to verify the identity of the purchaser and, where applicable, person to whom product is shipped;
5. Name of the chemical and total amount shipped (e.g., pseudoephedrine, 250 grams);
6. Date of shipment;
7. Product name (if drug product);
8. Dosage form (if drug product) (e.g., pill, tablet, liquid);
9. Dosage strength (if drug product) (e.g., 30 mg, 60 mg, per dose etc.);
10. Number of dosage units (if drug product) (100 doses per package);
11. Package type (if drug product) (e.g., bottle, blister pack, etc.);
12. Number of packages (if drug product) (e.g., 10 bottles);
13. Lot number (if drug product).

Reports of mail-order sales should be sent to:

Drug Enforcement Administration
Attn: Regulatory Section/DRG
8701 Morrissette Drive
Springfield, VA 22152

The written reports must be submitted on or before the 15th day of each month following the month in which the distributions took place. [21 CFR 1314.110\(a\)\(1\)](#). The report must be submitted under company letterhead, signed by the person authorized to sign the registration or self-certification application on behalf of the regulated person or regulated seller, respectively. [21 CFR 1314.110\(a\)\(1\)](#). Upon request to and approval by DEA, a regulated person may submit this report electronically to DEA. [21 CFR 1314.110\(a\)\(2\)](#).

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Exemptions from Reporting Requirements

Information regarding this subject can be found at [21 CFR 1310.05](#) and [1314.115](#).

Pursuant to [21 CFR 1310.05\(f\)](#) and [1314.115](#), the following distributions made by regulated persons to non-regulated persons, and the following export transactions, are exempted from the aforementioned reporting requirements: (*Exemptions to mail-order sales reporting requirements only apply to paragraphs 1 through 4 below.* [21 CFR 1314.115\(a\).](#))

1. Distributions of sample packages when those packages contain no more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.
2. Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities of a retail distributor, except that this does not apply to sales of SLCP at retail.
3. Distributions of drug products to a resident of a long term care facility or distributions to a long term care facility for dispensing to or use by a resident of that facility.
4. Distributions of drug products pursuant to a valid prescription.
5. Exports which have been reported to DEA under the transshipment reporting requirements ([21 CFR 1313.31](#)), or the international transaction reporting requirements ([21 CFR 1313.32](#)), or for which advance notification reporting requirements are waived.

DEA may revoke exemptions for regulated persons whose distributions of drug products are found to violate the CSA or the regulations. [21 CFR 1310.05\(g\)](#), [21 CFR 1314.115\(b\)](#).

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SECTION VII - IMPORTS, EXPORTS, INTERNATIONAL TRANSACTIONS, AND TRANSSHIPMENTS

This contact information should be used for all reporting requirements described in this section.

Drug Enforcement Administration
Attn: Import/Export Unit/DRI
8701 Morrissette Drive
Springfield, VA 22152
Phone: 202-307-7161
Fax: 202-307-4702
E-mail: chemical.imex@dea.gov

Required Forms for Importation or Exportation of Listed Chemicals (DEA Form 486 or 486A)

DEA Form 486 (Import/Export Declaration for List I and List II Chemicals) must be completed by each regulated person for each regulated import, export, or international transaction. [21 CFR 1313.12\(a\)](#), [1313.21\(a\)](#), [1313.32\(b\)](#). DEA Form 486A (Import Declaration for Ephedrine, Pseudoephedrine, and Phenylpropanolamine) must be used for imports of ephedrine, pseudoephedrine, and phenylpropanolamine. [21 CFR 1313.12\(a\)](#). DEA Form 486, DEA Form 486A, and corresponding instructions may be obtained from DEA's Office of Diversion Control website, www.DEAdiversion.usdoj.gov/21cfr_reports/chemicals/index.html. DEA Forms 486 and 486A must be with DEA [through](#) the DEA Diversion Control Division secure network application, <https://apps.DEAdiversion.usdoj.gov/imex/spring/login>. 21 CFR [1313.12\(b\)](#), [1313.21\(b\)](#), [1313.32\(b\)](#). Online transmission of DEA Forms 486 and 486A requires the importer/exporter have a username and password. Usernames and passwords may be requested by contacting the DEA Import/Export Unit.

Requirements for Importation of Listed Chemicals

Information regarding this subject can be found at [21 U.S.C. 957](#) and [971](#) and [21 CFR 1313.05](#), [1313.08](#), and [1313.12 - 1313.17](#).

Any List I or List II chemical may be imported if that chemical is necessary for medical, commercial, scientific, or other legitimate uses within the United States. [21 CFR 1313.13\(a\)](#).

Each regulated person who imports a listed chemical that meets or exceeds the threshold quantities identified in [Appendix D](#) or is a listed chemical for which no threshold has been established as identified in [Appendix D](#), shall notify DEA of the importation not later than 15 days before the date of release by a customs officer at the port of entry. [21 CFR 1313.12\(a\)](#).

The 15-day advance notification requirement for listed chemical imports may be waived for any importation where the regulated person has satisfied the requirements for reporting to DEA as a regular importer of the listed chemical, and the importer intends to transfer the listed chemicals to a person who is a regular customer for the chemical. [21 CFR 1313.12\(c\)](#).

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To establish a record as an importer, the regulated person must provide DEA with the following information under the waiver of 15-day advance notice requirements of [21 CFR 1313.08](#) and [1313.15](#):

1. The name, DEA registration number (where applicable), street address, telephone number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and
2. The frequency and number of transactions occurring during the preceding 12-month period.

As defined in [21 CFR 1300.02](#), a regular customer is a person with whom the regulated person has an established business relationship for a specified listed chemical(s) that has been reported to DEA.

To document that an importer has an established business relationship with a customer, the importer under [21 CFR 1313.05](#) must provide DEA with the following information under the waiver of 15-day advance notice requirements of [21 CFR 1313.15](#):

1. The name and street address of the chemical importer and of each regular customer;
2. The telephone number, contact person, and where available, the facsimile number for the chemical importer and for each regular customer;
3. The nature of the regular customer's business (e.g., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical(s) will be applied;
4. The duration of the business relationship;
5. The frequency and number of transactions occurring during the preceding 12-month period;
6. The amounts and the listed chemical(s) involved in regulated transactions between the chemical importer and regular customer;
7. The method of delivery (direct shipment or through a broker or forwarding agent); and
8. Other information that the chemical importer considers relevant for determining whether a customer is a regular customer.

For imports where advance notification is waived because the regulated person has satisfied the requirements for reporting to DEA as a regular importer of the listed chemical, and the importer intends to transfer the listed chemical(s) to a person who is a regular customer for the chemical(s), the DEA Form 486 must be filed with DEA through the DEA Diversion Control secure network application at least three business days before the date of release by a customs officer at the port of entry. [21 CFR 1313.12\(d\)](#).

The 15-day advance notification requirement for listed chemicals may also be waived for a specific listed chemical for which DEA determines that advance notification is not necessary for effective chemical diversion control. [21 CFR 1313.12\(c\)\(2\)](#). In this circumstance, no DEA Form 486 is required; however, the regulated person must submit quarterly reports to DEA's Diversion Control Division, Regulatory Section, no later than the 15th day of the month following the end of each quarter. [21 CFR 1313.12\(e\)](#). The report shall contain the following information regarding each individual importation as stated in [21 CFR 1313.12\(e\)\(1\)-\(5\)](#):

1. The name of the listed chemical;
2. The quantity and date imported;
3. The name and full business address of the supplier;
4. The foreign port of embarkation; and
5. The port of entry.

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The 15-day advance notification requirement set forth in [21 CFR 1313.12\(a\)](#) has been waived for imports of acetone, 2-butanone (or methyl ethyl ketone or MEK), and toluene. [21 CFR 1313.12\(f\)](#). Unless DEA notifies the chemical importer to the contrary, the qualification of a regular importer of any one of these three chemicals—acetone, 2-butanone (MEK), or toluene—qualifies that importer as a regular importer of all three of these chemicals. [21 CFR 1313.15\(d\)](#).

Information Required for Import Declaration (DEA Forms 486 and 486A)

Information regarding this subject may be found at [21 CFR 1313.13](#) and [1313.16](#).

Pursuant to [21 CFR 1313.13\(b\)](#), an importer of a List I or List II chemical into the United States must provide the following types of information on DEA Form 486/486A: (For a complete listing of information required, please review DEA Form 486/486A, available at the [DEAdiversion.usdoj.gov](https://www.dea.gov/DEAdiversion.usdoj.gov) website.)

1. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical importer; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the broker or forwarding agent (if any); and
2. The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as described by DEA in [21 CFR 1310.02](#), the size or weight of the container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof; and
3. The date of release by a customs officer at the port of entry, the foreign port and country of export, and the port of entry; and
4. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignor in the foreign country of exportation; and
5. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the person or persons to whom the importer intends to transfer the listed chemical and the quantity to be transferred to each transferee.

For a United States importer, the "transferee" is the person to whom the importer transfers the listed chemicals, i.e., the downstream customer. [21 CFR 1313.16\(e\)\(2\)](#).

Generally, following submission of a DEA Form 486 or DEA Form 486A by a regulated person (importer) to DEA, if the transferee identified in the DEA Form 486 or DEA Form 486A is not a regular customer, the importer may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the DEA Form 486 or DEA Form 486A was submitted to DEA. [21 CFR 1313.16\(a\)](#). Even if an importer was not previously required to file an initial notification 15 days in advance of the transaction because the importer is a regular importer selling to a regular customer, if the importer makes a sale to a new customer, the importer must file a DEA Form 486 or DEA Form 486A 15 days prior to transferring the chemical to the new customer. [21 CFR 1313.12\(a\), \(b\)](#). If the import is being made by a regular importer or intended for transfer to a regular customer, the period is three business days. [21 CFR 1313.16\(b\)](#).

After a DEA Form 486 or DEA Form 486A has been submitted to DEA, if circumstances change and the importer will not transfer the listed chemical to the transferee identified in the original DEA Form 486 or DEA Form 486A, or will transfer a greater quantity of the chemical than specified, the importer must update the DEA Form 486 or DEA Form 486A to identify the most recent prospective transferee or the most recent quantity, or both. [21 CFR 1313.16\(b\)](#). The importer may not transfer the listed chemical until after the

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expiration of the 15-day period beginning on the date on which the update is submitted to DEA, or, if the import is being made by a regular importer or intended for transfer to a regular customer, the period is three business days. [21 CFR 1313.16\(b\)](#). This requirement applies with respect to changing circumstances regarding a transferee or quantity identified in an updated DEA Form 486 or DEA Form 486A to the same extent and in the same manner as it applies with respect to changing circumstances regarding a transferee or quantity identified in the original DEA Form 486 or DEA Form 486A. [21 CFR 1313.16\(b\)](#).

DEA has 15 days from the time the customer information is submitted to review the proposed transaction. [21 CFR 1313.16\(b\)](#). DEA reviews each import transaction regarding the chemical to be imported and the transferee to whom the chemical is to be transferred. If DEA takes no action, the importer is thus granted regular importer status for transactions involving the specific chemical to be imported to the specific customer. [21 CFR 1313.16\(c\)](#). This new transferee, i.e., the downstream customer, is granted regular customer status for future imports of the specified chemical by the specified importer. [21 CFR 1313.16\(c\)](#).

Special Requirements for Imports of Ephedrine, Pseudoephedrine, and Phenylpropanolamine

Information regarding this subject can be found at [21 U.S.C. 952](#) and [971](#); and [21 CFR 1313.13](#), [1313.42](#), [1315.30](#), and [1315.34](#).

It is unlawful to import into the United States ephedrine, pseudoephedrine, and phenylpropanolamine except that such amounts as DEA finds to be necessary to provide for medical, scientific, or other legitimate purposes may be imported under DEA regulations. [21 U.S.C. 952\(a\)](#). DEA-registered importers must have an import quota issued by DEA prior to submitting a DEA Form 486A for the importation of ephedrine, pseudoephedrine, or phenylpropanolamine. [21 CFR 1315.30\(c\)](#). Any DEA-registered importers who desire to import during the next calendar year and ephedrine, pseudoephedrine, or phenylpropanolamine or drug products containing these chemicals, must apply on DEA Form 488 for an import quota for the chemicals, and a separate application must be made for each chemical desired to be imported. [21 CFR 1315.34\(a\)](#). Each reference in this manual to ephedrine, pseudoephedrine, or phenylpropanolamine includes the salts, optical isomers, and salts of optical isomers of the chemical. [21 U.S.C. 802\(34\)\(C\),\(I\),\(K\)](#).

An Import Declaration for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, DEA Form 486A, must be completed by each DEA-registered importer for each import. [21 CFR 1313.12\(a\)](#). DEA Form 486A and the instructions for completing and distributing it can be found online at www.DEAdiversion.usdoj.gov/21cfr_reports/chemicals/index.html. The completed copy must be filed with DEA through the DEA Diversion Control Division secure network application, <https://apps.DEAdiversion.usdoj.gov/imex/spring/login>. [21 CFR 1313.12\(b\)](#).

Further, any regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine must submit on DEA Form 486A all information known to the importer on the chain of distribution of the chemical from the manufacturer to the importer. [21 CFR 1313.13\(c\)](#).

The DEA Form 486A must be received by DEA at least 15 days prior to the import of ephedrine, pseudoephedrine, or phenylpropanolamine. [21 CFR 1313.12\(a\)](#).

To prevent or respond to the diversion of ephedrine, pseudoephedrine, or phenylpropanolamine for use in the illicit production of methamphetamine, DEA may request that a manufacturer or distributor in the foreign

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chain of distribution provide information known to the foreign manufacturer or distributor on the distribution of the chemical, including sales. [21 CFR 1313.42\(a\)](#). If DEA determines that a foreign manufacturer or distributor of ephedrine, pseudoephedrine, or phenylpropanolamine has refused to cooperate with a request by DEA for information known to the manufacturer or distributor on the distribution of the chemical, including sales, DEA may issue an order prohibiting the importation of the chemical in any case where that manufacturer or distributor is part of the chain of distribution. [21 CFR 1313.42\(a\)](#).

Not later than 60 days prior to issuing the order to prohibit importation, DEA is required to publish in the Federal Register a notice of intent to issue the order. [21 CFR 1313.42\(b\)](#). During the 60-day period, imports from the foreign manufacturer or distributor may not be restricted by DEA under the applicable CFR section. [21 CFR 1313.42\(b\)](#).

Return Declarations for Imports of Listed Chemicals

Information regarding this subject can be found at [21 U.S.C. 971](#) and [21 CFR 1313.17](#).

Within 30 days after an import transaction is completed, the importer must send to DEA a return declaration containing information regarding the transaction, including the date on which the listed chemical was released by a customs officer at the port of entry; the date on which the listed chemical arrived at the importer's registered location or place of business; the actual quantity of the listed chemical released; the actual quantity of the listed chemical that arrived at the importer's location; the date of any subsequent transfer; a description of the subsequent transfer, including the actual quantity transferred, chemical, container, and name of transferees; the actual port of entry; and any other information that DEA may specify. [21 U.S.C. 971\(g\)](#); [21 CFR 1313.17\(a\)](#). A single return declaration may include specific information regarding the importation and the distribution. [21 CFR 1313.17\(a\)](#). If the importer has not distributed all chemicals by the end of the initial 30-day period, the importer must file supplemental return declarations no later than 30 days from the date of any further distribution, until the distribution or other disposition of all chemicals imported under the import notification or any update are accounted for. [21 U.S.C. 971\(g\)](#); [21 CFR 1313.17\(a\)](#).

If an importation for which a DEA Form 486 or DEA Form 486A has been filed fails to take place, the importer must file an amended DEA Form 486 or DEA Form 486A notifying DEA that the importation did not occur. [21 CFR 1313.17\(b\)](#).

Requirements for Exportation of Listed Chemicals

Information regarding this subject can be found at [21 U.S.C. 960](#) and [971](#), and [21 CFR 1313.05](#) and [1313.21 - 1313.27](#).

No person shall export or cause to be exported any listed chemical, knowing or having reasonable cause to believe the export is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the Controlled Substances Act or the laws of the country to which the chemical is exported. [21 CFR 1313.21\(g\)](#). Any export from the United States in violation of the law of the country to which the chemical is exported is subject to the penalties of [21 U.S.C. 960\(d\)](#). [21 CFR 1313.25](#). Other provisions prohibit similar conduct, with the additional inclusion of non-listed chemicals, materials, and equipment. [21 U.S.C. 843\(a\)\(6\), \(7\)](#).

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No person shall export or cause to be exported from the United States a listed chemical that meets or exceeds the threshold quantities identified in [Appendix D](#) or is a listed chemical for which no threshold has been established as identified in [Appendix D](#), until DEA has been notified of the exportation. [21 CFR 1313.21\(a\)](#). Notification must be made not later than 15 days before the date of release by a customs officer at the port of export. [21 CFR 1313.21\(a\)](#).

The 15-day advance notification requirement for listed chemical exports may be waived for any regulated person who has satisfied the requirements for reporting to DEA an established business relationship with a foreign customer. [21 CFR 1313.21\(c\)\(1\)](#).

Pursuant to [21 CFR 1313.05](#), to document that an exporter has an established business relationship with a customer, the exporter must provide DEA with the following information under the waiver of 15-day advance notice requirements:

1. The name and street address of the chemical exporter and of each regular customer;
2. The telephone number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;
3. The nature of the regular customer's business (e.g., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;
4. The duration of the business relationship;
5. The frequency and number of transactions occurring during the preceding 12-month period;
6. The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and regular customer;
7. The method of delivery (direct shipment or through a broker or forwarding agent); and
8. Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

Each foreign customer identified on an initial DEA Form 486 shall, after the expiration of the 15-day period, qualify as a regular customer, unless DEA otherwise notifies the regulated person in writing. [21 CFR 1313.24\(c\)](#).

The qualification of a regular customer for acetone, 2-Butanone (MEK), or toluene qualifies that customer as a regular customer for all three of these chemicals, unless DEA notifies the chemical exporter to the contrary. [21 CFR 1313.24\(d\)](#).

For exports where advance notification is waived for any regulated person who has satisfied the requirements for reporting to DEA an established business relationship with a foreign customer, DEA Form 486 must be filed with the DEA at least three business days before the date of release by a customs officer. [21 CFR 1313.21\(d\)](#).

The 15-day advance notification requirement for listed chemical exports may also be waived for a specific listed chemical to a specified country for which DEA determines that advance notification is not necessary for effective chemical diversion control. [21 CFR 1313.21\(c\)\(2\)](#). In this circumstance, no DEA Form 486 is required; however, the regulated person must submit quarterly reports no later than the 15th day of the month following the end of each quarter. [21 CFR 1313.21\(e\)](#). Also pursuant to [21 CFR 1313.21\(e\)](#), the report shall contain the following information regarding each individual exportation:

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1. The name of the listed chemical;
2. The quantity and date exported;
3. The name and full business address of the foreign customer;
4. The port of embarkation; and
5. The foreign port of entry.

Information Required for Export Declaration (DEA Form 486)

Information regarding this subject can be found at [21 CFR 1313.22](#) and [1313.26](#).

Any List I or List II chemical which meets or exceeds the quantitative thresholds established by DEA or for which no threshold has been established may be exported if that chemical is needed for medical, commercial, scientific, or other legitimate uses. [21 CFR 1313.22\(a\)](#).

Pursuant to [21 CFR 1313.22\(b\)](#), the U. S. exporter of a List I or List II chemical must provide the following information on DEA Form 486:

1. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical exporter; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the export broker, if any;
2. The name of each listed chemical as it appears on the label or container, the name of each listed chemical as described by DEA in [21 CFR 1310.02](#), the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;
3. The anticipated date of release by a customs officer at the port of export, the United States Customs port of exportation, and the foreign port and country of entry; and

The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s); and a copy of the foreign permit, license or registration issued by the competent national authority of the consignee and any intermediate consignees.

After a DEA Form 486 has been submitted to DEA, if the transferee identified in the DEA Form 486 (i.e., the foreign importer) is not a regular customer, the regulated person may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the DEA Form 486 is submitted to DEA. [21 CFR 1313.26\(a\)](#).

If circumstances change and the U. S. exporter will not transfer the listed chemical to the transferee identified in the DEA Form 486, or will transfer a greater quantity of the chemical than specified, the exporter must update the DEA Form 486 to identify the most recent prospective transferee or the most recent quantity, or both. [21 CFR 1313.26\(b\)](#). The exporter may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to DEA, except that the 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer, in which case the exporter may not transfer the listed chemical until after the expiration of three business days. [21 CFR 1313.26\(b\)](#). This requirement applies with respect to changing circumstances regarding a transferee or quantity identified in an updated DEA Form 486 to the same extent and in the

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same manner that it applies with respect to changing circumstances regarding a transferee or quantity identified in the original DEA Form 486. [21 CFR 1313.26\(b\)](#).

In the case of a notice submitted under 21 CFR 1313.21(a), if the newly arranged sale is to a new customer (i.e., not a “regular customer”), the exporter must file an advance notice 15 days prior to transferring the chemical to the new customer. [21 CFR 1313.26\(a\)](#).

In the case of a transfer of a listed chemical that is subject to the 15-day restriction, the transferee shall, upon expiration of the 15-day period, be considered to qualify as a regular customer, unless DEA otherwise notifies the exporter in writing. [21 CFR 1313.26\(c\)](#).

Return Declarations for Exports of Listed Chemicals

Information regarding this subject can be found at [21 U.S.C. 971](#) and [21 CFR 1313.27](#).

Within 30 days after a listed chemical is released by a customs officer at the port of export, the exporter must send to DEA a return declaration containing information regarding the transaction including the date on which the listed chemical was released by a customs officer at the port of export, quantity, chemical, container, name of transferees, and any other information that DEA may specify. [21 CFR 1313.27\(a\)](#). If an exportation for which a DEA Form 486 has been filed fails to take place, the exporter must file an amended DEA Form 486 notifying DEA that the exportation did not occur. [21 CFR 1313.27\(b\)](#).

Declared Exports that are Refused

Information regarding this subject can be found at [21 CFR 1313.22](#).

Declared exports of listed chemicals that are refused, rejected, or otherwise deemed undeliverable may be returned to the U. S. chemical exporter of record. [21 CFR 1313.22\(c\)](#). A brief written notification (this does not require a DEA Form 486) outlining the circumstances must be sent to DEA following the return within a reasonable time. [21 CFR 1313.22\(c\)](#). This must be completed through the Diversion Control Division's [secure network application](#). [21 CFR 1313.22\(c\)](#). This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. [21 CFR 1313.22\(c\)](#). Returns to third parties in the United States are considered imports. [21 CFR 1313.22\(c\)](#).

Special Policy Regarding Exports of Certain Chemicals to Colombia

In March 1996, the United States took steps to decertify Colombia's status as a nation actively cooperating with the United States on drug control. [61 FR 13759](#), March 28, 1996. DEA has historically experienced great difficulty in determining the legitimacy and final destination of exports of chemicals from the United States to Colombian companies. *Id.* Additionally, DEA is unable to rely on the Colombian government to insure that listed chemicals imported from the United States and other sources are not diverted to illicit drug manufacture. *Id.* Following the United States decertification, DEA revoked regular customer status for all United States exports of the following cocaine-essential chemicals to Colombia: acetone, potassium permanganate, 2-Butanone (MEK), methyl isobutyl ketone (MIBK), toluene, and ethyl ether. *Id.* Despite the fact that since then Colombia has become conditionally certified, DEA continues to employ a heightened standard of review to scrutinize proposed exports and transshipments to Colombia because of

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the high probability that these chemicals may be diverted to the clandestine manufacture of cocaine. Exports of the above listed chemicals to Colombia require 15-day advance notification. [/d. at 13759-13760](#).

Disqualification of Waiver for Imports and Exports

Information regarding this subject can be found at [21 U.S.C. 971](#) and [21 CFR 1313.15](#), [1313.16](#), and [1313.26](#).

If there are grounds to believe that the chemical being imported or exported may be diverted to the clandestine manufacture of a controlled substance, DEA may disqualify the importer or exporter from the “regular customer” or “regular importer” status and thereby terminate the waiver of the advance notification requirement. [21 U.S.C. 971\(c\)](#); [21 CFR 1313.15\(c\)](#), [1313.16\(d\)\(1\)\(ii\)](#), [1313.26\(d\)\(1\)\(ii\)](#).

Suspension of Import and Export Shipments

Information regarding this subject can be found at [21 U.S.C. 971\(c\)](#) and [21 CFR 1313.41](#).

DEA may suspend any importation or exportation of a listed chemical based on evidence that the chemical may be diverted for use in the clandestine manufacture of a controlled substance. [21 CFR 1313.41\(a\)](#). When a shipment is suspended, DEA issues a suspension notice to the regulated person explaining the circumstances of the suspension along with instructions on how to request a hearing. [21 CFR 1313.41\(a\)](#).

Transshipment through the United States

Information regarding this subject can be found at [21 CFR 1313.31](#).

A listed chemical that meets or exceeds the threshold reporting requirements found in [21 CFR 1310.04\(f\)](#) and Appendix D may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that written advance notice is submitted to DEA. [21 CFR 1313.31\(a\)](#). The written notification must be in the form of a notice or letter (*not a DEA Form 486*) providing pertinent details of the transshipment and must be received by DEA no later than 15 days prior to the proposed transshipment date. [21 CFR 1313.31\(b\)](#). Pursuant to [21 CFR 1313.31\(b\)](#), the written notification must contain the following information:

1. The date the notice was executed;
2. The complete name and description of the listed chemical as it appears on the label or container;
3. The name of the listed chemical as designated by [21 CFR 1310.02](#);
4. The number of containers and the size or weight of the container for each listed item;
5. The net weight of each listed chemical given in kilograms or parts thereof;
6. The gross weight of the shipment given in kilograms or parts thereof;
7. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) and type of business of the foreign exporter;
8. The foreign port and country of export;
9. The approximate date of exportation;
10. The complete identification of the exporting carrier;
11. The name, address, business, telephone number, and, where available, the facsimile number of the importer, transferor, or transshipper;

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12. The U.S. port of entry;
13. The approximate date of entry;
14. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) and type of business of the consignee at the foreign port or country of entry;
15. The shipping route from the U.S. port of export to the foreign port or country of entry at final destination;
16. The approximate date of receipt by the consignee at the foreign port of entry; and
17. The signature of the importer, transferor or transshipper, or his agent, accompanied by the agent's title.

The notification may be sent via regular mail, e-mail, or fax or (see contact information at the beginning of this section). See Transshipment Notification Instructions (www.DEAdiversion.usdoj.gov/chem_prog/transshipment_chem_instruct.pdf) and Sample Letter (www.DEAdiversion.usdoj.gov/chem_prog/transshipment_chem_sampleltr.pdf) for details. Unless notified by DEA to the contrary prior to the expected date of delivery, the importation for transshipment or transfer is considered approved. [21 CFR 1313.31\(c\)](#).

International Transactions

Information regarding this subject can be found at [21 U.S.C. 971](#) and [21 CFR 1313.32](#), [1313.33](#), [1313.34](#), and [1313.35](#).

An international transaction involving a listed chemical which meets or exceeds the quantitative thresholds established by DEA may be arranged by a broker or trader ([see Section II - Definitions](#)) if the chemical is needed for medical, commercial, scientific, or other legitimate uses. [21 CFR 1313.33\(a\)](#).

A broker or trader shall notify DEA prior to an international transaction that meets or exceeds the threshold amount established by DEA in which the broker or trader participates. [21 CFR 1313.32\(a\)](#). Notification must be made no later than 15 days before the transaction is to take place. [21 CFR 1313.32\(a\)](#).

A completed DEA Form 486 must be received from the broker or trader by DEA no later than 15 days prior to the transaction. [21 CFR 1313.32\(b\)](#).

No person shall serve as a broker or trader for an international transaction involving a listed chemical knowing or having reasonable cause to believe that the transaction is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported. DEA publishes a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in [21 CFR 1313.25](#). [21 CFR 1313.32\(c\)](#). For applicable offenses and penalties, see [21 U.S.C. 960\(d\)\(2\)](#), (4).

Information Required for International Transactions - DEA Form 486

Information regarding this subject can be found at [21 CFR 1313.32](#), [1313.33](#), and [1313.16\(b\)](#).

Pursuant to [21 CFR 1313.33\(c\)](#), the broker or trader ([see Section II - Definitions](#)) of a List I or List II chemical must provide the following types of information on the DEA Form 486:

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1. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical exporter; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical importer;
2. The name of each listed chemical as it appears on the label or container, the name of each listed chemical as described by DEA in [21 CFR 1310.02](#), the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;
3. The anticipated date of release at the foreign port of export, the anticipated foreign port and country of exportation, and the foreign port and country of entry.
4. The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

After a DEA Form 486 has been submitted to DEA, if circumstances change and the broker or trader is not transferring the listed chemical to the transferee identified in the original DEA Form 486, or will transfer a greater quantity of the chemical than specified, the broker or trader must update the DEA Form 486 to identify the most recent prospective transferee or the most recent quantity, or both. [21 CFR 1313.32\(d\)](#). The broker or trader may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to DEA. [21 CFR 1313.32\(d\)](#). This applies with respect to changing circumstances regarding a transferee or quantity identified in an amended DEA Form 486 to the same extent and in the same manner as it applies with respect to changing circumstances regarding a transferee or quantity identified in the original DEA Form 486. [21 CFR 1313.32\(d\)](#).

Return Declarations for International Transactions

Information regarding this subject can be found at [21 U.S.C. 971](#) and [21 CFR 1313.35](#).

Within 30 days after a transaction is completed, the broker or trader must send to DEA through the Diversion Control Division [secure network application](#) a return declaration containing information regarding the transaction including the date(s) on which the listed chemical was released by the foreign customs officer(s) at the ports(s), quantity, chemical, container, name of transferees, and any other information that DEA may specify. [21 CFR 1313.35\(a\)](#). If a transaction for which a DEA Form 486 has been filed fails to take place, the broker or trader must file an amended DEA Form 486 as soon as the broker or trader becomes aware of the circumstances, notifying the DEA that the transaction did not occur. [21 CFR 1313.35\(b\)](#).

Imports/Exports of Tableting/Encapsulating Machines

Information regarding this subject can be found at [21 CFR 1310.05](#) and [1310.06](#).

Each regulated person who imports or exports a tableting machine or an encapsulating machine must file a report of such importation or exportation with DEA on DEA Form 452 through the DEA Diversion Control Division [secure network application](#) at least 15 calendar days before the anticipated arrival at the port of entry or port of export. [21 CFR 1310.05\(c\)](#).

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Any tableting or encapsulating machine may be imported or exported if that machine is needed for medical, commercial, scientific, or other legitimate uses. [21 CFR 1310.05\(c\)](#). However, an importation or exportation of a tableting machine or encapsulating machine may not be completed with a person whose description or identifying characteristics have previously been furnished to the regulated person by DEA, unless the transaction is approved by DEA. [21 CFR 1310.05\(c\)](#).

In the event that a shipment of tableting or encapsulating machine(s) has been denied release by a customs officer at the port of entry for any reason, the importer who attempted to import the shipment must, within five business days of the denial, report to DEA that the shipment was denied, the basis for denial, and such other information as is required by [21 CFR 1310.06\(g\)](#). The report must be submitted through the DEA Diversion Control Division secure network application. Upon the importer's report of a denied entry, DEA assigns the report a transaction identification number and the original import notification becomes void and of no effect. No shipment of tableting machines or encapsulating machines denied entry for any reason are allowed entry without a subsequent refile of an amended DEA Form 452 by the regulated person. In such circumstances, the regulated person may proceed with the release of the tableting machines or encapsulating machines upon receipt of a transaction identification number for the refiled and amended DEA Form 452 without regard to the 15-day advance filing requirement in 21 CFR 1310.05(c)(1), so long as the tableting or encapsulating machine is otherwise cleared for entry under U.S. customs laws. [21 CFR 1310.05\(c\)\(2\)](#).

Declared Exports of Tableting and Encapsulating Machines that are Refused

Information regarding this subject may be found at [21 CFR 1310.06](#).

Declared exports of machines which are refused, rejected, or otherwise deemed undeliverable may be returned to the U. S. exporter of record. A brief written report (*not a DEA Form 486*) outlining the circumstances must be filed with DEA through the DEA Diversion Control Division [secure network application](#), following the return at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States are regarded as imports. [21 CFR 1310.06\(i\)](#)

SECTION VIII - QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE

This mailing address should be used for all reporting requirements described in this section.

Mail: Drug Enforcement Administration
Attn: UN Reporting and Quota Section/DRQ
8701 Morrisette Drive
Springfield, VA 22152

Online: Quota Applications
https://www.deadiversion.usdoj.gov/quotas/quota_apps.htm

Background

Information regarding this subject can be found at [21 U.S.C. 826](#) and [952](#), [73 FR 73549](#), and [21 CFR Part 1315](#).

The CMEA amends the CSA to tighten controls on the manufacture, distribution, import, export, and retail sale of three List I chemicals--ephedrine, pseudoephedrine, and phenylpropanolamine--and drug products containing them. The CMEA imposes the following changes:

1. DEA must establish an assessment of the annual needs of the total quantity of these chemicals, including drug products containing them, necessary to be manufactured and imported for the estimated medical, scientific, research, and industrial needs of the United States; for lawful exports; and for the establishment and maintenance of reserve stocks. [21 CFR 1315.11\(a\)](#). That assessment establishes an upper limit on the quantity of the chemicals and products containing the chemicals that may be produced in or imported into the United States.
2. Importers must obtain an import quota to import any of the three chemicals in bulk or contained in drug products. [21 CFR 1315.34\(a\)](#).
3. Manufacturers who produce in bulk any of the above three chemicals, also referred to as bulk manufacturers ([21 CFR 1315.21](#), [1310.05\(d\)](#)), must first obtain an individual manufacturing quota for the quantity of the chemical. [21 CFR 1315.22](#). A bulk manufacturer of any of the above three chemicals that has obtained one or more individual manufacturing quotas may also produce products containing the chemical(s) covered by the individual manufacturing quota(s) utilizing the same manufacturer registration, and would not have to obtain a separate procurement quota where a procurement quota is for the purchase of one of the three chemicals in bulk. [21 CFR 1315.32\(a\)](#), [1309.21](#); see also [73 FR 73550](#).
4. Manufacturers who purchase the bulk chemicals to produce products must obtain a procurement quota before procuring any of the three chemicals. [21 CFR 1315.32\(a\)](#).
5. Manufacturers who package, repackage, label, or relabel must obtain a procurement quota before procuring any of the three chemicals. [21 CFR 1315.32\(a\)](#).

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Import Quotas

Information regarding this subject can be found at [21 U.S.C. 952](#) and [21 CFR 1315.30](#), [1315.34](#), and [1315.36](#).

DEA registered importers must have an import quota issued by DEA prior to submitting a DEA Form 486A for the importation of ephedrine, pseudoephedrine, and phenylpropanolamine. [21 CFR 1315.34\(a\)](#).

Only DEA registered chemical importers, or any person whose requirement of registration is waived pursuant to [21 CFR 1309.24\(c\)](#), may apply for an import quota for the three List I chemicals. A separate application is required for each chemical. [21 CFR 1315.34\(a\)](#). Each DEA registered chemical importer or person as described above that wishes to import ephedrine, pseudoephedrine, or phenylpropanolamine must follow the instructions to complete and file a DEA Form 488, Application for Import Quota, and its corresponding worksheet, DEA Form 488 (worksheet A), each year for each chemical the importer wishes to import. [21 CFR 1315.34\(a\)](#); see also [Quota Applications](#). Individual applications are required for importing either bulk chemical or finished dosage forms. [21 CFR 1315.34\(b\)\(4\)](#). Pursuant to [21 CFR 1315.34\(b\)](#), the importer must provide on each application the following information:

1. The applicant's name and DEA registration number.
2. The name and address of a contact person and contact information (telephone number, fax number, e-mail address).
3. Name of the chemical and the DEA Chemical Code Number.
4. Type of product (bulk or finished dosage forms).
5. For finished dosage forms, the official name, common or usual name, chemical name, or brand name, NDC number, and the authority to market the drug product under the Federal Food, Drug and Cosmetic Act of each form to be imported.
6. The amount requested expressed in terms of base.
7. For the current and preceding two calendar years, expressed in terms of base:
 - a. Distribution/Sales--name, address, and registration number (if applicable) of each customer and the amount sold.
 - b. Inventory as of December 31 (each form--bulk, in-process, finished dosage form).
 - c. Acquisition--imports.

For each form of the chemical (bulk or dosage unit), the applicant must state the quantity desired for import during the next calendar year. [21 CFR 1315.34\(c\)](#).

Applications for each import quota must be filed on or before April 1 of the year preceding the year for which the import quota is being applied. [21 CFR 1315.34\(d\)](#).

Import quotas are issued on a calendar year basis and can only be used during the calendar year for which they were issued. [21 CFR 1315.34\(a\), \(d\), \(f\)](#). Any person to whom an import quota has been issued may at any time request an increase in the import quota quantity by applying to DEA with a statement showing a need for the adjustment. [21 CFR 1315.36\(b\)](#).

DEA may approve the application for increase in the import quota quantity if DEA determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical. [21 CFR 1315.36\(b\)](#).

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Individual Manufacturing Quotas for Bulk Manufacturers of Ephedrine, Pseudoephedrine, and/or Phenylpropanolamine

Information regarding this subject can be found at [21 U.S.C. 826](#) and [21 CFR 1315.21](#), [1315.22](#), and [1315.25](#).

Each person registered to manufacture in bulk ephedrine, pseudoephedrine, or phenylpropanolamine (also referred to as bulk manufacturers, see [73 FR 73550](#), [21 CFR 1315.21](#), and [1310.05\(d\)](#)) must obtain an individual manufacturing quota before manufacturing in bulk may begin. [21 CFR 1315.22](#). Those persons whose sole activity consists of repackaging or relabeling of listed chemicals or the manufacture of drug dosage forms of products which contain a listed chemical do not need to obtain an individual manufacturing quota, but rather should obtain a procurement quota as is described below. An individual manufacturing quota represents the maximum amount of ephedrine, pseudoephedrine, or phenylpropanolamine a DEA registrant is authorized to manufacture in bulk in a calendar year. [21 CFR 1315.21](#). A separate individual manufacturing quota is required for each of the three chemicals desired to be manufactured. [21 CFR 1315.22](#). A bulk manufacturer of ephedrine, pseudoephedrine, and/or phenylpropanolamine that has obtained one or more individual manufacturing quotas may also produce products containing the same chemical(s) covered by the individual manufacturing quota(s) utilizing the same manufacturer registration, and would not have to obtain a separate procurement quota where a procurement quota is for the purchase of the same chemical that was manufactured in bulk. [21 CFR 1315.32\(a\)](#), [1309.21](#); see also [73 FR 73550](#).

A bulk manufacturer must complete and file a separate [DEA Form 189 \(Application for Manufacturing Quota\)](#), for each chemical by April 1 of each year preceding the year for which an individual manufacturing quota is being applied. [21 CFR 1315.22](#); see also [Quota Applications](#) on the DEA Diversion website. For specific information required, please review [21 CFR 1315.21](#), [1315.22](#), [1315.25](#), and DEA Form 189. Individual manufacturing quotas are issued on a calendar year basis and may only be used during the calendar year for which they were issued. [21 CFR 1315.22](#); [21 CFR 1315.23](#). Requests for increases in individual manufacturing quotas can be made at any time so long as another DEA Form 189 is completed. [21 CFR 1315.25\(a\)](#). Bulk manufacturers may also abandon or reduce their individual manufacturing quota by submitting a written notice to DEA. [21 CFR 1315.27](#).

DEA may at any time reduce an individual manufacturing quota for a chemical that was previously fixed to prevent the aggregate of the individual manufacturing quotas and import quotas outstanding or to be granted from exceeding the assessment of annual needs that has been established for that chemical. [21 CFR 1315.26](#).

Procurement Quotas

Information regarding this subject can be found at [21 U.S.C. 826](#) and [21 CFR 1315.30 - 1315.33](#).

A DEA registered (non-bulk) manufacturer of ephedrine, pseudoephedrine, or phenylpropanolamine, or any person whose requirement of registration is waived pursuant to [21 CFR 1309.24](#), must obtain a procurement quota before procuring any of these chemicals for manufacturing (including packaging, repackaging, labeling, and relabeling) activities. [21 CFR 1315.32\(a\)](#). A procurement quota represents the maximum amount or quantity of ephedrine, pseudoephedrine, or phenylpropanolamine that a DEA registered manufacturer is authorized to procure in a calendar year. [21 CFR 1315.32\(f\)](#). A separate procurement quota is required for each chemical. [21 CFR 1315.32\(a\)](#).

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A manufacturer must complete and file a [DEA Form 250](#) (Application for Procurement Quota), by April 1 of the year preceding the calendar year for which the procurement quota is being applied. [21 CFR 1315.32\(e\)](#). A separate application must be made for each chemical desired to be procured or used. [21 CFR 1315.32\(a\)](#); see also [Quota Applications](#).

Pursuant to [21 CFR 1315.32\(b\)](#), the applicant must state separately all of the following:

1. Each purpose for which the chemical is desired;
2. The quantity desired for each purpose during the next calendar year; and
3. The quantities used and estimated to be used, if any, for that purpose during the current and preceding two calendar years.

Additionally, if the purpose is to manufacture the chemical into dosage form, the applicant must state the official name, common or usual name, chemical name, or brand name of that form. If the dosage form produced is a controlled substance listed in any schedule, the applicant must also state the schedule number and National Drug Code Number, of the substance. [21 CFR 1315.32\(c\)](#).

Finally, if the purpose is to manufacture another chemical, the applicant must state the official name, common or usual name, chemical name, or brand name of the substance and the DEA Chemical Code Number, as set forth in 21 CFR Part 1310. [21 CFR 1315.32\(d\)](#).

Manufacturers holding a procurement quota may request an adjustment of the quota by applying to DEA with a statement showing the need for an adjustment. [21 CFR 1315.32\(g\)](#).

Certification of Quotas

Information regarding this subject can be found at [21 CFR 1315.32](#).

Any person to whom a procurement quota has been issued must, at or before placing an order with another manufacturer or importer requiring the distribution of a quantity of the chemical, certify in writing to the other registrant that the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine ordered does not exceed the person's unused and available procurement quota of the chemical for the current calendar year. [21 CFR 1315.32\(h\)](#). The written certification must be executed by a person authorized to sign the registration application or by a person granted power of attorney to sign the certifications. [21 CFR 1315.32\(h\)](#). A copy of such certification must be retained by the person procuring the ephedrine, pseudoephedrine, or phenylpropanolamine for two years from the date of the certification. [21 CFR 1315.32\(h\)](#). Registrants must not fill an order from persons required to apply for a procurement quota unless the order is accompanied by a certification. [21 CFR 1315.32\(h\)](#).

Pursuant to [21 CFR 1315.32\(i\)](#), the certification must contain all of the following:

1. The date of the certification.
2. The name and address of the registrant to whom the certification is directed.
3. A reference to the purchase order number to which the certification applies.
4. The name of the person giving the order to which the certification applies.
5. The name of the chemical to which the certification applies.

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6. A statement that the quantity (expressed in grams) of the requested chemical does not exceed the unused and available procurement quota of the chemical, issued to the person giving the order, for the current calendar year.
7. The signature of the individual authorized to sign a certification.

SECTION IX - RETAIL SALES OF SCHEDULED LISTED CHEMICAL PRODUCTS (SLCP)

This section is divided into four parts. The first part provides summary background information on amendments to the CSA concerning SLCPs. The second part discusses self-certification requirements and pertains to both regulated sellers of SLCPs, such as retail stores, as well as mail-order distributors. The third part discusses requirements pertaining only to regulated sellers. Finally, the fourth part discusses requirements pertaining only to mail-order distributors.

Part 1: Background

(For complete guidance as to the provisions of each area indicated below, please check the appropriate section of this Chemical Handler's Manual.)

In March 2006, the President signed the Combat Methamphetamine Epidemic Act (CMEA). This Act amended the CSA to change the regulations for selling products that contain ephedrine, pseudoephedrine, or phenylpropanolamine and that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as nonprescription drugs. The CMEA defines these products as scheduled listed chemical products or SLCPs.

Face-to-face sales to a customer, by a regulated seller (including mobile retail vendors), are subject to requirements for training employees who either are responsible for delivering SLCPs into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products. The regulated seller must certify annually to DEA that the employees have been trained. These regulated sellers must also check the identification of purchasers and maintain specific records (the logbook) of each sale of SLCPs. The only sales exempt from recordkeeping are purchases by individuals of single packages where the package contains not more than 60 milligrams of pseudoephedrine.

As of September 30, 2006, regulated sellers of SLCPs are required to maintain logbooks regarding their sales. The records must be readily retrievable and available for inspection and copying by DEA or other state or local law enforcement agencies. Logs must be kept for not fewer than two years from the date the entry was made.

In October 2008, the President signed the Methamphetamine Production Prevention Act (MPPA) which facilitates the creation of electronic logbooks. The MPPA and its implementing regulations provide greater flexibility for regulated sellers of SLCPs to choose several alternative ways in which to capture and maintain required logbook information: a fully written logbook, a fully electronic logbook, or a logbook where some information is captured electronically and the prospective purchaser's signature is captured and linked to that information.

In October 2010, the President signed the Combat Methamphetamine Enhancement Act (MEA). It established new requirements for mail-order distributors of SLCPs. Mail-order distributors must now train their employees and complete the self-certification process annually to sell SLCPs at retail. In addition, there is a provision in the law making it unlawful for both regulated sellers and mail-order distributors to negligently fail to self-certify. Distributors and businesses may check self-certification through DEA's Self-Certification Monthly List at www.DEAdiversion.usdoj.gov/meth/cmea/index.html.

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Part 2: Requirements for Both Regulated Sellers and Mail-Order Distributors

Self-Certification Requirements

Information regarding this subject can be found at [21 U.S.C. 830](#), [21 CFR 1314.35 - 1314.42](#), and [1314.101 - 1314.103](#).

Before the regulated seller, mail-order distributor, or individual employees of the regulated seller or mail-order distributor may sell SLCPs, all regulated sellers and mail-order distributors must train their employees and complete the self-certification process which stipulates the employee(s) has been trained. [21 U.S.C. 830\(e\)\(1\)\(B\)\(i\)](#), [21 CFR 1314.40\(a\)](#); [21 U.S.C. 830\(e\)\(2\)\(C\)](#), [21 CFR 1314.102](#). Regulated sellers, including pharmacies, must self-certify to engage in retail sales of SLCPs even if state law mandates that a prescription be issued for the product. [21 CFR 1314.40](#).

A separate self-certification is required for each place of business at which SLCPs are sold at retail by regulated sellers, including mobile retail vendors ([see Section II - Definitions](#)). The self-certification for each location is required even if the same person(s) sells at each of the different locations. [21 CFR 1314.40\(c\)](#). Procedures are also available for chains to register multiple locations in a single transaction. Information regarding the chain self-certification process can be obtained by contacting the DEA Headquarters at 1-800-882-9539 or via e-mail at DEA.Registration.Help@dea.gov.

Self-certification is required for each mail-order distributor at each place of business at which there are retail sales of SLCPs. [21 CFR 1314.102\(c\)](#). For a mail-order distributor, this means each location that prepares or packages product for distribution to customers, and each location where employees accept payment for such sales.

The process of self-certification for regulated sellers and mail-order distributors is subject to the provisions of [18 U.S.C. 1001](#). [21 U.S.C. 830\(e\)\(1\)\(B\)\(iii\)\(II\)](#). A regulated seller or mail-order distributor who knowingly or willfully certifies to statements or representations that are not true is subject to fines and imprisonment. [18 U.S.C. 1001\(a\)](#). It is also unlawful for regulated sellers and mail-order distributors to negligently fail to self-certify as required under [21 U.S.C. 830](#). [21 U.S.C. 842\(a\)\(10\)](#).

When the regulated seller (including a mobile retail vendor) and mail-order distributor self-certifies, the regulated seller or mail-order distributor is confirming that:

1. Employees engaged in the sale of SLCPs have been trained regarding provisions of CMEA. [21 CFR 1314.35](#), [1314.101](#).
2. Records of training are being maintained. [21 CFR 1314.35\(b\)](#), [1314.101\(b\)](#).
3. Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine in a single calendar day. [21 CFR 1314.20\(a\)](#), [1314.100\(a\)](#).
4. For mobile retail vendors and mail-order distributors, sales to an individual in a 30-day period may not exceed 7.5 grams. [21 CFR 1314.20\(b\)](#), [1314.100\(b\)](#).
5. Non-liquid forms are packaged as required. [21 CFR 1314.05](#).
6. Regulated sellers store SLCPs behind the counter or in a locked cabinet. [21 CFR 1314.25\(b\)](#).
7. Regulated sellers who are mobile retail vendors store SLCPs in a locked cabinet. [21 CFR 1314.25\(b\)](#).
8. All regulated sellers (including mobile retail vendors) properly maintain a written or electronic logbook. [21 CFR 1314.30](#).

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9. The disclosure of information in the logbook is restricted as follows, pursuant to [21 CFR 1314.45](#):
- i. The information shall be disclosed as appropriate to DEA and to State and local law enforcement agencies.
 - ii. The information in the logbooks shall not be accessed, used, or shared for any purpose other than to ensure compliance with Title 21 of the CFR or to facilitate a product recall to protect public health and safety.
 - iii. A regulated seller who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

How to Self-Certify

The only way to self-certify is through the Internet at www.DEAdiversion.usdoj.gov/meth/index.html#self_cert. Self-certification can be accomplished on any computer, whether at home, at a public library, or at any other location. DEA charges a non-refundable fee for self-certification. [21 CFR 1314.42](#), [1314.103](#). At the end of the self-certification process, a credit/debit card is needed to pay the self-certification fee. A printer is needed to print the certificate for the location. If a printer is not available, the system can be prompted to mail the certificate.

Pursuant to 21 CFR 1314.02, it is the responsibility of all regulated persons who sell SLCPs for personal use, whether through face-to-face sales at stores or mobile retail vendors, or by the U.S. Postal Service or by private or common carriers, to annually renew the self-certification before the certificate expires if they wish to continue selling SLCPs at retail. [21 CFR 1314.40\(b\)](#), [1314.102\(b\)](#). Once the expiration date has passed, the mail-order distributors and regulated sellers cannot recertify or update the self-certification. [21 CFR 1314.40\(b\)](#), [1314.102\(b\)](#). There is no authority to sell SLCPs until a new self-certification is completed. [21 CFR 1314.40\(a\)](#), [1314.102\(a\)](#).

Self-Certification Training Materials

DEA has posted training materials on its website at www.DEAdiversion.usdoj.gov/meth/index.html#self_cert. Employers must use the criteria issued by DEA when training the employees who sell SLCPs. [21 CFR 1314.35\(a\)](#), [1314.101\(a\)](#). An employer may include content in addition to DEA's information, but DEA's material must be included in the training. For example, an employer may elect to incorporate DEA's material into initial training for new employees.

Orders to Show Cause

Information regarding this subject can be found at [21 CFR 1314.150](#).

If it is determined that a regulated seller or a distributor required to submit reports under [21 CFR 1310.03\(c\)](#) has sold a SLCP in violation of the CSA, ([21 U.S.C. 842\(a\)\(12\)](#) or (13)), DEA will serve upon the regulated seller or distributor an order to show cause why the regulated seller or distributor should not be prohibited from selling SLCPs. [21 CFR 1314.150\(a\)](#).

The order to show cause shall call upon the regulated seller or distributor to appear before DEA at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. [21 CFR 1314.150\(b\)](#). The order to show cause shall also contain a statement of the legal basis for such

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hearing and for the prohibition and a summary of the matters of fact and law asserted. [21 CFR 1314.150\(b\)](#).

Upon receipt of an order to show cause, the regulated seller or distributor must, if he desires a hearing, file a request for a hearing as specified in [21 CFR Part 1316, Subpart D](#). [21 CFR 1314.150\(c\)](#). If a hearing is requested, DEA shall hold a hearing at the time and place stated in the order. [21 CFR 1314.150\(c\)](#). Any authorized agent of DEA may serve the order to show cause. [21 CFR 1314.150\(d\)](#).

Suspension Pending Final Order

Information regarding this subject can be found at [21 CFR 1314.155](#).

DEA may suspend the regulated seller or distributor's right to sell SLCPs at the time of, or after, the service of an Order to Show Cause why the regulated seller or distributor should not be prohibited from selling SLCPs, in any case where DEA finds that there is an imminent danger to the public health or safety. [21 CFR 1314.155\(a\)](#). An order of immediate suspension shall contain a statement of DEA's findings regarding the danger to public health or safety. [21 CFR 1314.155\(a\)](#).

Pursuant to [21 CFR 1314.155\(b\)](#), upon receiving the order of immediate suspension, the regulated seller or distributor shall, as instructed by the DEA Administrator:

1. Deliver all of the SLCPs in their possession to the nearest DEA office or to DEA authorized agents; or
2. Place all of the SLCPs under seal as described in [21 U.S.C. 824\(f\)](#).

Any suspension shall continue in effect until the conclusion of all proceedings upon the prohibition, including any judicial review, unless sooner withdrawn by DEA or dissolved by a court of competent jurisdiction. [21 CFR 1314.155\(c\)](#). Any regulated seller or distributor whose right to sell SLCPs is suspended under this section may request a hearing on the suspension at a time earlier than specified in the order to show cause. [21 CFR 1314.155\(c\)](#). DEA will establish a date for such hearing as early as reasonably possible. [21 CFR 1314.155\(c\)](#).

Part 3: Requirements for Regulated Sellers

Employment Measures

Information regarding this subject can be found at [21 CFR 1314.50](#).

A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of SLCPs. [21 CFR 1314.50](#). This may include, notwithstanding State law, asking applicants whether they have been convicted of any crime involving or related to SLCPs or controlled substances. [21 CFR 1314.50](#).

Proof of Identity Requirements for Regulated Sellers

Information regarding this subject can be found at [21 CFR 1314.30](#).

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The regulated seller must not sell an SLCP at retail unless the purchaser presents an identification card that contains a photograph and is issued by a State or the Federal Government. [21 CFR 1314.30\(b\)\(1\)](#). See [Appendix J](#) for a list of alternate forms of identification acceptable under [8 CFR 274a.2\(b\)\(1\)\(v\)\(A\)](#) and [274a.2\(b\)\(1\)\(v\)\(B\)](#).

General Logbook Requirements

Information regarding this subject may be found at [21 U.S.C. 830](#) and [21 CFR 1314.30](#).

Except for purchase by an individual of a single sales package containing not more than 60 milligrams of pseudoephedrine, the regulated seller must maintain, under criteria issued by DEA, a written or electronic list of each SLCP sale that identifies the products by name, the quantity sold, the names and addresses of the purchasers, and the dates and times of the sales (referred to as the "logbook"). [21 CFR 1314.30\(a\)](#). The logbook may be maintained on paper or in electronic form. [21 CFR 1314.30\(a\)](#).

Regulated sellers, including pharmacies, must maintain a logbook for sales of SLCPs even if state law mandates that the product only be sold by prescription. [21 CFR 1314.30](#).

Logbook Requirements for Seller

Information regarding this subject may be found at [21 CFR 1314.30](#).

The regulated seller must enter in the logbook the name of the product and the quantity sold. [21 CFR 1314.30\(b\)\(3\)](#). Examples of methods to record the quantity sold include the weight of the product per package and number of packages of each chemical, the cumulative weight of the product for each chemical, or quantity of product by Universal Product Code. These examples do not exclude other methods of displaying the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology. Such electronic records must comply with the requirements of [21 CFR 1314.30\(g\)](#) in a human readable form so that the requirements of [21 CFR 1314.30\(a\)](#) are satisfied. [21 CFR 1314.30\(b\)\(3\)](#).

Pursuant to [21 CFR 1314.30\(c\)](#), the logbook maintained by the seller must include the prospective purchaser's name, address, and the date and time of the sale, as follows:

1. If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on the identification and that the date and time entered are correct.
2. If the seller enters the information, the prospective purchaser must verify that the information is correct.
3. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

Warning Notice

Information regarding this subject can be found at [21 CFR 1314.30](#).

Pursuant to [21 CFR 1314.30\(d\)](#), the regulated seller must include in the written or electronic logbook or display by the logbook the following notice:

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WARNING: [Section 1001 of Title 18, United States Code](#), states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than \$250,000 if an individual or \$500,000 if an organization, imprisoned not more than five years, or both.

Logbook Requirements for Purchaser

Information regarding this subject can be found at [21 CFR 1314.30](#).

Pursuant to [21 CFR 1314.30\(b\)\(2\)](#), the purchaser signs the logbook as follows:

1. For written logbooks, enters in the logbook his name, address, and the date and time of the sale.
2. For electronic logbooks, provides a signature using one of the following means:
 - a. Signing a device presented by the seller that captures signatures in an electronic format. The device must display the required warning notice. Any device used must preserve each signature in a manner that clearly links that signature to the other electronically captured logbook information relating to the prospective purchaser providing that signature.
 - b. Signing a bound paper book. The bound paper book must include, for such purchaser, either:
 - i. A printed sticker affixed to the bound paper book at the time of sale that either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or
 - ii. A unique identifier that can be linked to that information and that is written into the book by the seller at the time of sale. The purchaser must sign adjacent to the printed sticker or written unique identifier of that sale.
 - c. Signing a printed document that includes, for the purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. The document must be printed by the seller at the time of the sale. The document must contain a clearly identified signature line for a purchaser to sign. The printed document must display the required warning notice. Each signed document must be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

Recordkeeping Requirements for Logbooks

Information regarding this subject can be found at [21 U.S.C. 830](#) and [880](#), and [21 CFR 1314.30](#).

The regulated seller must maintain each entry in the written or electronic logbook for not fewer than two years after the date on which the entry is made. [21 CFR 1314.30\(e\)](#).

A record must be kept at the regulated seller's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated seller if the regulated seller has notified DEA of the intention to do so. [21 CFR 1314.30\(f\)](#). Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the [DEA Divisional Office](#) for the area in which the records are required to be kept. [21 CFR 1314.30\(f\)](#).

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The required records must be readily retrievable and available for inspection and copying by authorized employees of DEA under the provisions of the CSA. [21 CFR 1314.30\(g\)](#).

A record developed and maintained to comply with a State law may be used to meet these requirements if the record includes the information required by the CSA and its implementing regulations. [21 CFR 1314.30\(h\)](#).

Privacy Protections

Information regarding this subject can be found at [21 U.S.C. 830](#) and [21 CFR 1314.45](#).

Pursuant to [21 CFR 1314.45](#), the disclosure of information in logbooks is restricted as follows:

1. The information shall be disclosed as appropriate to DEA and to State and local law enforcement agencies.
2. The information in the logbooks shall not be accessed, used, or shared for any purpose other than to ensure compliance with this title or to facilitate a product recall to protect public health and safety.
3. A regulated seller who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

Sales Limits at Retail

Information regarding this subject may be found at [21 U.S.C. 830](#) and [844](#), and [21 CFR 1314.20](#) and [1315.03](#).

The CMEA established sales and purchase limits for SLCPs:

1. Sales to individuals by a regulated seller, including a mobile retail vendor, may not exceed 3.6 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a single calendar day, regardless of the number of transactions. [21 CFR 1314.20\(a\)](#).
2. For mobile retail vendors, sales to an individual in a 30-day period may not exceed 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base. [21 CFR 1314.20\(b\)](#).
3. For purchasers, there is a nine gram purchase limit for ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a 30-day period, not more than 7.5 grams of which may be imported by means of shipping through any private or commercial carrier or the Postal Service (see [Appendix I](#)). [21 U.S.C. 844\(a\)](#), [21 CFR 1315.03](#).

Storage Requirements

Information regarding this subject can be found at [21 U.S.C. 830](#) and [21 CFR 1314.25](#).

The regulated seller must place the SLCP so that customers do not have direct access to the product before the sale is made. [21 CFR 1314.25\(b\)](#). SLCPs must be kept behind the counter, which includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility where customers do have direct access. [21 CFR 1314.25\(b\)](#). Mobile retail vendors must keep SLCPs in a locked cabinet. [21 CFR 1314.25\(b\)](#).

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The regulated seller must place the SLCPs so that customers do not have direct access to the product before the sale is made (otherwise referred to as “behind-the-counter” placement). [21 CFR 1314.25\(b\)](#). If the SLCPs are stored in a locked cabinet that is located in an area of the facility where customers do have direct access, this would comply with the “behind-the-counter” requirement. [21 CFR 1314.25\(b\)](#). The regulated seller must deliver the SLCP directly into the custody of the purchaser. [21 CFR 1314.25\(c\)](#). Mobile retail vendors must place the product in a locked cabinet. [21 CFR 1314.25\(b\)](#).

Part 4: Requirements for Mail-Order Distributors

Proof of Identity Requirements for Mail-Order Distributors

Information regarding this subject can be found at [21 CFR 1314.105](#).

Prior to shipping the product, the mail-order distributor must receive from the purchaser a copy of an identification card that contains a photograph and is issued by a State or the Federal Government, or an alternate form of identification considered acceptable under [8 CFR 274a.2\(b\)\(1\)\(v\)\(A\)](#) and [274a.2\(b\)\(1\)\(v\)\(B\)](#) (see [Appendix J](#)). [21 CFR 1314.105\(a\)](#). Prior to shipping the product, the mail-order distributor must determine that the name and address on the identification card correspond to the name and address provided by the purchaser as part of the sales transaction. [21 CFR 1314.105\(a\)](#). If the mail-order distributor cannot verify the identities of both the purchaser and the recipient, the product may not be shipped. [21 CFR 1314.105\(a\)](#).

If the product is being shipped to a third party, the mail-order distributor must comply with the above described requirements to verify that both the purchaser and the person to whom the product is being shipped live at the addresses provided. [21 CFR 1314.105\(b\)](#). If the mail-order distributor cannot verify the identities of both the purchaser and the recipient, the mail-order distributor may not ship the product. [21 CFR 1314.105\(b\)](#).

Sales Limits for Mail-Order Distributors

Information regarding this subject can be found at [21 U.S.C. 830](#) and [21 CFR 1314.100](#).

For mail-order distributors, the CMEA mandates that sales to an individual do not exceed 3.6 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a single calendar day, regardless of the number of transactions. [21 CFR 1314.100\(a\)](#). CMEA also establishes a sales limit of not more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base to an individual per 30-day period. [21 CFR 1314.100\(b\)](#).

Reports of Mail-Order Sales of SLCPs

Information regarding this subject can be found at [21 CFR 1314.110](#).

Information regarding mail-order sales, including distributions for which reports are not required, can be found in [Section VI, Reports to DEA](#).

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Pursuant to [21 CFR 1314.110\(b\)](#), each monthly report of SLCPs must provide the following information for each distribution:

1. Supplier name and registration number;
2. Purchaser's name and address;
3. Name/address shipped to (if different from purchaser's name/address);
4. Method used to verify the identity of the purchaser and person to whom product is shipped, where applicable;
5. Name of the chemical contained in the SLCP and total quantity shipped (e.g., pseudoephedrine, 3 grams);
6. Date of shipment;
7. Product name;
8. Dosage form (e.g., tablet, liquid);
9. Dosage strength (e.g., 30 mg, 60 mg, per dose, etc.);
10. Number of dosage units (e.g., 100 doses per package);
11. Package type (blister pack, etc.);
12. Number of packages; and
13. Lot number.

Reports of mail-order sales should be sent to:

Drug Enforcement Administration
Attn: Import/Export Unit/DRI
8701 Morrisette Drive
Springfield, VA 22152

The written reports must be submitted on or before the 15th day of each month following the month in which the distributions took place. [21 CFR 1314.110\(a\)\(1\)](#). If the report is submitted in writing, the report must be submitted under company letterhead, signed by the person authorized to sign the registration or self-certification on behalf of the regulated person or regulated seller, respectively. [21 CFR 1314.110\(a\)\(1\)](#). Upon request to, and approval by, DEA, a regulated person may submit this report electronically to DEA. [21 CFR 1314.110\(a\)\(2\)](#).

Appendices

APPENDIX A - Abbreviated List of Legal Requirements Applying to Regulated Persons and Regulated Transactions

	List I 21 CFR 1310.02(a)	List II 21 CFR 1310.02(b)
<p>Advance Notice on Transshipments and In-Transit Shipments 21 U.S.C. 971(a); 21 CFR 1313.31 A listed chemical that meets or exceeds the threshold imported into the United States for transshipment or transshipped within the United States for immediate exportation must be reported to the DEA no later than 15 days prior to the proposed date the chemical will transship or transfer through the United States.</p>	√	√
<p>Authorization of International Transaction 21 U.S.C. 971(e); 21 CFR 1313.32 and 1300.02(b) A broker or trader located in the United States and participating in a shipment of a listed chemical that meets or exceeds threshold amounts across an international border, other than a U.S. border, must notify the DEA no later than 15 days prior to shipment.</p>	√	√
<p>Import/Export Notification 21 U.S.C. 971(a); 21 CFR Part 1313 Each regulated person who imports or exports a listed chemical that meets or exceeds threshold quantities shall notify the DEA not later than 15 days before the transaction (unless the DEA waives the 15 day requirement).</p>	√	√
<p>Mail-Order Reports 21 U.S.C. 830(b)(3); 21 CFR 1310.03(c) Each regulated person who engages in a transaction with a non-regulated person or who engages in an export transaction which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) and who uses or attempts to use the Postal Service or any private or commercial carrier shall report monthly. See 21 U.S.C. 830(b)(3)(D) for exemptions.</p>	√	
<p>Other Required Reports 21 U.S.C. 830; 21 CFR 1310.05-1310.06 Every regulated bulk manufacturer shall submit manufacturing, inventory, and use data on an annual basis. For tableting and encapsulating machines, each domestic sale, each importation, and each exportation shall be reported.</p>	√	√
<p>Proof of Identity 21 U.S.C. 830(a)(3); 21 CFR 1310.07 It is the duty of each regulated person who engages in a regulated transaction to identify each party to the transaction.</p>	√	√
<p>Registration 21 U.S.C. 822 and 957; 21 CFR part 1309</p>	√	

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Each person who manufactures, distributes, imports, or exports any List I Chemical shall obtain a registration.

Records

[21 U.S.C. 830\(a\)](#); [21 CFR part 1310](#)

Each regulated person who engages in a regulated transaction shall keep a readily retrievable record of the transaction for two years.

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Reports of Certain Transactions

[21 U.S.C. 830\(b\)\(1\)](#); [842\(a\)\(10\)](#); [21 CFR 1310.05\(a\)](#)

Each regulated person shall report certain transactions, as stipulated in [Section VI of this manual](#), under “What Must be Reported,” to the Special Agent in Charge of the local DEA Divisional Office ([APPENDIX P](#)) for the area in which the regulated person making the report is located.

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Security

[21 U.S.C. 823\(h\)](#); [21 CFR 1309.71 - 1309.73](#)

Regulated persons must maintain effective controls to prevent diversion.

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APPENDIX B - Identification Codes for List I Chemicals

Information regarding this subject can be found at [21 CFR 1310.02](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-1310/subpart-1310.02). Note that individual salts, isomers, esters, salts of esters, and salts of isomers have unique Chemical Abstract Numbers.

Chemical	DEA Code	Harmonized Code (Schedule B)	Chemical Abstract Number
Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN)	8512		
N-Acetylanthranilic acid, its esters, and its salts	8522	2924.23.1000	[89-52-1]
Anthranilic acid, its esters, and its salts	8530	2922.43.0000	[118-92-3]
Benzaldehyde	8256	2912.21.0000	[100-52-7]
Benzyl cyanide	8735	2926.90.4700	[140-29-4]
Ephedrine, its salts, optical isomers, and salts of optical isomers	8113	2939.41.0000	[299-42-3]
Ergocristine and its salts	8612	2939.69.0000	[511-08-0]
Ergonovine and its salts (Tariff name: Ergometrine)	8675	2939.61.0000	[60-79-7]
Ergotamine and its salts	8676	2939.62.0000	[113-15-5]
Ethylamine and its salts	8678	2921.19.1000	[75-04-7]
Gamma-butyrolactone (other names include: GBL; dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone)	2011	2932.29.5010	[96-48-0]
Hydriodic acid (57%)	6695	2811.19.6050	[10034-85-2]
Hypophosphorous acid and its salts	6797	2811.19.6050	[6303-21-5]
Iodine	6699	2801.20.0000	[7553-56-2]
Isosafrole	8704	2932.91.0000	[120-58-1]
Methylamine and its salts	8520	2921.11.0000	[74-89-5]
3,4-Methylenedioxyphenyl-2-propanone (Tariff name: 1-(1,3-benzodioxol-5-yl)-2-propanone)	8502	2932.92.0000	[4676-39-5]
N-Methylephedrine and its salts, optical isomers, and salts of optical isomers	8115	2939.49.0000	[522-79-4]
N-Methylpseudoephedrine and its salts, optical isomers, and salts of optical isomers	8119	2939.49.0000	[14222-20-9] [51018-28-1]
N-phenethyl-4-piperidone (NPP)	8332	TBD	[39742-60-4]
Nitroethane	6724	2904.20.5000	[79-24-3]
Norpseudoephedrine and its salts, optical isomers, and salts of optical isomers	8317	2939.49.0000	[429-39-7]
Phenylacetic acid, its esters and its salts	8791	2916.34.1000	[103-82-2]
Phenylpropanolamine and its salts, optical isomers, and salts of optical isomers	1225	2939.40.0050	[14838-15-4]
Piperidine and its salts	2704	2933.32.1000	[110-89-4]
Piperonal (heliotropin)	8750	2932.93.0000	[120-57-0]
Propionic anhydride	8328	2915.50.5000	[123-62-6]
Pseudoephedrine and its salts, optical isomers, and salts of optical isomers	8112	2939.42.0000	[90-84-2]
Red Phosphorous	6795	2804.70.0000	[7723-14-0]
Safrole (includes safrole-rich essential oils, such as sassafras oil and camphor oil 1070)	8323	2932.94.0000	[94-59-7]
White or Yellow Phosphorus	6796	2804.70.0000	[7723-14-0]

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APPENDIX C - Identification Codes for List II Chemicals

Information regarding this subject can be found at [21 CFR 1310.02](#). Note that individual salts, isomers, esters, salts of esters, and salts of isomers have unique Chemical Abstract Numbers.

Chemical	DEA Code	New Harmonized Code (Schedule B)	Chemical Abstract Number
Acetic anhydride	8519	2915.24.0000	[108-24-7]
Acetone	6532	2914.11.1000/ 2914.11.5000	[67-64-1]
Benzyl chloride	8570	2903.69.2000	[100-44-7]
Ethyl ether	6584	2909.11.0000	[60-29-7]
Hydrochloric acid including anhydrous hydrogen chloride	6545	2806.10.0000	[7647-01-0]
Methyl ethyl ketone (2-Butanone)	6714	2914.12.0000	[78-93-3]
Methyl isobutyl ketone (MIBK)	6715	2914.13.0000	[108-10-1]
Potassium permanganate	6579	2841.61.0000	[7722-64-7]
Sulfuric acid	6552	2807.00.0000	[7664-93-9]
Sodium permanganate	6588	2841.69.0000	[10101-50-5]
Toluene	6594	2902.30.0000	[108-88-3]

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APPENDIX D - Thresholds for Regulated Transactions in List I and List II Chemicals

Information regarding this subject can be found at [21 CFR 1310.04](#).

Pursuant to [21 CFR 1310.04\(f\)](#), for those listed chemicals for which thresholds have been established, the quantitative threshold or the cumulative amount for multiple transactions within a calendar month, to be utilized in determining whether a receipt, sale, importation, or exportation is a regulated transaction is as follows:

Chemical code	List I Chemical	Threshold by base weight
8522	N-Acetylanthranilic acid and its salts and esters	40 kilograms
8530	Anthranilic acid and its salts and esters	30 kilograms
8256	Benzaldehyde	4 kilograms
8735	Benzyl cyanide	1 kilogram
8675	Ergonovine and its salts	10 grams
8676	Ergotamine and its salts	20 grams
8678	Ethylamine and its salts	1 kilogram
6695	Hydriodic acid (57%)	1.7 kilograms (or 1 liter by volume)
8704	Isosafrole	4 kilograms
8520	Methylamine and its salts	1 kilogram
8502	3,4-Methylenedioxyphenyl-2-propanone	4 kilograms
8115	N-Methylephedrine and its salts, optical isomers, and salts of optical isomers	1 kilogram
8119	N-Methylpseudoephedrine and its salts, optical isomers, and salts of optical isomers	1 kilogram
6724	Nitroethane	2.5 kilograms
8317	Norpseudoephedrine and its salts, optical isomers, and salts of optical isomers	2.5 kilograms
8791	Phenylacetic acid and its salts and esters	1 kilogram
2704	Piperidine and its salts	500 grams
8750	Piperonal (heliotropin)	4 kilograms
8328	Propionic anhydride	1 gram
8323	Safrole includes safrole-rich essential oils, such as sassafras oil and camphor oil 1070	4 kilograms

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List II Chemicals	Domestic Sales		Imports and Exports	
	By volume	By weight	By volume	By weight
Acetic anhydride	250 gallons	1023 kgs	250 gallons	1023 kgs
Acetone	50 gallons ¹	150 kgs ¹	500 gallons ²	1500 kgs ²
Benzyl chloride	Not applicable	1 kg	Not applicable	4 kgs
Ethyl ether	50 gallons	135.8 kgs	500 gallons	1364 kgs
Hydrochloric acid ²	Not regulated	Not regulated	50 gallons ³	Not applicable ⁴
Anhydrous hydrogen chloride ²	Not applicable	0.0 kgs ⁴	Not applicable	27 kgs ³
Potassium permanganate	Not applicable	55 kgs	Not applicable	500 kgs
Methyl ethyl ketone (2-Butanone)	50 gallons ¹	145 kgs ¹	500 gallons ²	1455 kgs ²
Methyl isobutyl ketone (MIBK)	Not regulated	Not regulated	500 gallons ³	1523 kgs ³
Sulfuric acid	Not regulated	Not regulated	50 gallons ³	Not applicable ⁴
Toluene	50 gallons ¹	159 kgs ¹	500 gallons ²	1591 kgs ²
Sodium permanganate	Not applicable	55 kgs	Not applicable	500 kgs

¹ The cumulative threshold is not applicable to domestic sales of acetone, 2-butanone (methyl ethyl ketone or MEK), and toluene. [21 CFR 1310.04\(f\)\(2\)\(iii\)](#).

² The 15-day advance notification requirement for imports is waived. [21 CFR 1313.12\(f\)](#). Importers must provide quarterly reports as indicated in [21 CFR 1313.12\(e\)](#) and [21 CFR 1313.12\(f\)](#).

³ Threshold applies to exports, transshipments, and international transactions to Western Hemisphere except Canada. Imports are not regulated. [21 CFR 1310.08\(a\)](#), [\(d\)](#).

⁴ Except for exports to all South American countries and Panama. [21 CFR 1310.08\(b\)](#).

Exports, transshipments, and international transactions to designated countries, except those that are excluded as set forth in APPENDIX E.

Chemical	Threshold by volume	Threshold by weight
Hydrochloric acid	50 gallons	
Anhydrous hydrogen chloride		27 kilograms
Sulfuric acid	50 gallons	

Export and international transactions to designated countries, and importations for transshipment or transfer to designated countries, except those that are excluded as set forth in APPENDIX E.

Chemical	Threshold by volume	Threshold by weight
Methyl isobutyl ketone (MIBK)	500 gallons	1523 kilograms

For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction as set forth in [21 CFR 1300.02\(b\)](#). [21 CFR 1310.04\(g\)](#). All such transactions, regardless of size, are subject to

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recordkeeping and reporting requirements as set forth in [21 CFR Part 1310](#) and notification provisions for importation, exportation, international transactions, and transshipment as set forth in [21 CFR Part 1313](#). [21 CFR 1310.04\(g\)](#).

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[21 CFR 1310.04\(g\)\(1\)](#) designates listed chemicals for which no thresholds have been established:

1. Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN)
2. Ephedrine, its salts, optical isomers, and salts of optical isomers
3. Ergocristine and its salts
4. Gamma-butyrolactone (other names include: GBL; dihydro-1(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)
5. Hypophosphorous acid and its salts (including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, and sodium hypophosphite)
6. Iodine
7. *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts
8. *N*-phenethyl-4-piperidone (NPP)
9. *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4-AP), its amides, its carbamates, and its salts
10. Pseudoephedrine, its salts, optical isomers, and salts of optical isomers
11. Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers
12. Red phosphorus
13. White phosphorus (other names: yellow phosphorus)

The thresholds and conditions described above will apply to transactions involving regulated chemical mixtures. [21 CFR 1310.04\(h\)](#). Pursuant to [21 CFR 1310.04\(h\)](#), for purposes of determining whether the weight or volume of a chemical mixture meets or exceeds the applicable quantitative threshold, the following rules apply:

1. For chemical mixtures containing List I or List II chemicals other than those listed in bullet #2 below, the threshold is determined by the weight of the listed chemical in the chemical mixture.
2. For the List II chemicals acetone, ethyl ether, 2-butanone, toluene, and methyl isobutyl ketone, the threshold is determined by the weight of the entire chemical mixture.
3. If two or more listed chemicals are present in a chemical mixture, and the quantity of any of these chemicals equals or exceeds the threshold applicable to that chemical, then the transaction is regulated.

APPENDIX E - Excluded Transactions

Information regarding this subject can be found at [21 U.S.C. 802\(39\)](#) and [21 CFR 1300.02\(b\)](#).

Pursuant to the definition of *regulated transaction* in [21 CFR 1300.02\(b\)](#), the following transactions are not regulated:

1. A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.
2. Delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier or to or by a warehouseman for storage, unless the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third party, in which case this paragraph does not relieve a distributor, importer, or exporter from compliance with Parts 1309, 1310, 1313 and 1315 of Title 21 of the Code of Federal Regulations.
3. Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by DEA regulations as excluded from this definition as unnecessary for enforcement of the Act.
4. Any transaction in a listed chemical that is contained in a drug other than a scheduled listed chemical product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act subject to paragraph (v) of the definition of *regulated transaction* found at [21 CFR 1300.02\(b\)](#) unless,
 - a. DEA has determined that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and
 - b. the quantity of the listed chemical contained in the drug included in the transaction(s) equals or exceeds the threshold established for that chemical.
5. Any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or distributor required to submit reports under [21 CFR 1310.03\(c\)](#); or
6. Any transaction in a chemical mixture designated in [21 CFR 1310.12](#) and [1310.13](#) that DEA has exempted from regulation.

Additionally, pursuant to [21 CFR 1310.08](#), the following transactions have been determined by DEA to be excluded from the definition of regulated transaction:

Acetone, ethyl ether, 2-butanone, and/or toluene

- Domestic and import transactions in chemical mixtures that contain acetone, ethyl ether, 2-butanone, and/or toluene, unless regulated because of being formulated with other List I or List II chemical(s) above the concentration limit. [21 CFR 1310.08\(l\)](#).

Anhydrous hydrogen chloride

- Exports, transshipments, and international transactions except for exports, transshipments, and international transactions to Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Panama, Paraguay, Peru, Suriname, Uruguay, and Venezuela. [21 CFR 1310.08\(b\)](#).
- Import transactions. [21 CFR 1310.08\(g\)](#).
- Domestic distributions weighing 12,000 pounds (net weight) or more in a single container. [21 CFR 1310.08\(h\)](#).

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- Domestic distributions by pipeline. [21 CFR 1310.08\(i\)](#).

Gamma-butyrolactone

- Domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container. [21 CFR 1310.08\(k\)](#).

Hydrochloric acid and sulfuric acid (but not anhydrous hydrogen chloride)

- Domestic and import transactions. [21 CFR 1310.08\(a\)](#).
- Exports, transshipments, and international transactions of hydrochloric (including anhydrous hydrogen chloride) and sulfuric acids, except for exports, transshipments, and international transactions to Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Panama, Paraguay, Peru, Suriname, Uruguay, and Venezuela. [21 CFR 1310.08\(b\)](#).

Iodine

- Domestic and international transactions of Lugol's Solution (consisting of 5% iodine and 10% potassium iodide in an aqueous solution) in the original manufacturer's packaging of one fluid ounce (30 milliliters) or less, and no greater than one package per transaction. [21 CFR 1310.08\(f\)](#).

Methyl isobutyl ketone (MIBK)

- Domestic transactions. [21 CFR 1310.08\(c\)](#).
- Import transactions destined for the United States. [21 CFR 1310.08\(d\)](#).
- Export transactions, international transactions, and import transactions for transshipment or transfer destined for Canada or any country outside of the Western Hemisphere. [21 CFR 1310.08\(e\)](#).

Red or white (also known as yellow) phosphorus

- Domestic and international return shipments of reusable containers from customer to producer containing residual quantities of red or white (also known as yellow) phosphorus in rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2500 gallons in a single container). [21 CFR 1310.08\(j\)](#).

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APPENDIX F - Table of Concentration Limits for Exempt Chemical Mixtures

Information regarding this subject can be found at [21 CFR 1310.12](#).

The below listed chemical mixtures, in the concentrations specified, are exempted from application of the requirement of registration and from recordkeeping and reporting requirements. [21 CFR 1310.12\(a\)](#). No exemption granted affects the criminal liability for illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture or the civil liability for unlawful acts relating to exempt chemical mixtures, including distribution, in violation of [21 U.S.C. 842\(a\)\(11\)](#). [21 CFR 1310.12\(b\)](#).

Mixtures containing a listed chemical in concentrations equal to or less than those specified in the table below are designated as exempt chemical mixtures. [21 CFR 1310.12\(c\)](#). The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight. [21 CFR 1310.12\(c\)](#).

DEA may, at any time, terminate or modify the exemption for any chemical mixture in this appendix. Details regarding such termination or modification may be found at [21 CFR 1310.12\(e\)](#).

DEA may also modify any part of the criteria for exemption upon evidence of diversion or attempted diversion. Details regarding such modification can be found at [21 CFR 1310.12\(f\)](#).

List I Chemicals	DEA Chemical Code Number	Concentration	Special conditions
N-Acetylanthranilic acid, its salts and esters	8522	20% by weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Alpha-phenylacetoacetonitrile, 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.
Anthranilic acid, and its salts and esters.	8530	50% by weight	Concentration is based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde	8256	50% by weight or volume	
Benzyl cyanide	8570	20% by weight or volume	
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	Not exempt at any concentration	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to

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			concentration, unless otherwise exempted.
Ergocristine and its salts	8612	Not exempt at any concentration.	Chemical mixtures containing any amount of ergocristine and its salts are not exempt.
Ergonovine and its salts	8675	Not exempt at any concentration	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt
Ergotamine and its salts	8676	Not exempt at any concentration	Chemical mixtures containing amount of any ergotamine, including its salts, are not exempt.
Ethylamine and its salts	8678	20% by weight or volume	Ethylamine or its salts in an inert carrier solvent is not considered a mixture. Concentration is based on ethylamine in the mixture and not the combination of ethylamine and carrier solvent, if any.
Gamma-Butyrolactone	2011	70% by weight or volume	
Hydriodic acid	6695	20% by weight or volume	
Hypophosphorous Acid and its salts	6797	30% by weight if a solid, weight or volume if a liquid	The weight is determined by measuring the mass of hypophosphorous acid and its salts in the mixture, the concentration limit is calculated by summing the concentrations of all forms of hypophosphorous acid and its salts in the mixture. The DEA does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. Therefore, any solution consisting of hypophosphorous acid (and its salts), dispersed in water, alcohol, or another inert carrier, is not considered a chemical mixture and is therefore subject to chemical regulatory controls at all concentrations.
Iodine	6699	2.2	Calculated as weight/volume (w/v)
Isosafrole	8704	20% by weight or volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with safrole.

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Methylamine and its salts	8520	20% by weight	Methylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on methylamine in the mixture and not the combined weight of carrier solvent, if any.
3,4-Methylenedioxyphenyl-2-propanone	8502	20% by weight	
N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	8115	0.1% by weight	Concentration based on any combination of salts N-methylephedrine, N-methylpseudoephedrine and their salts, optical isomers and salts of optical isomers.
N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8119	0.1% by weight	Concentration based on any combination of N-methylpseudoephedrine, N-methylephedrine, and their salts, optical isomers and salts of optical isomers.
Nitroethane	6724	20% by weight or volume	
Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8317	0.6% by weight	Concentration based on any combination of norpseudoephedrine, phenylpropanolamine and their salts, optical isomers and salts of optical isomers.
N-phenethyl-4-piperidone (NPP)	8332	Not exempt at any concentration	Chemical mixtures containing any amount of NPP are not exempt.
Phenylacetic acid, and its salts and esters.	8791	40% by weight	Concentration is based on any combination of phenylacetic acid and its salts and esters.
Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	1225	0.6% by weight	Concentration based on any combination of phenylpropanolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers.
Phosphorus (red)	6795	80% by weight	
Phosphorus (white or yellow)	6796	Not exempt at any concentration.	Chemical mixtures containing any amount of white phosphorus are not

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			exempt due to concentration, unless otherwise exempted.
Piperidine, and its salts	2704	20% by weight or volume	Concentration based on any combination of piperidine and its salts. Concentration based on weight if a solid, weight or volume if a liquid.
Piperonal	8750	20% by weight or volume	
Propionic anhydride	8328	20% by weight or volume	

Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	Not exempt at any concentration	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
Safrole	8323	20% by volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with isosafrole.
List II Chemicals	DEA Chemical Code Number	Concentration	Special conditions
Acetic Anhydride	8519	20% by weight or volume	
Acetone	6532	35% by weight or volume	Exports only; Limit applies to acetone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Benzyl chloride	8568	20% by weight or volume	
2-butanone	6714	35% by weight or volume	Exports only; Limit applies to 2-butanone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.

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Ethyl ether	6584	35% by weight or volume	Exports only; Limit applies to ethyl ether or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Hydrochloric acid	6545	20% by weight or volume	Hydrogen chloride in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on hydrogen chloride in the mixture and not the combined weight of the carrier solvent, if any.
Methyl isobutyl ketone	6715	35% by weight or volume	Exports only pursuant to 21 CFR 1310.08 ; limit applies to methyl isobutyl ketone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Potassium permanganate	6579	15% by weight	
Sodium permanganate	6588	15% by weight	
Sulfuric acid	6552	20% by weight or volume	Sulfuric acid in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on sulfuric acid in the mixture and not the combined weight of the carrier solvent, if any.
Toluene	6594	35% by weight or volume	Exports only; Limit applies to toluene or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.

APPENDIX G - Automatically Exempt Chemical Mixtures

Pursuant to [21 CFR 1310.12\(d\)](#), the following categories of chemical mixtures are automatically exempt from certain provisions of the CSA:

1. Chemical mixtures that are distributed directly to an incinerator for destruction or directly to an authorized waste recycler or re-processor where such distributions are documented on United States Environmental Protection Agency Form 8700-22; persons distributing the mixture to the incinerator or recycler must maintain and make available to agents of the Administration, upon request, such documentation for a period of no less than two years.
2. Completely formulated paints and coatings—only those formulations that contain all of the components of the paint or coating for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. Included in this category are clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings, and film-forming agents.
3. Iodine products classified as iodophors that exist as an iodine complex to include poloxamer-iodine complex, polyvinyl pyrrolidone-iodine complex (i.e., povidone-iodine), undecoylium chloride iodine, nonylphenoxypoly (ethyleneoxy) ethanol-iodine complex, iodine complex with phosphate ester of alkylaryloxy polyethylene glycol, and iodine complex with ammonium ether sulfate/polyoxyethylene sorbitan monolaurate.
4. Iodine products that consist of organically bound iodine (a non-ionic complex) (e.g., iopamidol, iohexol, and amidarone).

DEA may, at any time, terminate or modify the exemption for any chemical mixture in this appendix. Details regarding such termination or modification may be found at [21 CFR 1310.12\(e\)](#).

DEA may also modify any part of the criteria for exemption upon evidence of diversion or attempted diversion. Details regarding such modification can be found at [21 CFR 1310.12\(f\)](#).

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APPENDIX H - Summary of Requirements for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products

Information regarding this subject can be found at [21 U.S.C. 830](#) and [844](#), and [21 CFR Part 1314](#).

Provisions of the Combat Methamphetamine Epidemic Act (CMEA) and subsequent legislation regarding retail sales establish different requirements for the various types of sales of scheduled listed chemical products.

This summary is provided as a quick reference to the provisions of the CMEA. It is not intended to replace any statutory or regulatory requirement thereof. For complete guidance as to the provisions of each area indicated below, please check the appropriate section of this Chemical Handler's Manual.

Summary of Requirements by Type of Seller

	Regulated sellers (store)	Mobile retail vendors	Mail-order distributors
Daily sales limit	3.6 gm/chemical	3.6 gm/chemical	3.6 gm/chemical
30 day sales limit	NA	7.5 gm/chemical	7.5 gm/chemical
Blister packs	Yes	Yes	Yes
Storage	Behind the counter Locked cabinet	Locked cabinet	NA
Logbook	Yes	Yes	NA
Customer ID	Examine photo ID	Examine photo ID	Verify ID
Train employees	Yes	Yes	Yes
Self-Certify	Yes	Yes	Yes
Notice of misrepresentation	Yes	Yes	NA
Monthly reports	No	No	Yes
Theft and loss reports	Yes	Yes	Yes

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APPENDIX I - Retail Transaction Limits for Scheduled Listed Chemical Products

The Combat Methamphetamine Epidemic Act (CMEA) established sales and purchase limits for transactions involving scheduled listed chemical products. CMEA limits the quantity of each of the chemicals that may be sold to an individual in a day to 3.6 grams of the chemical, without regard to the number of transactions. For mobile retail vendors and mail-order distributors, CMEA requires sellers to limit sales to an individual in a 30-day period to 7.5 grams. For individuals, CMEA limits purchases in a 30-day period to nine grams, of which not more than 7.5 grams may be imported by means of a private or commercial carrier or the U.S. Postal Service.

Number of Tablets/Milliliters That Equal Retail Transaction Limits (as Base) for Scheduled Listed Chemical Products

Scheduled listed chemical product	Transaction limits		
	3.6 gm	7.5 gm	9.0 gm
Ephedrine:			
25 mg Ephedrine HCl	175	366	439
25 mg Ephedrine Sulfate	186	389	466
Pseudoephedrine (as HCl):			
30 mg Pseudoephedrine HCl	146	305	366
60 mg Pseudoephedrine HCl	73	152	183
120 mg Pseudoephedrine HCl	36	76	91
Pseudoephedrine (as Sulfate):			
30 mg Pseudoephedrine Sulfate	155	324	389
60 mg Pseudoephedrine Sulfate	77	162	194
120 mg Pseudoephedrine Sulfate	38	81	97
240 mg Pseudoephedrine Sulfate	19	40	48

Scheduled listed chemical product	Number of mL		
	3.6 gm	7.5 gm	9.0 gm
Ephedrine			
6.25 mg/5 ml Ephedrine HCl	3,515	7,323	8,788
Pseudoephedrine (as HCl):			
15 mg/1.6 mL Pseudoephedrine HCl	468	976	1,171
7.5 mg/5 mL Pseudoephedrine HCl	2,929	6,103	7,323
15 mg/5 mL Pseudoephedrine HCl	1,464	3,051	3,661
15 mg/2.5 mL Pseudoephedrine HCl	732	1,525	1,830
30 mg/5 mL Pseudoephedrine HCl	732	1,525	1,830
30 mg/2.5 mL Pseudoephedrine HCl	366	762	915
60 mg/5 mL Pseudoephedrine HCl	366	762	915

The number of dosage units and milliliters (mL) that may be purchased under the sales limits and purchase limit are shown above. These limits are calculated on the base, not salt, content of the ephedrine or pseudoephedrine in each tablet. For example, approximately 18 percent of the molecular weight of a 30-mg. tablet of pseudoephedrine HCl weight is hydrochloric salt. Therefore, a 30-mg. tablet of pseudoephedrine HCl has 24.6 mgs. of pseudoephedrine base. A purchase of 146 tablets x 24.6 mgs. is 3.5916 grams, less than the daily sales limit of 3.6 grams.

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The Food and Drug Administration issued a voluntary recall of phenylpropanolamine products as being unsafe for humans so no phenylpropanolamine over-the-counter (OTC) product should be available for human consumption. Veterinary use is by prescription only.

APPENDIX J - Alternate Forms of Identification Acceptable for Verification of Identity for Purchasers of Scheduled Listed Chemical Products

The Combat Methamphetamine Epidemic Act requires on and after September 30, 2006, that an individual must present an identification card that includes a photograph and is issued by a State or the Federal Government or a document considered acceptable under [8 CFR 274a.2\(b\)\(1\)\(v\)\(A\) and \(B\)](#). [Title 8 CFR 274a.2\(b\)\(1\)\(v\)](#) states that only unexpired documents are acceptable. Those documents currently include the following:

- United States passport.
- Alien Registration Receipt Card or Permanent Resident Card (Form I-551).
- A foreign passport that contains a temporary I-551 stamp, or temporary I-551 printed notation on a machine-readable immigrant visa.
- An Employment Authorization Document which contains a photograph (Form I-766).
- In the case of an individual who is employment-authorized incident to status or parole with a specific employer, a foreign passport with an Arrival/Departure Record, Form I-94 (as defined in [8 CFR 1.4](#)) or Form I-94A, bearing the same name as the passport and containing an endorsement by DHS indicating such employment-authorized status or parole, as long as the period of endorsement has not yet expired and the employment is not in conflict with the individual's employment-authorized status or parole.
- A passport from the Federated States of Micronesia (FSM) or the Republic of the Marshall Islands (RMI) with Form I-94 or Form I-94A indicating nonimmigrant admission under the Compact of Free Association Between the United States and FSM or RMI.
- In the case of an individual lawfully enlisted for military service in the Armed Forces under 10 U.S.C. 504, a military identification card issued to such individual may be accepted only by the Armed Forces.
- For individuals 16 years of age or older:
 - A driver's license or identification card containing a photograph, issued by a State or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall be included such as name, date of birth, sex, height, color of eyes, and address.
 - School identification card with a photograph.
 - Voter's registration card.
 - U.S. military card or draft record.
 - Identification card issued by Federal, State, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as name, date of birth, sex, height, color of eyes, and address.
 - Military dependent's identification card.
 - Native American tribal documents.
 - United States Coast Guard Merchant Mariner Card.
 - Driver's license issued by a Canadian government authority.
- For individuals under age 18 who are unable to produce a document from the list above of acceptable documents for persons age 16 years and older:
 - School record or report card.
 - Clinic doctor or hospital record.
 - Daycare or nursery school record.

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The list of acceptable forms of identification, as identified in [8 CFR 274a.2\(b\)\(1\)\(v\)\(A\) and \(B\)](#), may change. DEA has no discretion to alter the list.

APPENDIX K - Special Surveillance List of Chemicals, Products, Materials, and Equipment Used in Illicit Production

The Comprehensive Methamphetamine Control Act of 1996 (MCA) makes it unlawful for any person to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, with reckless disregard for the illegal uses to which such laboratory supply will be put. [21 U.S.C. 842\(a\)\(11\)](#). Individuals who violate this provision are subject to a civil penalty of not more than \$25,000; businesses which violate this provision are subject to a civil penalty of not more than \$250,000 for a first violation. [21 U.S.C. 842\(c\)\(1\)\(A\)](#), [842\(c\)\(2\)\(C\)](#). The term "laboratory supply" is defined as "a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and scheduled listed chemicals." [21 U.S.C. 842\(a\)](#).

Special Surveillance List

All listed chemicals as specified in [21 CFR 1310.02\(a\) or \(b\)](#) or [21 U.S.C. 802\(34\) or \(35\)](#). This includes all chemical mixtures and all over-the-counter (OTC) products and dietary supplements which contain a listed chemical, regardless of their dosage form or packaging and regardless of whether the chemical mixture, drug product, or dietary supplement is exempt from regulatory controls.

Ammonia Gas	Organomagnesium Halides (Grignard Reagents) (e.g., ethylmagnesium bromide and phenylmagnesium bromide)
Ammonium Formate	
Bromobenzene	Phenylethanolamine and its salts
1,1-Carbonyldiimidazole	Phosphorus Pentachloride
Cyclohexanone	Potassium Dichromate
1,1-Dichloro-1-fluoroethane (e.g., Freon 141B)	Pyridine and its salts
Diethylamine and its salts	Red Phosphorus
2,5-Dimethoxyphenethylamine and its salts	Sodium Dichromate
Formamide	Sodium Metal
Formic Acid	Thionyl Chloride
Hypophosphorous Acid	Ortho-Toluidine
Lithium Metal	Trichloromonofluoromethane
Lithium Aluminum Hydride	(e.g., Freon-11, Carrene-2)
Magnesium Metal (Turnings)	Trichlorotrifluoroethane (e.g., Freon 113)
Mercuric Chloride	
N-Methylformamide	

Equipment: Hydrogenators, Tableting Machines, Encapsulating Machines, and 22 Liter Heating Mantels

Additional Information: The Special Surveillance List appeared as a Final Notice in the Federal Register on May 13, 1999. [64 FR 25910](#). A Correction to the Final Notice appeared in the Federal Register on September 17, 1999. [64 FR 50541](#).

APPENDIX L - Notice: Ephedrine and Pseudoephedrine can be used in the illicit Manufacture of Methamphetamine

NOTICE

Ephedrine and Pseudoephedrine can be used in the illicit Manufacture of Methamphetamine

The Drug Enforcement Administration (DEA) is issuing this notice to inform individuals and businesses handling ephedrine (EPH) or pseudoephedrine (PSE), or drug products containing these substances that these chemicals can be used in the illicit manufacture of methamphetamine.

Methamphetamine abuse is a major drug problem in the United States.

Criminals search for sources of EPH and PSE. EPH and PSE are List I chemicals under federal law, whether in bulk, single entity, or combination dosage forms.

Regulated persons need to know their customers so as not to become unwitting suppliers to a clandestine methamphetamine laboratory.

Regulated persons shall report to the DEA Special Agent in Charge of the local DEA office the following information:

1. Any regulated transaction involving:
 - an extraordinary quantity of EPH or PSE,
 - an uncommon method of payment or delivery, or
 - any other circumstance that the regulated person believes may indicate that the EPH or PSE will be used in violation of the Controlled Substances Act.
2. Any proposed regulated transaction with a person whose description or other identifying characteristic DEA has previously furnished to the regulated person.
3. Any unusual or excessive loss or disappearance of EPH or PSE under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

Please refer to [21 CFR 1310.05\(b\)](#) for details on method and timing of reports and [21 CFR 1310.03](#) and [1310.04](#) for details regarding recordkeeping requirements.

Additional requirements may apply such as import and production quotas ([21 CFR part 1315](#)) and transactions involving retail sales ([21 CFR part 1314](#)).

It is unlawful for any person knowingly or intentionally to possess or distribute EPH or PSE, knowing, or having reasonable cause to believe, the EPH or PSE will be used to illegally manufacture methamphetamine. The Drug Enforcement Administration thanks you for your cooperation in this matter.

APPENDIX M - Notice: Iodine can be used in the illicit Manufacture of Methamphetamine

NOTICE

Iodine can be used in the illicit Manufacture of Methamphetamine

The Drug Enforcement Administration (DEA) is issuing this notice to inform individuals and businesses handling iodine and products containing iodine that this chemical is used in the illicit manufacture of methamphetamine.

Methamphetamine abuse is a major drug problem in the United States.

Criminals search for sources of iodine. Iodine is a List I chemical under federal law.

Regulated persons need to know their customers so as not to become unwitting suppliers to a clandestine methamphetamine laboratory.

Regulated persons shall report to the DEA Special Agent in Charge of the local DEA office the following information:

1. Any regulated transaction involving:
 - an extraordinary quantity of iodine,
 - an uncommon method of payment or delivery, or
 - any other circumstance that the regulated person believes may indicate that the iodine will be used in violation of the Controlled Substances Act.
2. Any proposed regulated transaction with a person whose description or other identifying characteristic DEA has previously furnished to the regulated person.
3. Any unusual or excessive loss or disappearance of iodine under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

Please refer to [21 CFR 1310.05\(b\)](#) for details on method and timing of reports and [21 CFR 1310.03](#) and [1310.04](#) for details regarding recordkeeping requirements.

It is unlawful for any person knowingly or intentionally to possess or distribute iodine, knowing, or having reasonable cause to believe, the iodine will be used to illegally manufacture methamphetamine.

The Drug Enforcement Administration thanks you for your cooperation in this matter.

APPENDIX N - Notice: Red Phosphorus, White (Yellow) Phosphorus, and Hypophosphorous Acid can be used in the illicit Manufacture of Methamphetamine

NOTICE

Red Phosphorus, White (Yellow) Phosphorus, and Hypophosphorous Acid can be used in the illicit Manufacture of Methamphetamine

The Drug Enforcement Administration (DEA) is issuing this notice to inform individuals and businesses handling red phosphorus, white (yellow) phosphorus, and hypophosphorous acid that these chemicals can be used in the illicit manufacture of methamphetamine.

Methamphetamine abuse is a major drug problem in the United States.

Criminals search for sources of red phosphorus, white (yellow) phosphorus, and hypophosphorous acid. These substances are List I chemicals under federal law.

Regulated persons need to know their customers so as not to become unwitting suppliers to a clandestine methamphetamine laboratory.

Regulated persons shall report to the DEA Special Agent in Charge of the local DEA office the following information:

1. Any regulated transaction involving:
 - an extraordinary quantity of these list I chemicals,
 - an uncommon method of payment or delivery, or
 - any other circumstance that the regulated person believes may indicate that these list I chemicals will be used in violation of the Controlled Substances Act.
2. Any proposed regulated transaction with a person whose description or other identifying characteristic DEA has previously furnished to the regulated person.
3. Any unusual or excessive loss or disappearance of red phosphorus, white (yellow) phosphorus, or hypophosphorous acid under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

Please refer to [21 CFR 1310.05\(b\)](#) for details on method and timing of reports and [21 CFR 1310.03](#) and [1310.04](#) for details regarding recordkeeping requirements.

It is unlawful for any person knowingly or intentionally to possess or distribute red phosphorus, white phosphorus, or hypophosphorous acid, knowing, or having reasonable cause to believe, these substances will be used to illegally manufacture methamphetamine.

The Drug Enforcement Administration thanks you for your cooperation in this matter.

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APPENDIX O - Notice: Safrole and Sassafras Oil can be used in the illicit Manufacture of MDMA

NOTICE

Safrole and Sassafras Oil can be used in the illicit Manufacture of MDMA

The Drug Enforcement Administration (DEA) is issuing this notice to inform individuals and businesses handling safrole and essential oils rich in safrole, such as sassafras oil, "brown" camphor oil 1.070, also referred to as Chinese sassafras oil, that they are sometimes used in the manufacture of MDMA. MDMA is also known as ecstasy, and is often spelled XTC. MDMA is a Schedule I controlled substance under federal law.

MDMA abuse is a major drug problem in the United States.

Criminals search for sources of safrole and essential oils rich in safrole (both will be referred to as "safrole"). Safrole is a list I chemical under federal law.

Regulated persons need to know their customers so as not to become unwitting suppliers to a clandestine MDMA laboratory.

Regulated persons shall report to the DEA Special Agent in Charge of the local DEA office the following information:

1. Any regulated transaction involving:
 - an extraordinary quantity of safrole,
 - an uncommon method of payment or delivery, or
 - any other circumstance that the regulated person believes may indicate that the safrole will be used in violation of the Controlled Substances Act.
2. Any proposed regulated transaction with a person whose description or other identifying characteristic DEA has previously furnished to the regulated person.
3. Any unusual or excessive loss or disappearance of safrole under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

Please refer to [21 CFR 1310.05\(b\)](#) for details on method and timing of reports and [21 CFR 1310.03](#) and [1310.04](#) for details regarding recordkeeping requirements.

It is unlawful for any person knowingly or intentionally to possess or distribute safrole, knowing, or having reasonable cause to believe, the safrole will be used to manufacture MDMA. The Drug Enforcement Administration thanks you for your cooperation in this matter.

APPENDIX P - DEA Diversion Field Office Locations

DRUG ENFORCEMENT ADMINISTRATION
DIVERSION FIELD OFFICE LOCATIONS

Visit [DEA Contact Us - Search Utility](#).

APPENDIX Q - Small Business and Agriculture Regulatory Enforcement Ombudsman

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman annually evaluates the enforcement activities and rates each agency's responsiveness to small business. If you wish to comment on DEA enforcement actions, you may contact the Ombudsman at 1-888-REG-FAIR (1-888-734-3247).

APPENDIX R - Additional Assistance and Plain Language Statement

Additional Assistance

This publication is intended to provide guidance and information on the requirements of the CSA and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding the DEA's requirements or regulatory activities, please contact your local DEA Diversion Field Office (see [APPENDIX P](#)). Every effort will be made to respond promptly to your inquiry.

Plain Language

The Drug Enforcement Administration has made every effort to write this manual in clear, plain language. If you have suggestions as to how to improve the clarity of this manual, please contact us at:

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