

# Chemical Handler's Manual

A Guide to Chemical Control Regulations

Revised 2013<sup>1</sup>

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<sup>1</sup> 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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Michele M. Leonhart  
Administrator  
Drug Enforcement Administration

Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control

Cathy A. Gallagher  
Chief, Liaison and Policy Section

This manual was prepared by the Drug Enforcement Administration, Office of Diversion Control, 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.

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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 (21 U.S.C.) §§ 801-904; the Controlled Substances Import and Export Act (CSIEA), 21 U.S.C. §§ 951-971; and the DEA regulations, Title 21 Code of Federal Regulations (21 C.F.R.), 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 the DEA. Readers should refer to the most current copy of the laws (CSA and CSIEA), regulations (C.F.R.), and Federal Register notices to obtain a complete and accurate representation of regulated chemical laws and regulations.

Printed copies of the complete regulations implementing the CSA (21 C.F.R. 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 C.F.R. and the Federal Register (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.fdsys.gov](http://www.fdsys.gov)

Unofficial copies of pertinent C.F.R. citations and this chemical handler's manual may be found on the Internet within the DEA's Office of Diversion Control website:

[www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov)

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

If you encounter errors in this document, please notify:

Editor, DEA Chemical Handler's Manual  
Attn: Liaison and Policy Section/ODL  
Drug Enforcement Administration  
8701 Morrissette Drive  
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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## Authorization for Public Dissemination

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## Message from the Deputy Assistant Administrator

The Drug Enforcement Administration, Office of Diversion Control, is pleased to provide you with the 2013 edition of the Chemical Handler's Manual.

The Office of Diversion Control carries out the mandates of the Controlled Substances Act (21 U.S.C. §§ 801-971) by preventing the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of these substances and chemicals for legitimate medical, scientific, research, and industrial purposes.

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, a resurgence of methamphetamine abuse occurred in the 1980s, and it is currently considered a major drug of abuse. The widespread availability of methamphetamine today is largely fueled by illicit production in large and small clandestine laboratories throughout the United States and illegal production and importation from Mexico.

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 the Drug Enforcement Administration.

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,



Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control  
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 Controlled Substances Act (CSA), to consolidate and replace more than 50 pieces of national drug legislation. The CSA went into effect on May 1, 1971. The DEA was established in 1973 to serve as the single Federal agency to coordinate the Federal government's drug control activities.

Large quantities of chemicals are required to synthesize, extract, and purify most illicit drugs. The 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, the 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.

The DEA embarked upon a broad chemical control program in 1989 that was based on the Chemical Diversion and Trafficking Act (CDTA) of 1988. The CDTA regulated 12 precursor chemicals (now referred to as List I chemicals), 8 essential chemicals (now referred to as List II chemicals), tableting machines, and encapsulating machines by imposing recordkeeping and reporting requirements on certain transactions. It 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.

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), the Comprehensive Methamphetamine Control Act of 1996 (MCA), the Methamphetamine Anti-Proliferation Act of 2000 (MAPA), the Combat Methamphetamine Epidemic Act of 2005 (CMEA), the Methamphetamine Production Prevention Act of 2008 (MPPA), and the Combat Methamphetamine Enhancement Act of 2010 (MEA). 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 U.S. 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. 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 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.

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- When single-entity ephedrine products became regulated, drug traffickers turned to pseudoephedrine. This change in strategy was addressed by the MCA which expanded 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 9 grams of pseudoephedrine base or phenylpropanolamine base in a single transaction and limited package sizes to contain no more than 3 grams of pseudoephedrine base or phenylpropanolamine base. The Act 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 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 Act also established daily sales limits of 3.6 grams per customer for each chemical and limits purchases of these products to 9 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. The 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.

It is the DEA's goal to effectively regulate while maintaining a positive working relationship with the regulated community. The DEA seeks to inform and educate industry on the CSA and its implementing regulations. The DEA understands that it can best serve the public interest by working in voluntary cooperation with the chemical and pharmaceutical industries in developing programs designed to prevent the diversion of legal pharmaceutical controlled substances and regulated chemicals into the illicit market.

## SECTION II - DEFINITIONS

The official language for most definitions presented in this section may be found at 21 U.S.C. § 802 or 21 C.F.R. § 1300.02.

### **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.

### **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](#)).

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## **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 C.F.R. § 1310.12 is exempt from CSA chemical regulatory provisions such as registration, recordkeeping, and import/export notification requirements (see [Appendix E](#)). [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 C.F.R. § 1310.02.

## **List I Chemical**

A chemical specified by regulation that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

## **List II Chemical**

A chemical, other than a List I chemical, specified by regulation that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

## **Mail-Order Sale**

A retail sale of scheduled listed chemical products for personal use 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.

## **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.

## **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).

## **Net Disposal**

A complete definition can be found at 21 C.F.R. § 1315.02.

## **Person**

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

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## **Readily Retrievable**

Means that certain records 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 the 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 the 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 the 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 the DEA establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the 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 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 C.F.R. 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,

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and Cosmetic Act, subject to paragraph (v) of the definition of regulated transaction found at 21 C.F.R. § 1300.02(b), unless -

- (1) The DEA has determined pursuant to the criteria in 21 C.F.R. § 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 C.F.R. § 1310.03(c); or
- F. Any transaction in a chemical mixture designated in 21 C.F.R. §§ 1310.12 and 1310.13 that the 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)**

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.

## **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 cohesive 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 C.F.R. part 1309 and 21 C.F.R. §§ 1310.12 and 1310.13.

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 C.F.R. § 1300.02(b).

(\*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.)

Persons who handle List II chemicals only are not required to register with the 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.

### Factors Used by the DEA in Approving List I Chemical Applications

Information regarding these factors may be found at 21 U.S.C. § 823(h).

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.

### Exceptions to Registration

There are waivers of registration requirements for certain activities, exemptions for law enforcement officials, an exemption for regulated sellers of scheduled listed chemical products (SLCP), and an exemption for mail-order distributors of SLCPs. These waivers and exemptions are explained in the succeeding 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 may be found in 21 C.F.R. §§ 1310.12 and 1310.13.

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## Waiver of Registration Requirement for Certain Activities

Information regarding these waivers may be found at 21 C.F.R. § 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 (iv) of the definition of "regulated transaction" found at 21 C.F.R. § 1300.02(b), if that person is registered with the 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 (iv) of the definition of "regulated transaction" found at 21 C.F.R. § 1300.02(b), if that person is registered with the 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 (iv) of the definition of regulated transaction found at 21 C.F.R. § 1300.02(b).
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 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.

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.

The 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 C.F.R. §§ 1309.43 - 1309.46 and §§ 1309.51 - 1309.55. In considering the revocation or suspension of a person's waiver granted pursuant to paragraph 2 or 3 above, the 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.

Any person exempted from the registration requirement listed above must comply with the security requirements set forth in 21 C.F.R. §§ 1309.71 - 1309.73 and the recordkeeping and reporting requirements set forth under 21 C.F.R. parts 1310, 1313, 1314, and 1315.

## Exemption of Law Enforcement Personnel

Information regarding this waiver may be found at 21 C.F.R. § 1309.26.

# DEA Chemical Handler's Manual

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The requirement of registration is waived for the following persons:

1. Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, any other Federal 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.

## **Registration Exemption for Regulated Sellers of Scheduled Listed Chemical Products (SLCP)**

This exemption may be found at 21 U.S.C. § 823(h).

Registration is not required for regulated sellers of SLCPs. A regulated seller is a retail distributor (including a pharmacy or a mobile retail vendor).

Although exempt from registration, regulated sellers must self-certify with the DEA pursuant to Federal law (see [Section IX, Retail Sales of Scheduled Listed Chemical Products](#)). This self-certification must be renewed annually.

## **Registration Exemption for Mail-Order Distributors of Scheduled Listed Chemical Products (SLCP)**

This exemption may be found at 21 U.S.C. § 823(h).

Mail-order distributors of SLCPs to non-regulated parties (a consumer or end-user who does not re-distribute) are exempt from registration.

Although exempt from registration, mail-order distributors must self-certify with the DEA pursuant to Federal law (see [Section IX, Retail Sales of Scheduled Listed Chemical Products](#)). This self-certification must be renewed annually.

## **Separate Registration for Independent Activities**

Information regarding this subject may be found at 21 C.F.R. § 1309.22.

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.

## DEA Chemical Handler's Manual

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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 C.F.R. §§ 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.
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.

### **Separate Registration for Separate Locations**

Information regarding this subject may be found at 21 C.F.R. § 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.

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
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 may be found at 21 C.F.R. §§ 1309.31, 1309.32 and 1309.42.

Any person wishing to manufacture, distribute, import, or export listed chemicals shall obtain a DEA registration annually by filling out the DEA Form 510 which may be completed online at [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm). The application fee is indicated when a business activity is selected.

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The screenshot shows the website for the Office of Diversion Control, part of the U.S. Department of Justice Drug Enforcement Administration. The page is titled "Registration Applications" and "Office of Diversion Control Web Interactive Forms (ODWIF) NEW APPLICATIONS". It provides information for registration help, including the email address [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov), and a note to include the DEA Registration number in the email. A table lists various application processes and their corresponding user types. A section titled "MINIMUM ON-LINE REQUIREMENTS" states that data will be entered through a secure connection and that the web browser must support 128-bit encryption.

U.S. Department of Justice Drug Enforcement Administration  
**Office of Diversion Control**

Registration > ODWIF

**Registration Applications**

**Office of Diversion Control Web Interactive Forms (ODWIF)  
NEW APPLICATIONS**

For Registration Help  
[DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov)  
Please be sure to include your DEA Registration number in your email.

<a href="#">Begin Application Process</a>	Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner, Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter, Narcotic Treatment Program, Domestic Chemical
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**MINIMUM ON-LINE REQUIREMENTS**

The DEA Forms listed below 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. Your 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 [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://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/ODR  
P.O. Box 2639  
Springfield, VA 22152-2639



## DEA Chemical Handler's Manual

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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 the DEA has approved the application, the DEA will mail a Certificate of Registration (DEA Form 223) to the registered address. 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.

If a registrant needs a duplicate DEA Certificate of Registration, he/she may:

- Download online at <https://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@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov)

### Renewal of Chemical Registration

Information regarding this subject may be found at 21 C.F.R. § 1309.32.

A chemical registration must be renewed every year utilizing DEA Form 510a, Renewal Application for DEA Registration. To renew a registration, the most current information from the chemical handler's existing registration must be utilized. A registrant can renew online no more than 60 days prior to the current expiration date. The DEA Form 510a may be completed online and can be found at [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm). The cost of the application fee is provided on the online form.

# DEA Chemical Handler's Manual

The screenshot shows the DEA Office of Diversion Control website. The header includes the U.S. Department of Justice Drug Enforcement Administration logo and the text "Office of Diversion Control". A navigation menu on the left lists "Home", "Registration", "Reporting", "Info & Legal Resources", and "Inside Diversion Control". The main content area is titled "Registration Applications" and "Office of Diversion Control Web Interactive Forms (ODWIF) RENEWAL APPLICATIONS". It provides a link for registration help: [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov). A table lists three options: "Log in to Begin Renewal Process", "Obtain Receipt", and "Duplicate Certificate". Below the table, it lists "MINIMUM ON-LINE REQUIREMENTS" and provides a list of information needed to complete the form: Tax ID number and/or Social Security Number, State Controlled Substance Registration Information, State Medical License Information, and Credit Card (VISA, MasterCard, Discover or American Express). A note states that the ODWIF system can only process credit card transactions at this time.

<a href="#">Log in to Begin Renewal Process</a>	Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner, Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter, Domestic Chemicals, Narcotic Treatment Programs
<a href="#">Obtain Receipt</a>	This link may be used ONLY if you have previously submitted a Renewal Application through this tool and need an additional receipt
<a href="#">Duplicate Certificate</a>	On-line tool to request certificates for additional, misplaced, illegible, or destroyed originals.

**MINIMUM ON-LINE REQUIREMENTS**

The DEA Forms listed below 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. Your web browser must support 128-bit encryption.

You will need to have the following information handy in order to complete the form:

- Tax ID number and/or Social Security Number
- State Controlled Substance Registration Information
- State Medical License Information
- Credit Card (VISA, MasterCard, Discover or American Express)

The ODWIF system can only process credit card transactions at this time. If you are paying by check, you will need to use the PDF version of the form, then print and mail the form to the address listed on the form.

If the registrant has not renewed online approximately 45 days before the registration expiration date, a renewal application is sent to the registrant at the mailing address listed on the current registration. If the renewal form (DEA Form 510a) is not received by the 30<sup>th</sup> day before the expiration date of the current registration, the chemical handler should 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 <http://www.dea diversion.usdoj.gov/drugreg/offices/index.html>
- Call DEA Headquarters at 1-800-882-9539
- Send e-mail to [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov)

**Note:** Once the expiration date has passed and no renewal application has been received by the DEA, the chemical handler has no authority to handle List I chemicals.

## Modification of Registration

Information regarding this subject may be found at 21 C.F.R. § 1309.61.

Any registrant may apply to modify his/her registration to authorize the handling of additional List I chemicals or to change his/her name or address by submitting a request online at [http://www.dea diversion.usdoj.gov/drugreg/change\\_requests/index.html](http://www.dea diversion.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/ODR  
P.O. Box 2639  
Springfield, VA 22152-2639

The letter shall contain the registrant's name, address, and registration number as printed on the Certificate of Registration (DEA Form 223). The request for modification shall be handled in the same manner as an application for registration. There is no fee to modify a registration. If the modification is approved, the DEA will issue a new Certificate of Registration. The registrant should maintain the new certificate with the old certificate until expiration.

## 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, per 21 C.F.R. § 1309.63.

## Termination of Registration

Information regarding this subject may be found at 21 C.F.R. § 1309.62.

The registration of any person shall terminate, without any further action by the DEA, if and when such person dies, ceases legal existence, discontinues business or professional practice, or surrenders a registration. If a registration is surrendered, termination shall occur upon receipt by any DEA employee of a duly executed DEA Form 104c or any signed writing indicating the desire to surrender a registration. 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.

## Suspension or Revocation of Registration

Information regarding this subject may be found at 21 U.S.C. §§ 823(h) and 824(a).

The 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 Controlled Substances Act (CSA) or the Controlled Substances Import and Export Act (CSIEA);
2. Has been convicted of a felony under the CSA or CSIEA or any other law of the U.S., 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;
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 will be considered:

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- 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).

## SECTION IV - SECURITY

Information regarding this subject may be found at 21 C.F.R. §§ 1309.71 - 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. Specific attention should be paid to the following areas:

1. The regulated seller must place the scheduled listed chemical products (SLCP) so that customers do not have direct access to the product before the sale is made. SLCPs must be kept behind the counter or stored in a locked cabinet. Mobile retail vendors must keep SLCPs in a locked cabinet.
2. Chemicals must be stored in a container sealed in such a way that will reveal any attempts at tampering. 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.
3. The registrant should 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 the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause. 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. The registrant shall assess the risks involved in employing such persons, including the potential for suspension or revocation of the registrant's DEA registration.
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. 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. A failure to report information of chemical diversion will 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.

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 C.F.R. § 1309.71 - 1309.73.

In evaluating the effectiveness of security controls and procedures, the following factors shall be considered:

1. The type, form, and quantity of List I chemicals handled,
2. The location of the premises and the relationship such location bears on the 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

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8. The adequacy of systems for monitoring receipt, distribution, and disposition of List I chemicals.

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/ODG  
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.

A regulated person is required to verify that a customer for List I chemicals possesses a valid DEA registration or is exempt from that requirement. 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 may be found at 21 U.S.C. § 830(a)(3) and 21 C.F.R. § 1310.07.

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

Each regulated person engaging in a regulated transaction must identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine, or encapsulating machine.

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. Verification of documents may be accomplished through the following sources, including, but not limited to the: telephone directory, local credit bureau, local Chamber of Commerce, or local Better Business Bureau. Proof of identity may also be verified by the DEA registration status if the ordering party is a registrant. A DEA registrant can verify the other party's DEA registration by visiting <https://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.

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.

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,

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or other identification. Once the authorized purchasing agent has been established, the agent list may be updated annually rather than on each order. The regulated person must ensure that shipments are not made unless the order is placed by an authorized agent of record.

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.

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. 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. Official documents provided by the purchaser may confirm the existence and apparent validity of the business entity.

Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person must obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport information and photograph. 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.

## SECTION V - RECORDKEEPING REQUIREMENTS

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

### Persons Required to Keep Records

Information regarding this subject may be found at 21 C.F.R. § 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 and file reports to the DEA as outlined in this section. 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. Thresholds can be found in [Appendix D](#).

### Contents of Regulated Transaction Records

Information regarding this subject may be found at 21 C.F.R. § 1310.06.

Each record for a domestic transaction 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 form of packaging of the listed chemical, or description of the tableting machine or encapsulating machine (including make, model, and serial number).
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.

### Location and Availability of Records

Information regarding this subject may be found at 21 C.F.R. § 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. Records may be kept at a single, central location of the regulated person if the regulated person has notified the DEA of the intention to do so. 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](#)).

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 purchases which are made from multiple locations to circumvent the cumulative threshold requirements.

The records required to be kept shall be readily retrievable and available for inspection and copying by duly authorized DEA officials.

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## **Maintenance of Records**

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. However, as with all regulations, regulated persons are advised to check with other Federal, State, and local agencies to verify compliance with those regulations as well. Information regarding this subject may be found at 21 C.F.R. § 1310.04.

## **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. Information regarding this subject may be found at 21 C.F.R. § 1310.03.

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## SECTION VI - REPORTS TO THE DRUG ENFORCEMENT ADMINISTRATION

### What Must be Reported

Information regarding this subject may be found at 21 U.S.C. § 830(b) and 21 C.F.R. § 1310.05.

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 will be used in violation of the CSA.
2. Any proposed regulated transaction with a person whose description or other identifying characteristic the 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 4 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. 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. Detailed reporting requirements are found in 21 C.F.R. § 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 the DEA unless the transaction is approved by the DEA.

### Bulk Manufacturers' Reports

Regulated bulk manufacturers of listed chemicals are required to submit manufacturing, inventory, and use data on an annual basis to:

Drug Enforcement Administration  
Attn: Drug and Chemical Evaluation Section/ODE  
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 being submitted. Information regarding this subject may be found at 21 C.F.R. §§ 1310.05(d) and 1310.06(h).

### Reports of Mail-Order Sales

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

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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.

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. Name of the chemical and total amount shipped (i.e., pseudoephedrine, 250 grams);
5. Date of shipment;
6. Product name (if drug product);
7. Dosage form (if drug product) (i.e., pill, tablet, liquid);
8. Dosage strength (if drug product) (i.e., 30 mg, 60 mg, per dose etc.);
9. Number of dosage units (if drug product) (100 doses per package);
10. Package type (if drug product) (bottle, blister pack, etc.);
11. Number of packages (if drug product) (10 bottles);
12. Lot number (if drug product).

Reports of mail-order sales should be sent to:

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

The written reports must be submitted on or before the 15<sup>th</sup> day of each month following the month in which the distributions took place. The report shall 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. If the regulated person or regulated seller is not a DEA registrant, the report should be signed by a company official with similar authority. Upon request to and approval by the DEA, a regulated person may submit this report electronically to the DEA.

## **Exemptions from Reporting Requirements**

Information regarding this subject may be found at 21 C.F.R. §§ 1310.05 and 1314.115.

The following distributions made by regulated persons to non-regulated persons or export transactions that involve ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and use or attempt to use the Postal Service or any private or commercial carrier are exempted from the aforementioned reporting requirements. *Exemptions to mail-order sales reporting requirements only apply to paragraphs 1 through 4 below.*

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.

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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 scheduled listed chemical products (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 the DEA under the transshipment reporting requirements (21 C.F.R. § 1313.31), or the international transaction reporting requirements (21 C.F.R. § 1313.32), or for which advance notification reporting requirements are waived.

The DEA may revoke exemptions for regulated persons whose distributions of drug products are found to violate the CSA or the regulations.

### 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/ODGI  
8701 Morrisette Drive  
Springfield, VA 22152  
Phone: 202-307-7161  
Fax: 202-307-4702  
E-mail: [chemical.imex@usdoj.gov](mailto:chemical.imex@usdoj.gov)

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

An Import/Export Declaration for List I and List II Chemicals, DEA Form 486, must be completed by each regulated person for each regulated import, export, or international transaction. An Import Declaration for Ephedrine, Pseudoephedrine and Phenylpropanolamine, DEA Form 486A, must be used for imports of ephedrine, pseudoephedrine, and phenylpropanolamine. The DEA Form 486, DEA Form 486A, and corresponding instructions may be obtained from DEA's Office of Diversion Control website, [http://www.deadiversion.usdoj.gov/21cfr\\_reports/chemicals/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/chemicals/index.html). The completed copy may be sent to DEA via regular mail, e-mail, or fax. (see contact information above.) The DEA Form 486 and 486A can also be transmitted to DEA online at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov). Online transmission of DEA Form 486 and 486A requires that 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 may be found at 21 U.S.C. §§ 957 and 971 and 21 C.F.R. §§ 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.

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 the DEA of the importation not later than 15 days before the transaction is to take place.

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 the 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.

To establish a record as an importer, the regulated person must provide the DEA with the following information under the waiver of 15-day advance notice requirements of 21 C.F.R. §§ 1313.08 and 1313.15:

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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 C.F.R. § 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 the DEA.

To document that an importer has an established business relationship with a customer, the importer must provide the DEA with the following information under the waiver of 15-day advance notice requirements of 21 C.F.R. § 1313.05:

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 (i.e., 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 the 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 received by the DEA on or before the date of importation.

The 15-day advance notification requirement for listed chemicals may also be waived for a specific listed chemical for which the DEA determines that advance notification is not necessary for effective chemical diversion control. In this circumstance, no DEA Form 486 is required; however, the regulated person must submit quarterly reports no later than the fifteenth day of the month following the end of each quarter. The report shall contain the following information regarding each individual importation:

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.

The 15-day advance notification requirement has been waived for imports of acetone, 2-butanone (or methyl ethyl ketone or MEK), and toluene. The qualification of a regular importer of acetone, 2-butanone, or toluene qualifies that person as a regular importer of all three of these chemicals.

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## Information Required for the Import Declaration (DEA Form 486 and 486A)

Information regarding this subject may be found at 21 C.F.R. §§ 1313.13 and 1313.16.

The United States importer of a List I or List II chemical must provide the following types of information on the DEA Form 486 or DEA Form 486A. (For a complete listing of information required, please review the regulations and DEA Form 486 or DEA Form 486A.)

1. Contact information for the United States chemical importer, and contact information for the broker or forwarding agent (if any);
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 the DEA in 21 C.F.R. § 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;
3. The proposed import date, the foreign port of exportation, and the first U.S. Customs port of entry;
4. Contact information of the consigner in the foreign country of exportation; and
5. Contact information of the person(s) 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.

After a DEA Form 486 or DEA Form 486A has been submitted to the DEA, if circumstances change and the United States importer will not be transferring the listed chemical to the transferee identified in the original DEA Form 486 or DEA Form 486A, or will be transferring 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. The importer 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 the DEA. 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 that it applies with respect to changing circumstances regarding a transferee or quantity identified in the original DEA Form 486 or DEA Form 486A. The 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer of the importer. This exception, however, does not extend to imports of ephedrine, pseudoephedrine, and phenylpropanolamine.

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.

The DEA will have 15 days from the time the customer information is submitted to review the proposed transaction. The DEA reviews each import transaction regarding the chemical to be imported and the transferee to whom the chemical will be transferred. If the DEA takes no action, the importer will thus be granted regular importer status for transactions involving the specific chemical to be imported to the specific customer. This new transferee, i.e., the downstream customer, will be granted regular customer status for future imports of the specified chemical by the specified importer.

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## **Special Requirements for Imports of Ephedrine, Pseudoephedrine, and Phenylpropanolamine**

Information regarding this subject may be found at 21 U.S.C. §§ 952 and 971; and 21 C.F.R. §§ 1313.13 and 1313.42.

It is unlawful to import into the United States ephedrine, pseudoephedrine, and phenylpropanolamine except such amounts as the DEA finds to be necessary to provide for medical, scientific, or other legitimate purposes. DEA-registered importers must have an import quota issued by the DEA prior to submitting a DEA Form 486A for the importation of ephedrine, pseudoephedrine, or phenylpropanolamine. Each reference in this manual to ephedrine, pseudoephedrine, or phenylpropanolamine includes the salts, optical isomers, and salts of optical isomers of the chemical.

An Import Declaration for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, DEA Form 486A, must be completed by each DEA-registered importer for each import. The DEA Form 486A and the instructions for completing and distributing it can be found online at [http://www.deadiversion.usdoj.gov/21cfr\\_reports/chemicals/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/chemicals/index.html). The completed copy may be sent to the DEA via fax or mail (see contact information above.)

Further, any regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine must submit on the DEA Form 486A all information known to the importer on the chain of distribution of the chemical from the manufacturer to the importer.

The DEA Form 486A must be received by the DEA at least 15 days prior to the import of ephedrine, pseudoephedrine, or phenylpropanolamine. The waiver of the 15-day advance notification requirement does not apply to the import of these three chemicals.

To prevent or respond to the diversion of ephedrine, pseudoephedrine, or phenylpropanolamine for use in the illicit production of methamphetamine, the DEA may request that a manufacturer or distributor in the foreign chain of distribution provide information known to the foreign manufacturer or distributor on the distribution of the chemical, including sales. If the DEA determines that a foreign manufacturer or distributor of ephedrine, pseudoephedrine, or phenylpropanolamine has refused to cooperate with a request by the DEA for information known to the manufacturer or distributor on the distribution of the chemical, including sales, the 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.

Not later than 60 days prior to issuing the order to prohibit importation, the DEA is required to publish in the Federal Register a notice of intent to issue the order. During the 60-day period, imports from the foreign manufacturer or distributor may not be restricted by the DEA. The DEA is not otherwise prohibited from suspending the import under 21 U.S.C. § 971(c).

## **Return Declarations for Imports of Listed Chemicals**

Information regarding this subject may be found at 21 U.S.C. § 971 and 21 C.F.R. § 1313.17.

Within 30 days after an import transaction is completed, the importer must send to the DEA a return declaration containing information regarding the transaction including the date, quantity, chemical, container, name of transferee(s), and any other information that the DEA may specify. A single return declaration may include specific information regarding the importation and the distribution. If the importer has not distributed all chemicals by the end of the initial 30-day period, the importer must file supplemental

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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.

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 the DEA that the importation did not occur.

## Requirements for Exportation of Listed Chemicals

Information regarding this subject may be found at 21 U.S.C. §§ 960 and 971 and 21 C.F.R. §§ 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. 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).

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. Notification must be made not later than 15 days before the transaction is to take place.

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 the DEA an established business relationship with a foreign customer.

To document that an exporter has an established business relationship with a customer, the exporter must provide the 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 (i.e., 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 the DEA otherwise notifies the regulated person in writing.

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 the DEA notifies the chemical exporter to the contrary.

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For exports where advance notification is waived for any regulated person who has satisfied the requirements for reporting to the DEA an established business relationship with a foreign customer, the DEA Form 486 must be received by the DEA on or before the date of exportation.

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 the DEA determines that advance notification is not necessary for effective chemical diversion control. In this circumstance, no DEA Form 486 is required; however, the regulated person must submit quarterly reports no later than the fifteenth day of the month following the end of each quarter. The report shall contain the following information regarding each individual exportation:

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 the Export Declaration (DEA Form 486)

Information regarding this subject may be found at 21 C.F.R. §§ 1313.22 and 1313.26.

Any List I or List II chemical which meets or exceeds the quantitative thresholds established by the 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.

The United States exporter of a List I or List II chemical must provide the following types of information on the DEA Form 486. (For a complete listing of information required, please review the regulations and DEA Form 486.)

1. Contact information for the United States chemical exporter and contact information for the export broker, if any;
2. The name of each listed chemical as described by the DEA in 21 C.F.R. § 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 proposed export date, the U.S. Customs port of exportation, and the foreign port of entry;
4. Contact information of the consignee(s) in the country where the chemical shipment is destined, and contact information of any intermediate consignee(s).

For a United States exporter, the "transferee" is the foreign importer.

After a DEA Form 486 has been submitted to the 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 the DEA.

If circumstances change and the United States exporter will not be transferring the listed chemical to the transferee identified in the original DEA Form 486, or will be transferring 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. The exporter may not transfer the listed chemical until after

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the expiration of the 15-day period beginning on the date on which the update is submitted to the DEA, except that the 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. 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 same manner that it applies with respect to changing circumstances regarding a transferee or quantity identified in the original DEA Form 486.

Even if an exporter is exempted from the 15-day advance notice requirement, 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.

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 the DEA otherwise notifies the exporter in writing.

### **Return Declarations for Exports of Listed Chemicals**

Information regarding this subject may be found at 21 U.S.C. § 971 and 21 C.F.R. § 1313.27.

Within 30 days after a transaction is completed, the exporter must send to the DEA a return declaration containing information regarding the transaction including the date, quantity, chemical, container, name of transferees, and any other information that the DEA may specify. 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 the DEA that the exportation did not occur.

### **Declared Exports that are Refused**

Information regarding this subject may be found at 21 C.F.R. § 1313.22.

Declared exports of listed chemicals that are refused, rejected, or otherwise deemed undeliverable may be returned to the United States chemical exporter of record. A brief written notification (this does not require a DEA Form 486) outlining the circumstances must be sent to the DEA following the return within a reasonable time. 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 considered imports.

### **Special Policy Regarding Exports of Certain Chemicals to Colombia**

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

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[FR 13759](#) which establishes and explains this policy. Exports of these listed chemicals to Colombia require 15-day advance notification.

## Disqualification of Waiver

Information regarding this subject may be found at 21 U.S.C. § 971 and 21 C.F.R. §§ 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, the 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.

## Suspension of Shipments

Information regarding this subject may be found at 21 U.S.C. § 971(c) and 21 C.F.R. § 1313.41.

The 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. When a shipment is suspended, the DEA will issue a suspension notice to the regulated person explaining the circumstances of the suspension along with instructions on how to request a hearing.

## Transshipment through the United States

Information regarding this subject may be found at 21 C.F.R. § 1313.31.

A listed chemical that meets or exceeds the threshold reporting requirements found in 21 C.F.R. § 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 notice is submitted to the DEA. The 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 the DEA no later than 15 days prior to the proposed transshipment date. 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 ([http://www.deadiversion.usdoj.gov/chem\\_prog/transshipment\\_chem\\_instruct.pdf](http://www.deadiversion.usdoj.gov/chem_prog/transshipment_chem_instruct.pdf)) and Sample Letter ([http://www.deadiversion.usdoj.gov/chem\\_prog/transshipment\\_chem\\_sampleltr.pdf](http://www.deadiversion.usdoj.gov/chem_prog/transshipment_chem_sampleltr.pdf)) for details. Unless notified by the DEA to the contrary prior to the expected date of delivery, the importation for transshipment or transfer is considered approved.

## International Transactions

Information regarding this subject may be found at 21 U.S.C. § 971 and 21 C.F.R. §§ 1313.33 - 1313.35.

An international transaction involving a listed chemical which meets or exceeds the quantitative thresholds established by the DEA may be arranged by a broker or trader if the chemical is needed for medical, commercial, scientific, or other legitimate uses.

A broker or trader shall notify the DEA prior to an international transaction that meets or exceeds the threshold amount established by the DEA in which the broker or trader participates. Notification must be made no later than 15 days before the transaction is to take place.

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A completed DEA Form 486 must be received from the United States broker or trader by the DEA no later than 15 days prior to the transaction.

## **Information Required for International Transactions - DEA Form 486**

Information regarding this subject may be found at 21 C.F.R. §§ 1313.32, 1313.33, and 1313.16(b).

The United States broker or trader of a List I or List II chemical must provide the following types of information on the DEA Form 486. For specific information required, please review the regulations or the DEA Form 486.

1. Contact information for the chemical exporter and contact information for the chemical importer.
2. The name of each listed chemical as described by the DEA in 21 C.F.R. § 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 proposed export date, the port of exportation, and the port of importation.
4. Contact information of the consignee in the country where the chemical shipment is destined, and contact information of any intermediate consignee(s).

After a DEA Form 486 has been submitted to the DEA, if circumstances change and the United States broker or trader will not be transferring the listed chemical to the transferee identified in the original DEA Form 486, or will be transferring 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. 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 the DEA. This 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 same manner as it applies with respect to changing circumstances regarding a transferee or quantity identified in the original DEA Form 486.

## **Return Declarations for International Transactions**

Information regarding this subject may be found at 21 U.S.C. § 971 and 21 C.F.R. § 1313.35.

Within 30 days after a transaction is completed, the broker or trader must send to the DEA a return declaration containing information regarding the transaction including the date, quantity, chemical, container, name of transferees, and any other information that the DEA may specify. 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 notifying the DEA that the transaction did not occur.

## **Imports/Exports of Tableting/Encapsulating Machines**

Information regarding this subject may be found at 21 C.F.R. §§ 1310.05 and 1310.06.

Each regulated person who imports or exports a tableting machine or an encapsulating machine must file a report (*not a DEA Form 486*) of such importation or exportation with the DEA by regular mail, e-mail, or fax on or before the date of importation or exportation (see contact information at the beginning of this section).

Any tableting or encapsulating machine may be imported or exported if that machine is needed for medical, commercial, scientific, or other legitimate uses. However, an importation or exportation of a tableting

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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 the DEA, unless the transaction is approved by the DEA.

### **Declared Exports of Tableting and Encapsulating Machines that are Refused**

Information regarding this subject may be found at 21 C.F.R. § 1310.06.

Declared exports of tableting or encapsulating machines that are refused, rejected, or otherwise deemed undeliverable may be returned to the United States exporter of record. A brief written notification (*not a DEA Form 486*) outlining the circumstances must be sent to the DEA following the return within a reasonable time. 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 considered imports.

### SECTION VIII - QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE

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

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

#### Background

Information regarding this subject may be found at 21 U.S.C. §§ 826 and 952, and 21 C.F.R. part 1315.

The Combat Methamphetamine Epidemic Act of 2005 (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. CMEA imposes the following changes:

1. The DEA must establish an assessment of the annual needs for the estimated medical, scientific, research, and industrial needs of the U.S.; for lawful exports; and for the establishment and maintenance of reserve stocks. That assessment establishes an upper limit on the quantity of the chemicals and products containing the chemicals that can be produced in or imported into the U.S.
2. Importers must obtain a quota to import the chemicals in bulk or contained in drug products.
3. Bulk manufacturers must obtain a manufacturing quota to produce any of the three chemicals.
4. Manufacturers who purchase the bulk chemicals to produce products must obtain a procurement quota before procuring any of the three chemicals.
5. Manufacturers who package, repackage, label, or relabel must obtain a procurement quota before procuring any of the three chemicals.

#### Import Quotas

Information regarding this subject may be found at 21 U.S.C. § 952 and 21 C.F.R. §§ 1315.30, 1315.34, and 1315.36.

DEA registered importers must have an import quota issued by the DEA prior to submitting a DEA Form 486A for the importation of ephedrine, pseudoephedrine, and phenylpropanolamine.

Only DEA registered chemical importers may apply for an import quota for the three List I chemicals. A separate quota is required for each chemical. Each DEA registered importer that wishes to import ephedrine, pseudoephedrine, or phenylpropanolamine must follow the [instructions](http://www.deadiversion.usdoj.gov/quotas/488/488_instruct.htm) [http://www.deadiversion.usdoj.gov/quotas/488/488\\_instruct.htm](http://www.deadiversion.usdoj.gov/quotas/488/488_instruct.htm) to complete and file a [DEA Form 488](#), Application for Import Quota, and its corresponding worksheet, [DEA Form 488 \(worksheet A\)](#), [http://www.deadiversion.usdoj.gov/quotas/488/488\\_worksheeta.pdf](http://www.deadiversion.usdoj.gov/quotas/488/488_worksheeta.pdf) each year for each chemical the importer wishes to import. Individual applications are required for importing either bulk chemical or finished dosage forms. The importer must provide on each application the following information:

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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, email 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.

Applications for individual import quotas must be filed on or before April 1 of the year preceding the year for which the quota is being applied.

Import quotas are issued on a calendar year basis and can only be used during the calendar year for which they were issued. Any person to whom an import quota has been issued may at any time request an increase in the quota quantity by applying to the DEA with a statement showing a need for the adjustment.

The DEA may approve the application if the DEA determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical.

## Manufacturing Quotas

Information regarding this subject may be found at 21 U.S.C. § 826 and 21 C.F.R. §§ 1315.21, 1315.22, and 1315.25.

Each person registered to manufacture in bulk ephedrine, pseudoephedrine, or phenylpropanolamine must obtain an individual manufacturing quota before manufacturing may begin. An individual manufacturing quota represents the maximum amount of ephedrine, pseudoephedrine, or phenylpropanolamine a DEA registrant is authorized to manufacture in a calendar year. A separate quota is required for each chemical.

A 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 quotas are being applied. For specific information required, please review 21 C.F.R. §§ 1315.21, 1315.22, 1315.25, and DEA Form 189. Manufacturing quotas are issued on a calendar year basis and can only be used during the calendar year for which they were issued. Requests for increases in manufacturing quotas can be made at any time so long as another DEA Form 189 is completed. Manufacturers may also abandon or reduce their quota by submitting a written notice to DEA.

The 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.

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## Procurement Quotas

Information regarding this subject may be found at 21 U.S.C. § 826 and 21 C.F.R. §§ 1315.30 - 1315.33.

A DEA registered manufacturer of ephedrine, pseudoephedrine, or phenylpropanolamine must obtain an individual procurement quota before procuring any of these chemicals for dosage form manufacturing, packaging, repackaging, labeling, and relabeling activities. An individual 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. A separate quota is required for each chemical.

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. A separate application must be made for each chemical desired to be procured or used.

The applicant must state separately all of the following:

1. A statement about the purpose(s) for the requested chemical and the quantity which will be used for each purpose during the next calendar year.
2. For the current and preceding two years:
  - a. Actual or estimated quantity used,
  - b. Actual net disposals, and
  - c. Actual inventory as of December 31 of each year; and
3. 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; or
4. If the purpose is to manufacture dosage forms, the applicant must state the official name, common or usual name, chemical name, or brand name of that dosage 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.

Manufacturers holding a procurement quota may request an adjustment of the quota by applying to the DEA with a statement showing the need for an adjustment.

## Certification of Quotas

Information regarding this subject may be found at 21 C.F.R. § 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. 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. 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. Registrants must not fill an order from persons required to apply for a procurement quota unless the order is accompanied by a certification.

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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.
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

This section is divided into four parts. The first part provides background information on amendments to the Controlled Substances Act concerning scheduled listed chemical products (SLCP). The second part pertains to both regulated sellers, such as retail stores, as well as mail-order distributors. The third part pertains only to regulated sellers. Finally, the fourth part pertains only to mail-order distributors.

### Part 1: Background

In March 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA). This Act amended the CSA to change the regulations for selling products that contain ephedrine, pseudoephedrine, and phenylpropanolamine that may be marketed or distributed lawfully in the U.S. under the Federal Food, Drug, and Cosmetic Act as nonprescription drugs. CMEA defines these products as 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 the 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 the 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 of 2008 (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 of 2010 (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 which makes it unlawful for both regulated sellers and mail-order distributors to negligently fail to self-certify. The MEA also mandated the DEA to make publicly available on its website, in an electronically downloadable format, a list of all persons who are currently self-certified. The DEA is developing a regulation to implement this MEA requirement.

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

#### Self-Certification Requirements

Information regarding this subject may be found at 21 U.S.C. § 830 and 21 C.F.R. §§ 1314.35 - 1314.42 and 1314.101 - 1314.103.

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Before the regulated seller or mail-order distributor or individual employees 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.

A separate self-certification is required for each separate physical location at which SLCPs are sold. Procedures are also available for chains to register multiple locations in a single transaction. Information regarding the chain self-certification process may be obtained by contacting the DEA Headquarters at 1-800-882-9539 or via e-mail at [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov).

Mobile retail vendors must complete the self-certification process for each location at which sales transactions occur. The self-certification for each location is required even if the same person(s) sells at each of the different locations.

Self-certification is required for each mail-order distributor at each place of business at which there are retail sales of SLCPs. For a mail-order distributor, this would mean 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. 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. 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.

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.
2. Records of training are being maintained.
3. Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine in a single day.
4. For mobile retail vendors and mail-order distributors, sales to an individual in a 30-day period may not exceed 7.5 grams.
5. Non-liquid forms are packaged as required.
6. Regulated sellers store SLCPs behind the counter or in a locked cabinet.
7. Mobile retail vendors store SLCPs in a locked cabinet.
8. Regulated sellers properly maintain a written or electronic logbook.
9. The logbook information will be disclosed only to Federal, state, or local law enforcement and only to ensure compliance with Title 21 of the United States Code or to facilitate a product recall.

## How to Self-Certify

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

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It is the responsibility of mail-order distributors as well as regulated sellers to annually renew the self-certification before the certificate expires if they wish to continue selling SLCPs at retail. Once the expiration date has passed, the mail-order distributors and regulated sellers cannot recertify or update the self-certification. There is no authority to sell SLCPs until a new self-certification is completed.

## **Self-Certification Training Materials**

The DEA has posted training materials on its website, [http://www.deadiversion.usdoj.gov/meth/index.html#self\\_cert](http://www.deadiversion.usdoj.gov/meth/index.html#self_cert). Employers must use the DEA's training materials when training the employees who sell SLCPs. An employer may include content in addition to the DEA's information, but the DEA's material must be included in the training. For example, an employer may elect to incorporate the DEA's material into initial training for new employees.

## **Orders to Show Cause**

Information regarding this subject may be found at 21 C.F.R. § 1314.150.

If it is determined that a regulated seller or a distributor required to submit reports under 21 C.F.R. § 1310.03(c) has sold a SLCP in violation of the CSA, (21 U.S.C. 842(a)(12) or (13)). The 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.

The order to show cause shall call upon the regulated seller or distributor to appear before the 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. The order to show cause shall also contain a statement of the legal basis for such hearing and for the prohibition and a summary of the matters of fact and law asserted.

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 C.F.R. part 1316 subpart D. If a hearing is requested, the DEA shall hold a hearing at the time and place stated in the order. Any authorized agent of the DEA may serve the order to show cause.

## **Suspension Pending Final Order**

Information regarding this subject may be found at 21 C.F.R. § 1314.155.

The DEA may suspend the regulated seller or distributor's right to sell SLCPs at the time of, or after, the issuance of an order to show cause why the regulated seller or distributor should not be prohibited from selling SLCPs; in any case where the DEA finds that there is an imminent danger to the public health or safety. An order of immediate suspension shall contain a statement of the DEA's findings regarding the danger to public health or safety.

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 his or her 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).

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Any suspension shall continue in effect until the conclusion of all proceedings upon the prohibition, including any judicial review, unless sooner withdrawn by the DEA or dissolved by a court of competent jurisdiction. 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. The DEA will establish a date for such hearing as early as reasonably possible.

## **Part 3: Requirements for Regulated Sellers**

### **Employment Measures**

Information regarding this subject may be found at 21 C.F.R. § 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. This may include, notwithstanding State law, asking applicants whether they have been convicted of any crime involving or related to SLCPs or controlled substances.

### **Proof of Identity Requirements for Regulated Sellers**

Information regarding this subject may be found at 21 C.F.R. § 1314.30.

The regulated seller must not sell an SLCP unless the purchaser presents an identification card that contains a photograph and is issued by a State or the Federal government. See [Appendix J](#) for a list of alternate forms of identification acceptable under 8 C.F.R. §§ 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 C.F.R. §§ 1314.30 and 1314.45.

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 the 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"). The logbook may be maintained on paper or in electronic form.

### **Logbook Requirements for Seller**

Information regarding this subject may be found at 21 C.F.R. § 1314.30.

The regulated seller must enter in the logbook the name of the product and the quantity sold. 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 C.F.R. § 1314.30(g) in a human readable form so that 21 C.F.R. § 1314.30(a) is satisfied.

The logbook maintained by the seller must include the prospective purchaser's name, address, and the date and time of the sale, as follows:

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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 may be found at 21 C.F.R. § 1314.30.

The regulated seller must include in the written or electronic logbook or display by the logbook the following notice:

**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 may be found at 21 C.F.R. § 1314.30.

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.

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## Recordkeeping Requirements for Logbooks

Information regarding this subject may be found at 21 U.S.C. §§ 830 and 880 and 21 C.F.R. § 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.

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 the DEA of the intention to do so. 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.

The required records must be readily retrievable and available for inspection and copying by authorized employees of the DEA under the provisions of the CSA.

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.

## Privacy Protections

Information regarding this subject may be found at 21 U.S.C. § 830 and 21 C.F.R. § 1314.45.

The disclosure of information in logbooks is restricted as follows:

1. The information shall be disclosed as appropriate to the 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 C.F.R. §§ 1314.20 and 1315.03.

The CMEA established sales and purchase limits for SLCPs:

1. Sales to individuals may not exceed 3.6 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a single day, regardless of the number of transactions.
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.
3. For purchasers, there is a 9 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](#)).

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## Storage Requirements

Information regarding this subject may be found at 21 U.S.C. § 830 and 21 C.F.R. § 1314.25. 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). 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. The regulated seller must deliver the SLCP directly into the custody of the purchaser. Mobile retail vendors must place the product in a locked cabinet.

## Part 4: Requirements for Mail-Order Distributors

### Proof of Identity Requirements for Mail-Order Distributors

Information regarding this subject may be found at 21 C.F.R. § 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 C.F.R. §§ 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B), see [Appendix J](#). 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. If the mail-order distributor cannot verify the identities of both the purchaser and the recipient, the product may not be shipped.

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. If the mail-order distributor cannot verify the identities of both the purchaser and the recipient, the product may not be shipped.

### Sales Limits for Mail-Order Distributors

Information regarding this subject may be found at 21 U.S.C. § 830 and 21 C.F.R. § 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. 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.

### Reports of Mail-Order Sales of SLCPs

Information regarding this subject may be found at 21 C.F.R. 1314.110.

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

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);

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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/ODGI  
8701 Morrisette Drive  
Springfield, VA 22152

The written reports must be submitted on or before the 15<sup>th</sup> day of each month following the month in which the distributions took place. 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. Upon request to, and approval by, the DEA, a regulated person may submit this report electronically to the DEA.

# Appendices

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

	<b>List I</b> 21 C.F.R. 1310.02(a)	<b>List II</b> 21 C.F.R. 1310.02(b)
<p><b>Advance Notice on Transshipments and In-Transit Shipments</b>  <i>21 U.S.C. § 971(a); 21 C.F.R. § 1313.31</i>                      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><b>Authorization of International Transaction</b>  <i>21 U.S.C. § 971(e); 21 C.F.R. §§ 1313.32 and 1300.02(b)</i>                      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><b>Import/Export Notification</b>  <i>21 U.S.C. § 971(a); 21 C.F.R. part 1313</i>                      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><b>Mail-Order Reports</b>  <i>21 U.S.C. § 830 (b)(3) 21 C.F.R. § 1310.03(c)</i>                      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><b>Other Required Reports</b>  <i>21 U.S.C. § 830; 21 C.F.R. § 1310.05-06</i>                      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><b>Proof of Identity</b>  <i>21 U.S.C. § 830 (a)(3); 21 C.F.R. § 1310.07</i>                      It is the duty of each regulated person who engages in a regulated transaction to identify each party to the transaction.</p>	√	√
<p><b>Registration</b>  <i>21 U.S.C. §§ 822 and 957; 21 C.F.R. part 1309</i>                      Each person who manufactures, distributes, imports, or exports any List I Chemical shall obtain a registration.</p>	√	

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## Records

*21 U.S.C. § 830 (a); 21 C.F.R. 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 C.F.R. § 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 C.F.R. §§ 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 may be found at 21 C.F.R. § 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
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 may be found at 21 C.F.R. § 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 may be found at 21 C.F.R. § 1310.04. 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 <sup>1</sup>	150 kgs <sup>1</sup>	500 gallons <sup>2</sup>	1500 kgs <sup>2</sup>
Benzyl chloride	Not applicable	1 kg	Not applicable	4 kgs
Ethyl ether	50 gallons	135.8 kgs	500 gallons	1364 kgs
Hydrochloric acid <sup>2</sup>	Not regulated	Not regulated	50 gallons <sup>3</sup>	Not applicable <sup>4</sup>
Anhydrous hydrogen chloride <sup>2</sup>	Not applicable	0.0 kgs <sup>4</sup>	Not applicable	27 kgs <sup>3</sup>
Potassium permanganate	Not applicable	55 kgs	Not applicable	500 kgs
Methyl ethyl ketone (2-Butanone)	50 gallons <sup>1</sup>	145 kgs <sup>1</sup>	500 gallons <sup>2</sup>	1455 kgs <sup>2</sup>
Methyl isobutyl ketone (MIBK)	Not regulated	Not regulated	500 gallons <sup>3</sup>	1523 kgs <sup>3</sup>
Sulfuric acid	Not regulated	Not regulated	50 gallons <sup>3</sup>	Not applicable <sup>4</sup>
Toluene	50 gallons <sup>1</sup>	159 kgs <sup>1</sup>	500 gallons <sup>2</sup>	1591 kgs <sup>2</sup>
Sodium permanganate	Not applicable	55 kgs	Not applicable	500 kgs

<sup>1</sup> The cumulative threshold is not applicable to domestic sales of acetone, 2-butanone (methyl ethyl ketone or MEK), and toluene.

<sup>2</sup> The 15 day advance notification requirement for imports is waived. Importers must provide quarterly reports as indicated in 21 C.F.R. § 1313.12(e) and 21 C.F.R. 1313.12(f).

<sup>3</sup> Threshold applies to exports, transshipments, and international transactions to Western Hemisphere except Canada. Imports are not regulated.

<sup>4</sup> Except for exports to all South American countries and Panama.

**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 C.F.R. § 1300.02(b). All such transactions, regardless of size, are subject to recordkeeping and reporting requirements as set forth in 21 C.F.R. part 1310 and notification provisions for importation, exportation, international transactions, and transshipment as set forth in 21 C.F.R. part 1313.

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### List I chemicals for which no thresholds have been established:

1. Ephedrine, its salts, optical isomers, and salts of optical isomers
2. Ergocristine and its salts
3. Gamma-butyrolactone (other names include: GBL; dihydro-1(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)
4. Hypophosphorous acid and its salts (including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, and sodium hypophosphite)
5. Iodine
6. N-phenethyl-4-piperidone (NPP)
7. Pseudoephedrine, its salts, optical isomers, and salts of optical isomers
8. Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers
9. Red phosphorus
10. White phosphorus (other names: yellow phosphorus)

The thresholds and conditions described above will apply to transactions involving regulated chemical mixtures. 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 may be found at 21 U.S.C. § 802(39) and 21 C.F.R. § 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 C.F.R. § 1300.02(b) unless,
  - a. the 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 C.F.R. § 1310.03(c); or
6. Any transaction in a chemical mixture designated in 21 C.F.R. §§ 1310.12 and 1310.13 that the DEA has exempted from regulation.

Additionally, the following transactions have been determined by the DEA to be excluded from the definition of regulated transaction. Information regarding this subject may be found at 21 C.F.R. § 1310.08:

### *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.

### *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
- Import transactions
- Domestic distributions weighing 12,000 pounds (net weight) or more in a single container
- Domestic distributions by pipeline

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### *Gamma-butyrolactone*

- Domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container

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

- Domestic and import transactions, 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

### *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

### *Methyl isobutyl ketone (MIBK)*

- Domestic transactions
- Import transactions destined for the United States
- Export transactions, international transactions, and import transactions for transshipment or transfer destined for Canada or any country outside of the Western Hemisphere

### *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)

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### APPENDIX F - Table of Concentration Limits for Exempt Chemical Mixtures

Information regarding this subject may be found at 21 C.F.R. § 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. 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).

Mixtures containing a listed chemical in concentrations equal to or less than those specified in the table below are designated as exempt chemical mixtures. 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.

The 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 C.F.R. § 1310.12(e).

The DEA may also modify any part of the criteria for exemption upon evidence of diversion or attempted diversion. Details regarding such modification may be found at 21 C.F.R. § 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.
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 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	Chemical mixtures containing any amount of ergonovine, including its

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		concentration	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.
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	

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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 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	

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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.
<b>List II Chemicals</b>	<b>DEA Chemical Code Number</b>	<b>Concentration</b>	<b>Special conditions</b>
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.
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.

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Methyl isobutyl ketone	6715	35% by weight or volume	Exports only pursuant to 21 C.F.R. § 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

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 amiodarone).

The 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 C.F.R. § 1310.12(e).

The DEA may also modify any part of the criteria for exemption upon evidence of diversion or attempted diversion. Details regarding such modification may be found at 21 C.F.R. § 1310.12(f).

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

Information regarding this subject may be found at 21 U.S.C. §§ 830 and 844, and 21 C.F.R. 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.

**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 9 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
<b>Ephedrine:</b>			
25 mg Ephedrine HCl	175	366	439
25 mg Ephedrine Sulfate	186	389	466
<b>Pseudoephedrine (as HCl):</b>			
30 mg Pseudoephedrine HCl	146	305	366
60 mg Pseudoephedrine HCl	73	152	183
120 mg Pseudoephedrine HCl	36	76	91
<b>Pseudoephedrine (as Sulfate):</b>			
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

	Number of mL		
<b>Ephedrine</b>			
6.25 mg/5 ml Ephedrine HCl	3,515	7,323	8,788
<b>Pseudoephedrine (as HCl):</b>			
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.

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 C.F.R. § 274a.2(b)(1)(v)(A) and (B). Title 8 C.F.R. § 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 a nonimmigrant alien authorized to work for a specific employer incident to status, a foreign passport with a Form I-94 or Form I-94A, bearing the same name as the passport and containing an endorsement of the alien's nonimmigrant status, as long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the Form.
- 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.

The list of acceptable forms of identification, as identified in 8 C.F.R. § 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. 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. 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."

#### Special Surveillance List

All listed chemicals as specified in 21 C.F.R. § 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
Ammonium Formate	Reagents) (e.g., ethylmagnesium
Bromobenzene	bromide and phenylmagnesium bromide)
1,1-Carbonyldiimidazole	Phenylethanolamine and its salts
Cyclohexanone	Phosphorus Pentachloride
1,1-Dichloro-1-fluoroethane (e.g., Freon 141B)	Potassium Dichromate
Diethylamine and its salts	Pyridine and its salts
2,5-Dimethoxyphenethylamine and its salts	Red Phosphorus
Formamide	Sodium Dichromate
Formic Acid	Sodium Metal
Hypophosphorous Acid	Thionyl Chloride
Lithium Metal	Ortho-Toluidine
Lithium Aluminum Hydride	Trichloromonofluoromethane
Magnesium Metal (Turnings)	(e.g., Freon-11, Carrene-2)
Mercuric Chloride	Trichlorotrifluoroethane (e.g., Freon 113
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. A Correction to the Final Notice appeared in the Federal Register on September 17, 1999.

## 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 the 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 C.F.R. § 1310.05(b) for details on method and timing of reports and 21 C.F.R. §§ 1310.03 and 1310.04 for details regarding recordkeeping requirements.

Additional requirements may apply such as import and production quotas (21 C.F.R. part 1315) and transactions involving retail sales (21 C.F.R. 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 the 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 C.F.R. § 1310.05(b) for details on method and timing of reports and 21 C.F.R. §§ 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 the 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 C.F.R. § 1310.05(b) for details on method and timing of reports and 21 C.F.R. §§ 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.

## 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 the 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 C.F.R. § 1310.05(b) for details on method and timing of reports and 21 C.F.R. §§ 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 [http://www.deadiversion.usdoj.gov/offices\\_n\\_dirs/fielddiv/index.html](http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html).

### **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 will annually evaluate the enforcement activities and rate 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:

Drug Enforcement Administration  
Attn: Liaison and Policy Section/ODL  
8701 Morrissette Drive  
Springfield, VA 22152  
E-mail: [ODLL@usdoj.gov](mailto:ODLL@usdoj.gov)