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Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1302, et al.

Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes To Implement the International Trade Data System; Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating Machines; and Technical Amendments; Proposed Rule

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration**

**21 CFR Parts 1300, 1301, 1302, 1303, 1304, 1308, 1309, 1310, 1312, 1313, 1314, 1315, 1316, and 1321**

[Docket No. DEA-403]

RIN 1117-AB41

**Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes To Implement the International Trade Data System; Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating Machines; and Technical Amendments**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration is proposing to update its regulations for the import and export of tableting and encapsulating machines, controlled substances, and listed chemicals, and its regulations relating to reports required for domestic transactions in listed chemicals, gamma-hydroxybutyric acid, and tableting and encapsulating machines. In accordance with Executive Order 13563, the Drug Enforcement Administration has reviewed its import and export regulations and reporting requirements for domestic transactions in listed chemicals (and gamma-hydroxybutyric acid) and tableting and encapsulating machines, and evaluated them for clarity, consistency, continued accuracy, and effectiveness. The proposed amendments clarify certain policies and reflect current procedures and technological advancements. The amendments also allow for the implementation, as applicable to tableting and encapsulating machines, controlled substances, and listed chemicals, of the President's Executive Order 13659 on streamlining the export/import process and requiring the government-wide utilization of the International Trade Data System. This proposal additionally contains amendments that would implement recent changes to the Controlled Substances Import and Export Act (CSIEA) for reexportation of controlled substances among members of the European Economic Area made by the Improving Regulatory Transparency for New Medical Therapies Act. The

proposal includes additional substantive and technical amendments.

**DATES:** Electronic comments must be submitted, and written comments must be postmarked, on or before October 17, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before October 17, 2016.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-403" on all correspondence, including any attachments.

The Drug Enforcement Administration encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB41/Docket No. DEA-403.

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

**SUPPLEMENTARY INFORMATION:**

**Posting of Public Comments**

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA or Administration) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

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

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference. The DEA specifically solicits written comments regarding the DEA's economic analysis of the impact of these proposed changes. The DEA requests that commenters provide detailed descriptions in their comments of any expected economic impacts, especially to small entities. Commenters should

provide empirical data to illustrate the nature and scope of such impact.

## Outline

- I. Background and Purpose
  - A. Legal Authority
  - B. Current Import/Export Practices and Regulatory Framework
    1. Import and Export Permits for Controlled Substances
    2. Import and Export Declarations for Controlled Substances
    3. Import and Export Declarations and Notices for Listed Chemicals
    4. Import and Export Reports for Tableting and Encapsulating Machines; Reports for Domestic Transactions in Listed Chemicals, Gamma-Hydroxybutyric Acid, and Tableting and Encapsulating Machines
    5. Transshipments of Controlled Substances
    6. Transshipments of Listed Chemicals
    7. Notifications of International Transactions by Brokers or Traders
  - C. Purpose of Regulatory Action
- II. Discussion of Technical Amendments and Proposed Significant Regulatory Changes
  - A. Proposed Amendments Directly Associated With Implementation of the International Trade Data System
    1. Applications, Notices and Other Filings
      - a. Import and Export Permits for Controlled Substances
      - b. Import and Export Declarations for Controlled Substances
      - c. Import and Export Declarations for Listed Chemicals
      - d. Import and Export Reports for Tableting and Encapsulating Machines
      - e. Transshipments of Controlled Substances
      - f. Transshipments of Listed Chemicals
      - g. Notifications of International Transactions by Brokers or Traders
    2. Security
    3. Miscellaneous
  - B. Proposed Amendments Indirectly Associated With Implementation of the International Trade Data System
    1. Terminology and Definitions
    2. Part 1302: Labeling and Packaging Requirements for Controlled Substances
    3. Part 1304: Records and Reports of Registrants
    4. Part 1308: Schedules of Controlled Substances
    5. Part 1309: Registration of Manufacturers, Distributors, Importers and Exporters of List I Chemicals
    6. Part 1310: Records and Reports of Listed Chemicals and Certain Machines
      - a. *Mail Order Reporting for Ephedrine, Pseudoephedrine, Phenylpropanolamine, and Gamma-Hydroxybutyric Acid*
      - b. *Listed Chemicals and Tableting and Encapsulating Machines*
    7. Part 1312: Importation and Exportation of Controlled Substances
    8. Reexportation of Controlled Substances—Including Implementation of section 4 of the Improving Regulatory Transparency for New Medical Therapies Act

9. Part 1313: Importation and Exportation of List I and List II Chemicals
10. Part 1316: Administrative Functions, Practices, and Procedures
- C. DEA Mailing Addresses
- III. Regulatory Analyses

## I. Background and Purpose

### A. Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are known as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or “CSA” for the purpose of this action. The DEA publishes implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and pursuant to 21 U.S.C. 812 (a) and (b), the current list of all scheduled substances is published at 21 CFR part 1308. Controlled substances generally include narcotics, stimulants, depressants, and hallucinogens that have a potential for abuse and physical and psychological dependence, as well as anabolic steroids. Listed chemicals are separately classified based on their use and importance to the illicit manufacture of controlled substances (list I or list II chemicals). 21 U.S.C. 802 (33)–(35).

Through the enactment of the CSA and its amendments, Congress has established a closed system of distribution making it unlawful to handle any controlled substance (manufacture, distribute, reverse distribute, dispense, conduct research, engage in narcotic treatment or maintenance, import, export, collect, conduct chemical analysis, dispose, or possess) or manufacture, distribute,

import, or export any listed chemical except in a manner authorized by the CSA. *See e.g., Gonzales v. Raich*, 545 U.S. 1, 12–13 (2005) (stating “The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. §§ 841(a)(1), 844(a.)”; H.R. Rep. No. 91–1444, pt. 1 at 3 (1970) (stating: “*Title II: Control and Enforcement.*— The bill provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.”).

In order to maintain this closed system of distribution, the CSA requires handlers of controlled substances, unless exempt from registration, to be registered with the DEA at each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed. 21 U.S.C. 822. The CSA also requires persons who manufacture or distribute, or who propose to manufacture or distribute, list I chemicals to be registered at each principal place of business or professional practice, unless exempt. 21 U.S.C. 822; 21 CFR 1309.22. A separate registration is also required for each principal place of business where controlled substances or list I chemicals are imported or exported, unless exempt from registration. 21 U.S.C. 958. A “registrant” is any person who is registered pursuant to either section 303 or section 1008 of the CSA (codified at 21 U.S.C. 823 or 958).<sup>1</sup> 21 CFR 1300.01(b). Registrants are permitted to possess controlled substances and list I chemicals as authorized by their registration and must comply with the applicable requirements associated with their registration. 21 U.S.C. 822 and 958.

In contrast, a “regulated person” means “a person who manufactures, distributes, imports, or exports a listed

<sup>1</sup> Unless otherwise noted, all references to registrant(s) in this preamble include persons exempt from DEA registration and persons not registered with the DEA as an importer or exporter who are authorized to perform importing or exporting activities as a coincident activity of their research or chemical analysis registration in accordance with 21 CFR 1301.13(e).

chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader<sup>2</sup> for an international transaction<sup>3</sup> involving a listed chemical, a tableting machine, or an encapsulating machine.” 21 U.S.C. 802(38). (Tableting machines and encapsulating machines are also commonly known as “pill presses” and “capsule fillers” respectively.) Regulated persons who engage in “regulated transactions,” defined at 21 U.S.C. 802(39),<sup>4</sup> are subject to specific recordkeeping and reporting requirements pursuant to 21 U.S.C. 830, 971; 21 CFR part 1310. In addition, a person located in the United States who is a broker or trader for an international transaction in a listed chemical that is a regulated transaction shall, with respect to that transaction, be subject to all of the notification, reporting, recordkeeping, and other requirements placed upon exporters of listed chemicals. 21 U.S.C. 971(e).

The CSA grants the Attorney General authority to promulgate rules and regulations relating to: the registration of controlled substance and list I chemical handlers; control of the manufacture, distribution, and dispensing of controlled substances; control of the manufacture and distribution of listed chemicals; maintenance and submission of records and reports; and for the efficient execution of her statutory functions. 21 U.S.C. 821–822, 825, 827–831, 871, 952, 954, 956, 958, 971. The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances or listed chemicals. 21 U.S.C. 958(f). The Attorney General has delegated these authorities to the

Administrator of the DEA, who in turn redelegated many of these authorities to the Deputy Administrator of the DEA and the Deputy Assistant Administrator of the DEA Office of Diversion Control. 28 CFR 0.100 *et seq.*

Within the DEA, the Office of Diversion Control is the strategic focus area that carries out the mandates of the CSA to ensure that adequate supplies of controlled substances and listed chemicals are available to meet legitimate domestic medical, scientific, industrial, and export needs. The Office of Diversion Control carries out the mission of the DEA to prevent, detect, and eliminate the diversion of these substances into the illicit drug market. Activities in support of the Office of Diversion Control and its mission include: Determination of program priorities; field management oversight; coordination of major investigations; drafting and promulgating regulations; the design and proposal of national legislation; advice and leadership on State legislation/regulatory initiatives; oversight of the importation and exportation of tableting and encapsulating machines, controlled substances, and listed chemicals; establishment of national drug production quotas; activities related to drug scheduling and compliance with international treaty obligations; the design and execution of diplomatic missions; computerized monitoring and tracking of the distribution of certain controlled substances; planning and allocation of program resources; and liaison efforts with industry and their representative associations as well as to the DEA’s regulatory and law enforcement counterparts at the federal, State, tribal, and local levels.

#### *B. Current Import/Export Practices and Regulatory Framework*

Under the CSA, a controlled substance, listed chemical, or tableting or encapsulating machine is considered imported if it is either brought into the customs territory from a place that is outside the customs territory but within the United States (*e.g.*, a shipment from an insular possession such as Guam into one of the 50 States) or brought into the United States from any other place (*e.g.*, a shipment from India into one of the 50 States or into an insular possession such as American Samoa). 21 U.S.C. 951, 952; *see also* 21 U.S.C. 802(39), 830(a). For purposes of the CSA, the “customs territory of the United States” includes only the 50 States, the District of Columbia, and Puerto Rico. 21 U.S.C. 951(a)(2). In contrast, an export of a controlled substance, listed chemical, or tableting or encapsulating machine

occurs when that item is taken out of, or removed from, the United States, which, pursuant to the definition at 21 U.S.C. 802(28), includes “all places and waters, continental or insular, subject to the jurisdiction of the United States.” *See* 21 U.S.C. 802 (38) and (39), 830(a), 953(a).

The DEA regulations are drafted to be consistent with the meaning of “import” and “export” under the CSA, which is broader in scope than the meaning of those terms as used in the U.S. Customs and Border Protection’s (CBP) regulations. The DEA regulations are also drafted to take into account the authority of customs officials of U.S. territories to enforce the CSA. The CSA and DEA regulations prohibit any person from importing or exporting any controlled substance or list I chemical unless that person is registered with the DEA (or exempt from registration). 21 U.S.C. 957. In addition, these substances may only be imported and exported if specific statutory criteria are met. For instance, schedule II controlled substances may be imported to the extent that the Attorney General finds such importation is “necessary to provide for the medical, scientific, or other legitimate needs of the United States \* \* \* in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses,” 21 U.S.C. 952(a)(2)(C), or in other limited circumstances. Schedule II narcotic drugs may be exported if, *inter alia*, “substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country.” 21 U.S.C. 953(a)(4). Depending on the circumstances surrounding the proposed import or export, in most cases the CSA and implementing regulations require importers and exporters, in advance of the import or export, to obtain a permit from the DEA, or to report the activity to the DEA by filing a declaration. 21 U.S.C. 952–953, 971; 21 CFR 1312.11, 1312.21, 1313.12, 1313.21.

#### 1. Import and Export Permits for Controlled Substances

Registrants (and those exempt from registration)<sup>5</sup> who wish to import a

<sup>2</sup> A “broker” and “trader” are persons that assist in arranging an international transaction in a listed chemical by: negotiating contracts; serving as an agent or intermediary; or bringing together a buyer and seller, a buyer and transporter, or a seller and transporter. 21 U.S.C. 802(43).

<sup>3</sup> An “international transaction” is a transaction that involves “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.” 21 U.S.C. 802(42).

<sup>4</sup> The CSA defines a “regulated transaction” as being: (1) with certain enumerated exceptions, “a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical;” and (2) “a distribution, importation, or exportation of a tableting machine or encapsulating machine.” 21 U.S.C. 802(39).

<sup>5</sup> As discussed in note 1, unless specifically noted otherwise, discussion of “registrants” also includes persons exempt from registration for purposes of the preamble portion of this notice.

controlled substance listed in schedule I or II; any narcotic drug listed in schedule III, IV, or V; any non-narcotic drug in schedule III that has been specifically designated by regulation in 21 CFR 1312.30; or any non-narcotic substance listed in schedule IV or V that is also listed in schedule I or II of the Convention on Psychotropic Substances, 1971, must apply (on DEA Form 357) for and be granted a permit from the DEA prior to the import. 21 U.S.C. 952; 21 CFR 1312.11, 1312.12, 1312.13. Similarly, registrants who wish to export any schedule I or II controlled substance; any narcotic drug in schedule III or IV; any non-narcotic drug in schedule III that has been specifically designated by regulation in 21 CFR 1312.30; or any non-narcotic substance listed in schedule IV or V that is also listed in schedule I or II of the Convention on Psychotropic Substances, 1971, must apply (on DEA Form 161 or 161R) for and be granted a permit from the DEA prior to the export. 21 U.S.C. 953; 21 CFR 1312.21, 1312.22, 1312.23. The DEA currently issues permits in sextuplet for imports and in septuplet for exports, serially numbered, on special paper. 21 CFR 1312.13(e), 1312.23(e). The copies are distributed among the importer, the foreign exporter, the foreign government authority, CBP, and the DEA in accordance with §§ 1312.14 and 1312.24. Permits expire on the date specified on the permit, but in no event shall the date be more than six months after the date the permit is issued. 21 CFR 1312.16(b), 1312.25. Unused permits are required to be returned to the DEA for cancellation. *Id.*

## 2. Import and Export Declarations for Controlled Substances

Those non-narcotic controlled substances listed in schedule III, IV, or V, that are not subject to the requirement of a permit, may be imported or exported if the registrant files a controlled substances import/export declaration (on DEA Form 236) with the DEA. 21 U.S.C. 952(b), 953(e); 21 CFR 1312.11(b), 1312.21(b). Likewise, narcotic controlled substances in schedule V may be exported if the registrant files a controlled substances export declaration. 21 U.S.C. 953(e); 21 CFR 1312.21(b). Currently, the declaration must be executed in quintuplicate and Copy 4 shall be filed with the DEA not later than 15 calendar days prior to the proposed date of importation or exportation. 21 CFR 1312.18, 1312.19, 1312.27, 1312.28. The five copies of the import/export declaration (DEA Form 236) are distributed among the importer, the

foreign shipper, the governmental authority of the foreign country, CBP, and the DEA in accordance with § 1312.19 or § 1312.28.

## 3. Import and Export Declarations and Notices for Listed Chemicals

The CSA and DEA regulations have established a system of recordkeeping and reporting requirements that provide the DEA with a mechanism to track international movement of listed chemicals in order to prevent their being diverted for use in the clandestine manufacture of controlled substances. The CSA generally requires regulated persons who import or export a listed chemical to report the transaction to the DEA, as delegated by the Attorney General, at least 15 days in advance. 21 U.S.C. 971(a). This requirement is modified for regulated persons engaging in a transaction with a “regular customer” and for regulated persons designated as “regular importers.” 21 U.S.C. 802 (36) and (37), 971(b); 21 CFR 1313.15, 1313.24. The DEA has the obligation to examine the report in order to determine if the shipment is legitimate and that the chemical will not be diverted into the illicit manufacture of controlled substances, pursuant to the authority granted in 21 U.S.C. 971 (c) and (d).

For listed chemicals at or above thresholds set forth in § 1310.04(f) and listed chemicals for which no threshold has been established as identified in § 1310.04(g), regulated persons may import or export list I or II chemicals by filing a listed chemical import declaration (on DEA Form 486/486A) or an export declaration (on DEA Form 486) with the Administration not later than 15 calendar days prior to the date of the proposed importation or exportation (unless DEA has waived such advance reporting through regulation). 21 CFR 1313.12, 1313.13, 1313.21, 1313.22. The United States importer or exporter must include on their declaration the name and address of each person to whom the listed chemical(s) will be transferred (*i.e.*, the transferee, consignee, and intermediate consignees), including the quantity. 21 U.S.C. 971(d); 21 CFR 1313.13(c), 1313.22(c). For an importer, the transferee is the person to whom the importer transfers the listed chemical (*i.e.*, the downstream customer). For an export from the United States, the transferee/consignee is the foreign importer. For a broker or trader, the transferee/consignee is the foreign customer purchasing the listed chemicals. Importers are also required to list their foreign supplier on their declaration. The DEA Form 486/486A

must be executed in triplicate. 21 CFR 1313.13, 1313.22. The three copies of the listed chemical import/export declaration are distributed among the importer/exporter, CBP, and the DEA in accordance with §§ 1313.14 and 1313.23.

If, after submission of the initial DEA Form 486/486A, the importer, exporter, broker or trader will not be transferring the listed chemical to the transferee named on the declaration, or if the quantity of listed chemical to be imported, exported, or transferred is greater than the quantity originally indicated on the declaration, the importer, exporter, broker or trader must file an amended DEA Form 486/486A reporting the change. 21 CFR 1313.16(b), 1313.26(b), 1313.32(d). Even if an importer or exporter did not have to file an initial notification—either because he or she is a regular importer selling to a regular customer, or an exporter selling to a regular customer—if the newly arranged spot market sale is not to a regular customer, the importer or exporter must file an advance notice 15 days prior to transferring the chemical to a new customer. 21 CFR 1313.16, 1313.26.

Within 30 days after an import or export of a listed chemical has occurred, the importer/exporter must file with the DEA a return declaration containing the particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and any other information as the Administration may specify. 21 U.S.C. 971(g); 21 CFR 1313.17(a), 1313.27(a). An importer may file a single return declaration including the particulars of both the importation and the distribution. 21 CFR 1313.17(a). If the importer has not distributed all chemicals imported by the end of the initial 30-day period, the importer must file supplemental return declarations every 30 days until the distribution or other disposition of all chemicals imported under the declaration or amended declaration have been accounted for. 21 CFR 1313.17(a). If an import/export for which a declaration has been filed does not in fact take place, the importer/exporter must file an amended declaration notifying the DEA that the transaction did not in fact occur. 21 CFR 1313.17(b), 1313.27(b).

## 4. Import and Export Reports for Tableting and Encapsulating Machines; Reports for Domestic Transactions in Listed Chemicals, Gamma-Hydroxybutyric Acid, and Tableting and Encapsulating Machines

Regulated persons who engage in a regulated transaction involving a listed chemical, a tableting machine, or an

encapsulating machine must keep records of the transaction and file reports in accordance with §§ 1310.03(a), 1310.04, and 1310.05. Regulated persons who import or export a tableting machine or encapsulating machine are not required to obtain prior approval from the DEA for the transaction, but they are required to file a report with the DEA of any importation or exportation of a tableting or an encapsulating machine on or before the date of importation or exportation. 21 U.S.C. 830(b)(1)(D); 21 CFR 1310.05(c), 1310.06 (e) and (f).

Regulated persons who engage in an export transaction that involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid (including drug products containing these chemicals or controlled substance) and use or attempt to use the U.S. Postal Service or a private or commercial carrier are required to file monthly reports of these transactions in accordance with §§ 1310.03(c), 1310.05(e), 1310.06(i), and 1314.110; *see also* § 1310.04. The report must be submitted to the Import/Export Unit of the DEA on company letterhead, signed by the person authorized to sign the registration application forms on behalf of the registrant. 21 CFR 1310.05(e). Regulated persons who engage in any domestic regulated transaction with a tableting machine or an encapsulating machine, including those following an import of such machines, must orally report, when possible, and subsequently file written reports with the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located. 21 CFR 1310.05 (a)(4) and (b).

Regulated persons are required to report regulated transactions involving extraordinary quantities of a listed chemical, uncommon method of payment or delivery, or other circumstances that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA and its implementing regulations. 21 CFR 1310.05 (a)(1) and (b). Regulated persons must also report the unusual or excessive loss or disappearance of a listed chemical under their control, 21 CFR 1310.05 (a)(3) and (b), and any proposed regulated transaction with a person whose description or identifying characteristic the Administration has previously provided. 21 CFR 1310.05(a)(2).

#### 5. Transshipments of Controlled Substances

The transshipment of controlled substances through the United States is

governed by 21 U.S.C. 954. Persons seeking to transship or transfer for immediate exportation schedule I controlled substances within the United States must apply for a permit at least 30 days in advance of the expected transshipment or, in the case of an emergency, as soon as practicable, and receive a transshipment permit from the DEA before the transshipment may occur. 21 CFR 1312.31. Controlled substances listed in schedule II, III, or IV may be so transshipped or transferred if 15 days advance written notice is provided to the DEA in accordance with 21 CFR 1312.32. 21 U.S.C. 954(2). A specific DEA Form is not required for transshipments, however the application for prior written approval (for schedule I substances) and the advance notice (for schedule II, III, or IV substances) must conform with very specific requirements outlined in § 1312.31 (b) and (c). *See* 21 CFR 1312.32(b).

#### 6. Transshipments of Listed Chemicals

As stated above, the CSA generally requires regulated persons who import or export a listed chemical to report the transaction to the DEA, as delegated by the Attorney General, at least 15 days in advance. 21 U.S.C. 971(a). This requirement is modified for regulated persons engaging in a transaction with a “regular customer” and for regulated persons designated as “regular importers.” 21 U.S.C. 802 (36) and (37), 971(b); 21 CFR 1313.15, 1313.24. No waiver of the 15-day advance notice is permitted under 21 CFR 1313.31(d) for importations for transshipment purposes of threshold or greater quantities of listed chemicals. Regardless of whether the shipment is a direct export or a transshipment, the DEA has the obligation to examine the report in order to determine if the shipment is legitimate and that the chemical will not be diverted into the illicit manufacture of controlled substances.

Persons seeking to transship or transfer listed chemicals in a quantity that meets or exceeds the threshold amounts found in § 1310.04(f) must provide advance notification to the DEA not later than 15 days prior to the proposed date that the listed chemical will transship or transfer through the United States. 21 CFR 1313.31. The notification must contain the information that is required by the DEA Form 486, but it is not required to be submitted to DEA using the DEA Form 486.

#### 7. Notifications of International Transactions by Brokers or Traders

Brokers or traders engaging in international transactions involving listed chemicals which meet or exceed the threshold amounts found in § 1310.04 must provide notification to the DEA not later than 15 days in advance of the transaction by filing DEA Form 486. 21 CFR 1313.32.

Within 30 days after an international transaction has occurred, the broker or trader must send the DEA a return declaration containing the particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and any other information as the Administration may specify. 21 CFR 1313.35(a). If an international transaction for which a DEA Form 486 has been filed does not in fact take place, the broker or trader must file an amended DEA Form 486 notifying the DEA that the transaction did not in fact occur. 21 CFR 1313.35(b).

#### C. Purpose of Regulatory Action

The DEA is proposing to update its regulations regarding the import and export of tableting and encapsulating machines, controlled substances, and listed chemicals. In accordance with Executive Order 13563, the DEA has reviewed its import and export regulations and reporting requirements for domestic transactions involving listed chemicals (and gamma-hydroxybutyric acid) and tableting and encapsulating machines, and evaluated them for clarity, consistency, continued accuracy, and effectiveness. The amendments would codify current practices and incorporate current procedures and technological advancements and allow for implementation of the President's Executive Order on streamlining the export/import process and requiring Government-wide utilization of the International Trade Data System (ITDS). Section 3 of the President's Executive Order 13659 of February 19, 2014, “Streamlining the Export/Import Process for America's Businesses,” directs participating agencies to have capabilities, agreements, and other requirements in place to allow electronic filing through ITDS and supporting systems of data and other relevant documents (exclusive of applications for permits, licenses, or certifications) required for imported and exported goods. Businesses are able to transmit their import and export data according to the Electronic Data Interchange (EDI), an electronic communication framework providing standards for exchanging data via any

electronic means. Data transmitted through EDI links to the Automated Commercial Environment (ACE), which serves as the single window for CBP and participating agencies. For purposes of this notice, the DEA will describe EDI, ACE, and any successor system to ACE, by the statutory term for the single window goal, which is ITDS.

As discussed above, current DEA regulations specifically require applications for permits, and declarations and other required notices and reports to be filed in paper form, or by electronic means in some circumstances. The DEA must amend its regulations in order to integrate DEA procedures related to the importation and exportation of tableting and encapsulating machines, controlled substances, and listed chemicals with the ITDS.

Because the ITDS excludes applications for permits, licenses, or certifications, the ITDS single window will not be used by DEA registrants, regulated persons, or brokers or traders applying for permits or filing import/export declarations, notifications or reports with the DEA. The DEA import/export application and filing processes will continue to remain separate from (and in advance of) the ITDS single window. Entities will continue to use the DEA application and filing processes; however, the processes will be electronic rather than paper. After DEA's approval or notification of receipt as appropriate, the DEA will transmit the necessary information electronically to the ITDS and the registrant or regulated person so that customs officers can validate importations and exportations subject to DEA regulations.

Because of the requirement that regulated persons submit reports of regulated transactions in tableting machines and encapsulating machines to the DEA, the DEA also proposes to require such domestic regulated transaction reports to be submitted through the DEA Office of Diversion Control secure network application, in addition to import and export regulated transactions. Mandatory reporting requirements for domestic regulated transactions are included as part of this proposal because it allows for the DEA to create, at one time, an efficient, streamlined reporting structure of regulated activities applicable to tableting and encapsulating machines. Additional information related to the proposed mandatory electronic reporting requirements for tableting and encapsulating machines is discussed in section II, B, 6, b of this document.

This proposal additionally contains amendments that would implement

section 4, Re-exportation Among Members of the European Economic Area, of the Improving Regulatory Transparency for New Medical Therapies Act, Public Law 114–89, which was signed into law on November 25, 2015. Section 4 amended section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) by making changes to paragraph (f) and adding paragraph (g) that allows for reexportation of controlled substances among members of the European Economic Area. Additional information related to the proposed revisions to implement section 4 of the Improving Regulatory Transparency for New Medical Therapies Act is discussed in section II, B, 8 of this document.

This proposal also includes technical and stylistic changes to several regulations to clarify and simplify the language and to further the goals of the President's memorandum on Transparency and Open Government. 74 FR 4685, Jan. 26, 2009.

## II. Discussion of Technical Amendments and Proposed Significant Regulatory Changes

### *A. Proposed Amendments Directly Associated With Implementation of the International Trade Data System*

#### 1. Applications, Notices, and Other Filings

The principal changes necessary to implement the ITDS are also those that will allow the efficient and standardized electronic exchange of required information.

To transmit data electronically to the ITDS, the first global change that the DEA is proposing is to mandate the electronic submission of all applications and other required filings and reports (e.g., declarations, notices, returns) associated with the importation or exportation of tableting and encapsulating machines, controlled substances, and listed chemicals. 21 U.S.C. 958(f). However, the DEA will not require electronic submission of transshipment data. (The electronic application and filing process is not feasible in such circumstances because foreign IP addresses are blocked by the Department of Justice's firewall and are prevented from accessing the DEA Office of Diversion Control secure network application.) Accordingly, the vast majority of persons subject to the CSA requirements and DEA regulations pertaining to imports and exports would be required to make all DEA-required submissions through the DEA Office of Diversion Control secure network application. The DEA will provide

customs information to validate importations subject to DEA regulations, and this change will enable the DEA to analyze and electronically transmit necessary information to the ITDS quickly and accurately. The DEA Office of Diversion Control secure network application will be accessed by DEA registrants and regulated persons through the DEA Office of Diversion Control Web site. Security of the new electronic system is discussed in section II, A, 2 of this document under the heading "Security." In addition, importers and exporters would obtain information regarding approved permits and DEA's receipt of completed declarations, notices, returns, and reports through the same DEA Office of Diversion Control secure network application. If importers and exporters were permitted to continue submitting paper documents, the DEA would have to manually transcribe the paper information into an electronic format for transmission to the ITDS. Such an intermediary step would cause unnecessary delay and is subject to error. In addition to providing for electronic filing of information to CBP through ITDS and reducing errors, electronic applications, approvals, declarations, notices, and reports strengthen the DEA's ability to monitor and prevent unauthorized imports and exports and will enhance information sharing between CBP/customs services of Insular Areas and the DEA.<sup>6</sup> Electronic processing is expected to help the DEA identify unauthorized or suspicious shipments prior to import or export, and diversion of in-transit shipments being exported or imported, by improving the quality and timeliness of data review and transaction authorization.

For the foregoing reasons, the DEA is proposing amendments to its regulations that would authorize electronic submission of data, and would make the procedure mandatory over paper in most circumstances. 21 U.S.C. 958(f). The use of electronic applications and filings is consistent not only with the requirements of Executive Order 13659, but also with the general principles outlined in the Government's Open Data Policy which requires agencies to collect or create information in a way that supports downstream information processing and

<sup>6</sup> For purposes of this preamble, "customs services of Insular Areas" means the governmental authority/authorities (federal or insular), charged with enforcement of the customs laws of the United States/Insular Area.

dissemination.<sup>7</sup> The Open Data Policy states that information should be collected electronically by default. As discussed in greater detail in the Regulatory Analyses section of this document, the DEA believes that the regulated community should be able to easily adapt to this new requirement with minimal effort or cost.

If an importer/exporter tries to submit an application, declaration, notice, report, or other required submission through the DEA Office of Diversion Control secure network application but does not complete all of the required fields or enters key data that is not valid or is inaccurate (e.g., unknown port or erroneous drug code) with the submission, the DEA Office of Diversion Control secure network application will automatically alert the filer to the fact that information is missing or does not meet the validation requirements.

Applications, declarations, notices, and reports filed through the DEA Office of Diversion Control secure network application would generally not be deemed filed until the DEA assigns a single-use, randomly-generated, unique identifier. This identifier would be referenced as the “transaction identification number,” except for permits, where the transaction identification number would continue to be called the “permit number” to correspond with current business practice. A permit number would be assigned once the DEA has approved an application for a permit. A transaction identification number would be assigned once the DEA reviews a declaration, notice, or other filing for completeness, and it is accepted for filing. Although issuance of a transaction identification number would signify that the declaration, notice, or other filing has been reviewed for completeness, the issuance of the transaction identification number does not mean that such filing has been “approved” by the DEA. The DEA reserves the right to cancel an import or export permit or declaration for cause and suspend shipments of listed chemicals in accordance with applicable regulations. Currently, the DEA assigns a Web Tracking Number to each filing submitted electronically to the DEA and would continue to do so under this proposal. However, unlike the proposed transaction identification number, the Web Tracking Number is assigned automatically upon submission to the DEA; the transaction

identification number would be assigned only after the DEA has reviewed the filing for completeness.

Instead of distributing “copies,” registrants and other importers/exporters, once logged into the DEA Office of Diversion Control secure network application through authenticated access, would be able to use the assigned permit or transaction identification number to access the “official record” of the filing from the DEA Office of Diversion Control secure network application. The registrant or other importer/exporter would then be responsible for forwarding official record information to their broker or any other of their agents needing the information contained therein to complete the release process through customs. Permit numbers and transaction identification numbers are discussed in more detail later in this document for each transaction category.

Declarations, permits, and most other filings with DEA would not be deemed filed until a transaction identification number (or permit number) is issued by the DEA. The transaction identification number would be issued by the DEA after any necessary corrections are complete. The DEA considered, but ultimately did not choose to propose, a specific timeframe in which transaction identification numbers (and permit numbers) will be issued because of concern of instances that require longer-than-average review and processing times that can result from any number of circumstances, not all of which are foreseeable. However, the DEA does not have reason to believe that by not having a stated timeframe that there will be any significant impact on import and export activities.

The DEA is proposing to have the option of deeming a submission filed on the date submitted, if a listed chemical import or export declaration, or other filing was complete at the time of filing and no additional follow-up action was required, instead of on the date the transaction identification number was issued. However, if a chemical importer or exporter made a submission on the last day that would comply with the reporting deadline, and DEA review subsequently found the submission not to be complete, then he or she would be in violation of the regulation. The requirement to submit applications, declarations, notices, reports, and other filings includes the duty that such filings be complete. If an importer or exporter has concerns that their information may not be complete they would be able to contact the DEA in advance of the submission to ask questions and/or submit the filing in

advance of the deadline to ensure that if changes or additional information is required that those changes can be made before the established 15-day filing deadline.

In association with this change, the DEA is proposing to globally amend its import and export regulations to provide that expiration periods, filing deadlines, and other timed action dates are to be generally calculated as “calendar days” (i.e., including weekends and holidays) unless otherwise noted in a regulation (e.g., in the case of amendments). This change corresponds with business rule policies that will be built into the DEA’s electronic systems of records for the impacted applications, notices, and other filings that will be required to be electronically submitted to the DEA.

#### (a) Import and Export Permits for Controlled Substances

The DEA proposes to incorporate the mandatory electronic application requirements for controlled substance imports and exports into §§ 1312.12 and 1312.22. Applicants for a permit to import or export controlled substances would be required to access, complete, and submit the DEA application for import, application for export, or application for reexport, as appropriate, to the DEA through the DEA Office of Diversion Control secure network application. This requirement would also be incorporated into a new § 1312.03, which references applicable forms for part 1312, and would state that such forms are electronic.

Other than for transshipments, current DEA regulations requiring import and export permits to be issued in multiples via paper form would be eliminated in favor of regulations making such information available via digital means. The DEA would continue to issue original permits under existing practices, and would still transmit the original permit to the pertinent foreign competent national authorities (CNAs); however, the DEA would eliminate issuing the other copies. The DEA proposes that “copies” currently issued by the DEA to registrants would only be accessible through the DEA Office of Diversion Control secure network application. The DEA would assign each approved permit a permit number (a unique identifier). Once the permit has been issued, registrants would be able to use the assigned permit number to access the digital copy of the permit, or the “official record of the permit.” Corresponding changes would be made throughout DEA import/export regulations. These changes will reference the data downloads from the

<sup>7</sup> OMB Memorandum M–13–13, *Open Data Policy—Managing Information as an Asset*, available at <https://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-13.pdf>.



secure network application by the registrant as an “official record of the permit” instead of a “copy.” These changes are proposed in §§ 1312.13, 1312.14, 1312.23, and 1312.24.

The DEA proposes to amend its import/export regulations to describe the procedures relating to amendments following issuance of an import or export permit. The DEA is proposing to revise §§ 1312.16 and 1312.25 to clearly specify how and under what conditions controlled substance import and export permits may be amended or cancelled after issuance and when a new permit is required instead of an amendment. Registrants would submit a request to amend or cancel an application for an import or export permit, amend an issued import or export permit, or request for a cancellation of an issued import or export permit to the Administration through the DEA Office of Diversion Control secure network application. Return information on imports and exports may not be amended.

Consistent with current practice, importers and exporters would continue to be able to request an amendment to a permit for the following data fields: The National Drug Control number, description of the packaging, or trade name of the product, so long as the description is for the same basic class of controlled substance(s) as in the original permit; the proposed port of entry or export; the proposed date of import or export;<sup>8</sup> the method of transport; any registrant notes; and the justification entered by the importer or exporter for why an import or export is needed to meet the medical, scientific, or other legitimate needs of the United States or foreign jurisdiction. The DEA allows amendments to these fields as these are areas that may be easily mis-keyed or subject to change as part of the normal import and export business practice. While the data contained in these fields is important to determining the risk of diversion and the tracking of controlled substances through the closed system of distribution, the DEA believes that the Administration is able to enforce the CSA and uphold U.S. obligations under international drug control treaties while potentially limiting burden on industry by allowing these fields to be amendable.

Consistent with current practice, importers and exporters would continue to generally be allowed to amend the base weight of controlled substance(s)

listed on their permit prior to the start of an import or export transaction (*i.e.*, prior to shipment). However, also consistent with current practice, exporters would not be allowed to exceed the total base weight of controlled substance(s) listed on the corresponding foreign permit. Also consistent with current practice, neither would exporters be allowed to exceed the strength of a controlled substance product if product strength information has been included on the import permit issued by the foreign competent national authority. Consistent with current § 1312.15(a), importers would continue to be allowed to request an amendment to the quantity of controlled substances specified on an import permit once a shipment has arrived at the U.S. customs port of entry if the increase in the amount of controlled substance to be imported is less than 1% of that listed on the issued import permit. Importers and exporters need not request an amendment for the sole purpose of decreasing the amount authorized.

Consistent with current practice, importers and exporters would continue to be able to request that an import or export permit be amended to remove a controlled substance. However, importers and exporters would no longer be able to amend permits to add a new controlled substance, replace the name of a controlled substance with a different controlled substance, or amend the controlled substance content of a drug or preparation. Instead, importers and exporters who needed to make changes to any of these fields would need to cancel the existing permit and apply for a new permit. The DEA understands that sometimes the incorrect controlled substance is identified on the permit application due to clerical error, for example because a similar item was selected from the drop-down selection in the DEA Office of Diversion Control secure network application that was located near the correct item. However, the DEA has closely considered this issue and ultimately determined that because the listed controlled substance proposed to be imported or exported is such a critical element of determining whether or not a permit should be issued and, if issued, the amount allowed to be imported or exported, this element should not be amendable. As stated elsewhere in this preamble, the DEA reminds importers and exporters that the duty to file reports and other documents with the DEA includes the duty that these filings be complete and accurate.

Similarly, in a change from current practice, the DEA is proposing to cease allowing exporters to amend foreign permit information on permit applications and issued permits. The DEA understands that sometimes, especially in the case of less experienced exporters, the incorrect foreign permit number is entered onto the permit application. This is often the result of numbers being transposed or a different number on the foreign permit being entered instead of the actual permit identification number. However, similar to the controlled substance identified on the permit, the DEA has closely considered this matter and ultimately determined that, because the authorization from the foreign competent national authority is such a critical element in determining whether a permit can be issued and the amount of the controlled substance to be exported, this element should not be amendable. As stated above and elsewhere in this document, the DEA reminds importers and exporters that the duty to file reports and other documents with the DEA includes the duty that these filings be complete and accurate.

Consistent with current practice, importers and exporters would not be able to request an amendment to a permit for changes to the importer or exporter's name (as it appears on their DEA certificate of registration) or the name of the foreign importer or exporter. The DEA considers the name of the foreign importer or exporter to be a key factor in determining associated risks of the diversion of controlled substances and subsequently whether or not to issue an import or export permit. Therefore, these fields would not be amendable.

However, also consistent with current practice, as stated above, the DEA would continue to allow importers and exporters to amend any additional associated company names they are DBA (doing business as) that they wish to have included in the notes section of the permit. The only change from current practice is that such amendments would be required to be made through the DEA Office of Diversion Control secure network application.

Importers and exporters would be required to make an official request through the DEA Office of Diversion Control secure network application for an amendment. Supplementary information submitted by an importer or exporter through the DEA Office of Diversion Control secure network application would not automatically trigger the amendment process. An

<sup>8</sup> The DEA is proposing to make global changes to DEA regulations to change usage, where applicable, of “import” and “export” to reference the date of release by customs officers for purposes of DEA recordkeeping and reporting requirements.

amendment would have no effect on the date of expiration of the permit; an amended import or export permit would have the same expiration date as the originally issued permit. Return information would not be allowed to be amended. Importers and exporters would be able to request that an issued import or export permit be canceled provided that no shipment has yet been made.

Under proposed § 1312.16(a)(5), registrants would be required to submit all requests for an amendment that would affect the total base weight of each controlled substance, other than those submitted in accordance with § 1312.15(a), at least three business days in advance of the date of release by a customs officer. Three business days are the minimum amount of time that the DEA needs to review this type of requested amendment, approve or deny the request, and transmit the applicable data to the ITDS. All other requests for amendment would be required to be submitted to the DEA at least one business day before the date of release by a customs officer at the port of entry. One business day is the minimum amount of time that the DEA needs to review the requested amendment, approve or deny the request, and transmit the applicable data to the ITDS.

For the reasons discussed above, the DEA is also proposing mandatory electronic reporting of return information for controlled substances imported or exported under permit procedures. The requirement of return information for imports and exports under permit procedure is discussed in greater detail in section II, B, 1 of this proposal under the heading "Terminology and Definitions."

#### (b) Import and Export Declarations for Controlled Substances

The DEA proposes to incorporate the mandatory electronic filing of DEA import declarations and DEA export declarations for controlled substances with the DEA into §§ 1312.18 and 1312.27. This requirement would also be incorporated into a new § 1312.03 which would reference a list of applicable forms for part 1312, and will state that the declaration forms are electronic. This information is currently listed multiple times in the applicable regulations. Consolidating this information into one section will make it easier for registrants to understand and comply.

Consistent with current requirements, controlled substance declarations would be required to be filed at least 15 calendar days in advance of the anticipated date of release by a customs

officer at the port of entry or port of export. 21 CFR 1312.18(b), 1312.27(a). Under proposed revised §§ 1312.18(b) and 1312.27(a), controlled substance declarations would not be deemed filed until the Administration issues a transaction identification number. The DEA proposes to allow registrants to proceed with the import or export transaction as soon as the transaction identification number has been issued, regardless of whether 15 calendar days have elapsed since its issuance. The 15-day advance notification period currently required by DEA regulations is now used to review notifications. Under this proposal, that review period would occur prior to the issuance of the transaction identification number. Therefore, the DEA would no longer need additional processing time after the issuance of the transaction identification number. Therefore under this proposal, importers of controlled substances under declaration procedures would more closely align with import procedures under permit procedures in regard to timing as to when they may proceed with the transaction. The DEA proposes to retain the 15-day-advance time period to ensure enough time for the DEA to review the submission for completeness and conduct any necessary follow-up prior to the import/export transaction. As discussed above, transaction identification numbers would be single-use identifiers, unique to a specific communication or transaction (*e.g.*, a notice, filing, report, application, etc.), signifying that a communication has been received, reviewed, and accepted. While current DEA regulations do not require confirmation of receipt from the DEA prior to importation or exportation pursuant to a declaration, the proposal to assign a transaction identification number is consistent with the DEA's current practice for declarations submitted online. Currently, the DEA assigns a Web Tracking Number to each declaration when it is submitted and accepted. However, unlike the proposed transaction identification number, the Web Tracking Number is assigned automatically upon submission to the DEA; the transaction identification number would be assigned only after the DEA has reviewed the filing for completeness. The proposed regulatory codification of the issuance of a transaction identification number is designed to ensure that electronically submitted declarations are indeed received by the DEA, are completed, and can be appropriately tracked and monitored; to streamline the declaration filing process; and to eliminate

duplicate filings. Current DEA regulations requiring declarations to be completed in triplicate would be eliminated.

The DEA proposes to amend its import/export regulations to describe the procedures relating to amendments following the filing of a controlled substance import or export declaration with implementation of the ITDS. The DEA proposes changes to §§ 1312.18(f) and 1312.27(e) to clearly specify how and under what conditions controlled substance import and export declarations may be amended or cancelled after having been filed and when a new declaration is required instead of an amendment. Registrants would submit a request to amend or cancel a filed declaration to the Administration through the DEA Office of Diversion Control secure network application. Return information may not be amended.

Consistent with current practice, importers and exporters would continue to be able to amend a declaration for the following data fields: The National Drug Control number, description of the packaging, or trade name of the product, so long as the description is for the same basic class of controlled substance(s) as in the original declaration; the proposed port of entry or export; the anticipated date of release by a customs officer at the port of entry or port of export; the method of transport; any registrant notes; and the justification entered by the importer or exporter for why an import or export is needed to meet the legitimate scientific or medical needs of the United States or foreign jurisdiction. The DEA allows amendments to these fields as these are areas that may be easily mis-keyed or subject to change as part of the normal import and export business practice. While the data contained in these fields is important to the tracking of controlled substances through the closed system of distribution, the DEA believes that the Administration is able to enforce the CSA and U.S. obligations under international drug control treaties while potentially limiting burden on industry by allowing these fields to be amendable.

Consistent with current practice, importers and exporters would continue to generally be allowed to amend the base weight of controlled substance(s) listed on their filed declaration prior to the start of an import or export transaction (*i.e.*, prior to shipment). However, also consistent with current practice, exporters would not be allowed to exceed the total base weight of controlled substance(s) listed on the corresponding authorization for import

issued by the foreign competent national authority. Also consistent with current practice, neither would exporters be allowed to exceed the strength of a controlled substance product if product strength information has been included on the authorization for import issued by the foreign competent national authority. Consistent with § 1312.15(a) for imports of controlled substances under permit procedure, importers under declaration procedure would be allowed to request an amendment to an import declaration regarding the quantity of controlled substances once a shipment has arrived at the U.S. customs port of entry if the increase in the amount of controlled substance to be imported is less than 1% of that listed on the filed declaration. Importers and exporters need not request an amendment for the sole purpose of decreasing the amount authorized.

Consistent with current practice, importers and exporters would continue to be able to amend a filed import or export declaration to remove a controlled substance. However, importers and exporters would no longer be able to amend declarations to add a new controlled substance or replace a controlled substance with another controlled substance. Instead, importers and exporters who needed to make changes to any of these fields would need to cancel the existing declaration and file a new declaration. The DEA understands that sometimes the incorrect controlled substance is identified on the declaration due to clerical error, for example because a similar item was selected from the drop-down selection in the DEA Office of Diversion Control secure network application that was located near the correct item. However, the DEA has closely considered this issue and ultimately determined that because the identification of the controlled substance proposed to be imported or exported is such a critical element of the closed system of distribution, that this element should not be amendable. As stated elsewhere in this preamble, the DEA reminds importers and exporters that the duty to file reports and other documents with the DEA includes the duty that these filings be complete and accurate.

Similarly, in a change from current practice, the DEA is proposing to cease allowing importers and exporters to amend information related to the authorization to import or export from the foreign competent national authority. The DEA understands that sometimes, especially in the case of less experienced importers and exporters,

the incorrect foreign authorization identifier is entered onto the declaration. This is often the result of numbers being transposed or a different number on the foreign permit being entered instead of the actual authorization identifier. However, similar to the identification of the controlled substance to be imported or exported, the DEA has closely considered this matter and ultimately determined that because the authorization from the foreign competent national authority to import or export a controlled substance is such a critical element to the Administration's ability to monitor and ensure the closed system of distribution, this element should not be amendable. As stated above and elsewhere in this document, the DEA reminds importers and exporters that the duty to file reports and other documents with the DEA includes the duty that these filings be complete and accurate.

Consistent with current practice, importers and exporters would not be able to request an amendment to a filed import or export declaration for changes to the importer or exporter's name (as it appears on their DEA certificate of registration) or the name of the foreign importer or exporter. The DEA considers the name of the foreign importer or exporter to be a key factor in determining associated risks of the diversion of controlled substances. Therefore, these fields would not be amendable.

However, also consistent with current practice, as stated above, the DEA would continue to allow importers and exporters to amend any additional associated company names they are DBA (doing business as) that they wish to have included in the notes section of the declaration. The only change from current practice is that such amendments would be required to be made through the DEA Office of Diversion Control secure network application.

Importers and exporters would be required to make an official request through the DEA Office of Diversion Control secure network application for an amendment. Supplementary information submitted by an importer or exporter through the DEA Office of Diversion Control secure network application would not automatically trigger the amendment process. An amendment would have no effect on the date of expiration of the declaration; an amended import or export declaration would have the same expiration date as the originally filed declaration. Return information would not be allowed to be amended. Importers and exporters

would be able to request that filed import or export declaration be canceled provided that no shipment has yet been made.

Registrants would be required to submit all requests for an amendment that would affect the total base weight of each controlled substance, other than those allowed to be released into the United States pursuant to §§ 1312.18(f) and 1312.16(a)(5), at least three business days in advance of the date of release by customs. Three business days are the minimum amount of time that the DEA needs to review this type of requested amendment and transmit the applicable data to the ITDS. All other requests for amendment would be required to be submitted to the DEA at least one business day before the anticipated date of release by a customs officer at the port of entry or port of export. One business day is the minimum amount of time that the DEA needs to review and accept the requested amendment and transmit the applicable data to the ITDS.

For the reasons stated above, the DEA is also proposing mandatory electronic filing of return information for controlled substances imported or exported under declaration procedures; see section II, B, 1 of this proposal under the heading "Terminology and Definitions" for additional discussion of "return information."

#### (c) Import and Export Declarations for Listed Chemicals

The DEA proposes to incorporate the mandatory electronic filing of import and export declarations for listed chemicals into §§ 1313.12 and 1313.21. Similar to the proposed § 1312.03, discussed above, the DEA is proposing a new § 1313.03, which references a list of applicable forms for part 1313, and will state that the declaration is electronic.

Under this proposal, the DEA would issue a transaction identification number once the DEA reviewed a listed chemical import or export declaration for completeness, and the 15-day reporting clock would begin on the date that the importer or exporter files a complete declaration. An import or export transaction of a listed chemical would not be allowed to take place until the transaction identification number has been issued and 15 calendar days have elapsed from the date a complete declaration was filed. Transaction identification numbers would be single-use numbers, unique to a specific transaction. While current DEA regulations do not require confirmation of receipt or acceptance from the DEA prior to importation or exportation pursuant to a declaration, the proposed

change aligns with current practices. In current practice, for notifications submitted through the DEA Office of Diversion Control secure network application and those that are not, industry waits until the transaction identification number has been issued to proceed with the transaction. The transaction identification number is assigned by the DEA only after the DEA has reviewed the filing for completeness. The proposed regulatory codification of current practices regarding the issuance of a transaction identification number is designed to ensure that electronically submitted declarations are indeed received by the DEA, are completed, and can be appropriately tracked and monitored; to streamline the declaration filing process; and to eliminate duplicate filings. Current DEA regulations requiring declarations to be completed in triplicate would be eliminated.

The DEA is also proposing to amend the language relating to waivers of the 15-day advance reporting requirement for importations by “regular importers” and export transactions between regulated persons and “regular customers” in §§ 1313.12, 1313.15, and 1313.21. With the implementation of the ITDS, it would be difficult for customs officers to clear a shipment of relevant listed chemicals without first receiving appropriate information from the DEA. The DEA has determined that three business days is the minimum amount of time that the DEA needs to review the information regarding the shipment and to transmit the applicable data accurately to the ITDS. The CSA requires the DEA to provide by regulation the circumstances in which the 15-day advance notice requirement required by 21 U.S.C. 971(a) does not apply for imports of listed chemicals by “regular importers” and exports of listed chemicals between regulated persons and “regular customers.” 21 U.S.C. 971(b). Pursuant to this authority, in the current regulations, the DEA has provided that specific circumstances allow for a waiver of the entire 15-day period of advance notification.<sup>9</sup> Because a waiver of the entire 15-day period will no longer be feasible after implementation of the ITDS, the DEA proposes now to describe circumstances in which importers and exporters will not be subject to the 15-day advance

notification requirement but must provide 3 calendar-days advance notification. The DEA does, however, propose to allow registrants to proceed with the import or export transaction as soon as the transaction identification number has been issued, regardless of whether the 3-calendar-day period has concluded. While the CSA also requires regulated persons subject to waivers to notify the DEA of the transaction “at the time of any importation or exportation,” the DEA intends to consider the notification provided to the DEA by customs officers at the time of release to serve this statutory purpose.

The DEA is proposing to revise §§ 1313.16, 1313.17, 1313.26, and 1313.27 to clarify the procedure for amending listed chemical import and export declarations after filing. Importers and exporters of listed chemicals would submit a request to amend or cancel a filed declaration to the Administration through the DEA Office of Diversion Control secure network application. Return information may not be amended. Requirements regarding updated notices for change in circumstances in §§ 1313.16 and 1313.26 would remain essentially the same. However, to accommodate implementation of the ITDS, the DEA would require that amendments be submitted through the DEA Office of Diversion Control secure network application. Importers and exporters for whom the 15-day advance reporting requirement has been partially waived pursuant to 21 U.S.C. 971(b) needing to make changes in advance of shipment, such as to increase the quantity of a listed chemical to be imported or exported, would be required to file their amendment at least three business days in advance of the date of release by a customs officer at the port of entry or port of export. As described above, three business days is the minimum amount of time that the DEA needs to review the amendment and transmit the applicable data to the ITDS.

For the reasons stated above, the DEA is also proposing mandatory electronic filing of return information for listed chemicals imported or exported under declaration procedures; see section II, B, 1 of this proposal under the heading “Terminology and Definitions” for additional discussion of “return information.”

#### (d) Import and Export Reports for Tableting and Encapsulating Machines

The DEA proposes to incorporate mandatory electronic reporting requirements into § 1310.05 for all regulated transactions involving tableting machines and encapsulating

machines, including domestic, import, and export transactions. To standardize and streamline the electronic filing of these reports, the DEA proposes to implement usage of a new form, DEA Form 452, Reports for Regulated Machines, which would cover imports, exports, and domestic regulated transactions of tableting and encapsulating machines, and whose usage would be referenced in the revised regulations. The new form would be accessed, completed, and submitted by regulated persons entirely through the DEA Office of Diversion Control secure network application. Upon receipt and review, the Administration will assign each completed report a transaction identification number. The DEA Form 452 would not be deemed filed until the Administration issues a transaction identification number. As discussed above, transaction identification numbers would be single-use identifiers, unique to a specific communication or transaction (*e.g.*, a notice, filing, report, application, etc.), signifying that a communication has been received, reviewed, and accepted. While current DEA regulations do not require confirmation of receipt from the DEA before the report is deemed filed, the proposed change is designed to ensure that electronically submitted reports are indeed received by the DEA, are completed, and can be appropriately tracked and monitored; to streamline the report filing process; and to eliminate duplicate filings. The current §§ 1310.05 and 1310.06 would be revised to reflect that these reports relating to tableting and encapsulating machines would now be submitted on the DEA Form 452.

Currently, regulated persons must provide notification of the import or export of a tableting machine or encapsulating machine on or before the date of importation or exportation. 21 CFR 1310.05(c). The DEA is proposing to require that the DEA Form 452 be submitted to the DEA 15 calendar days before the anticipated date of arrival at the port of entry or port of export in order to allow time for the DEA to review the information and transmit it to the ITDS. In order for these reports to be effective, they must be communicated by the DEA to CBP prior to arrival of the shipment at the port. The DEA has received reports that under current regulatory procedures, which require reporting “on or before” the date of importation, CBP has encountered machines at a hub or port of entry for which the importer has not provided DEA with notification, and

<sup>9</sup>Importers should be aware that these waivers of advance notification requirements apply only to the information the trade files with the DEA; for example, importers remain required to follow CBP’s Importer Security Filing and Additional Carrier Requirements (commonly known as “10+2”) rule, which applies to import cargo arriving to the United States by vessel.

that seizures have resulted.<sup>10</sup> Under the revised regulations, an importer may not initiate an import or export transaction involving a tableting machine or encapsulating machine until the regulated person has been issued a transaction identification number from the Administration. The importer or exporter could proceed with the import or export of the machine(s) as soon as the transaction identification number has been issued. These changes are proposed in a revised § 1310.05(c). Correspondingly, the DEA is proposing to amend § 1310.05(c) to provide clear direction that regulated persons are to submit notification of import or export of tableting or encapsulating machines through the DEA Office of Diversion Control secure network application.

The DEA is proposing in the revised § 1310.06(e)(1)(v) that reports of importation of tableting or encapsulating machines include the reason for the importation. This information would assist the DEA in understanding the intended medical, commercial, scientific, or other legitimate use of the machine.

Additionally, the DEA proposes to add a paragraph (c)(2) to § 1310.05 to address what regulated persons are to do in the event that an import shipment of tableting machines or encapsulating machines has been denied release by customs. Proposed requirements for denied shipments of imported tableting machines and encapsulating machines parallel the requirements for denied shipments of controlled substances and listed chemicals. Importers would be required to report to the Administration, through the DEA Office of Diversion Control secure network application, within 24 hours of denial, that the shipment was denied release by a customs officer into the United States and the reason for the denial. Under the proposal, denials of shipments must be reported whether or not the denial is based on a violation of the CSA or its implementing regulations. Reports of denied releases by customs officers at the port entry of tableting and encapsulating machines are needed to aid the DEA in identifying attempted unreported imports of tableting and encapsulating machines. The DEA does not believe that reports of shipments denied release from the United States at the port of export are required because the DEA should already have knowledge

of those machines through reports of their previous import (if applicable) and domestic regulated transactions required by the current § 1310.05(a)(4) and (c). A new proposed § 1310.06(g) would detail the information to be included in such report of denied release into the United States. If an importer subsequently receives notice from a customs officer that their shipment will be released into the United States, the importer would be required to file an amended DEA Form 452 with the DEA before the shipment may be released. In such circumstances, the regulated person may seek to have the tableting machines or encapsulating machines released by customs upon receipt of a transaction identification number for the refiled and amended DEA Form 452 without regard to the 15-day advance filing requirement.

For the reasons stated above, the DEA is also proposing mandatory electronic filing of return information for tableting and encapsulating machines imported or exported; see section II, B, 1 of this proposal under the heading “Terminology and Definitions” for additional discussion of “return information.” Return requirements would be incorporated into a new paragraph (h) in § 1310.06 and the existing paragraphs in the section correspondingly relabeled. This proposed change and other proposed changes to part 1310 not directly associated with the implementation of ITDS are discussed in more detail in section II, B, 6, b of this document.

The DEA also is proposing to revise the text that currently is located in § 1310.06(g) to require reports relating to exports of machines that are refused, rejected, or otherwise deemed undeliverable to be made through the DEA Office of Diversion Control secure network application. This provision, which is proposed to be moved to § 1310.06(i), does not require the use of a DEA Form 452. The DEA also proposes to require these reports to be submitted “at the earliest practicable opportunity” rather than the current standard of “within a reasonable time.” This proposed change would conform reporting requirements for declared exports of machines which are refused, rejected, or otherwise returned to the statutory language of 21 U.S.C. 830(b) which requires reports of regulated transactions in a tableting machine or encapsulating machine (including reports of importation or exportation of such machines) to be reported “at the earliest practicable opportunity.”

#### (e) Transshipments of Controlled Substances

Applications for transshipment permits would still be allowed to be submitted to the DEA via paper in accordance with the existing procedures under § 1312.31 for schedule I controlled substances. Information will be posted to the DEA Office of Diversion Control Web site informing persons seeking to transship schedule I controlled substances how to submit an application for a transshipment permit. Advance notification of transshipments for schedule II, III, and IV controlled substances would also still be allowed to be submitted to the DEA via paper in accordance with the current § 1312.32. The electronic application and filing process is not feasible in such circumstances because foreign IP addresses are blocked by the Department of Justice’s firewall and are prevented from accessing the DEA Office of Diversion Control secure network application. Although the transshippers themselves would not have direct access to the instructions on the DEA Web site due to the firewall protection, it is the DEA’s understanding that most transshippers have someone in the United States as a domestic presence facilitating the transaction who will be able to access the instructions. There is no change from the current operational system. The DEA also proposes to explicitly state in §§ 1312.31 and 1312.32 that a separate filing is required for each shipment, conforming the requirements of this section with the requirements for imports and exports of controlled substances in part 1312.

#### (f) Transshipments of Listed Chemicals

Advance notification would still be allowed to be submitted to the DEA via paper in accordance with the existing procedures under § 1313.31 for persons seeking to import a listed chemical into the United States for transshipment. Advance notification would still also be allowed to be submitted to the DEA via paper in accordance with the existing procedures under § 1313.31 for persons seeking to transfer, or transship listed chemicals within the United States for immediate exportation. The electronic application and filing process is not feasible in such circumstances because foreign IP addresses are blocked by the Department of Justice’s firewall and are prevented from accessing the secure network application on the DEA Office of Diversion Control Web site. While a broker or trader for an international transaction might be able to electronically submit the required

<sup>10</sup> As discussed in notes 5 and 9, and later in this document, the DEA is including in this proposal to make global changes to DEA regulations to change usage, where applicable, of “import” and “export” to reference the date of release by customs officers for purposes of DEA recordkeeping and reporting requirements.

information from a domestic IP address, for consistency and fairness across all transshipment activities, the DEA is proposing to allow paper applications and notices to continue for all transshipment transactions. Although the transshippers themselves would not have direct access to the instructions on the DEA Web site due to the firewall protection, it is the DEA's understanding that most transshippers have someone in the United States as a domestic presence facilitating the transaction who will be able to access the instructions. There is no change from the current operational system.

#### (g) Notifications of International Transactions by Brokers or Traders

The DEA proposes to incorporate in § 1313.32 the mandatory electronic filing of notifications of international transactions involving listed chemicals which meet or exceed the threshold amount identified in § 1310.04. While current DEA regulations do not require confirmation of receipt from the DEA prior to conducting an international transaction, the DEA is proposing to amend § 1313.32 to require that notifications of international transactions would not be deemed filed until a transaction identification number has been issued by the DEA. This change is designed to ensure that electronically submitted notifications are received by the DEA, are completed, and can be appropriately tracked and monitored; to streamline the notification filing process; and eliminate duplicate filings.

#### 2. Security

The DEA's secure application authentication methods allow only authorized persons to gain access to the application and ensure that persons can only gain access in the roles in which they are authorized. Because the secure network application can only be accessed through authentication, verifying the legitimacy of the reporter/applicant is possible without a requirement for a signature. Additional security protections are based on the requirement that return information is tied to a specific transaction. The reporter must have knowledge of the applicable transaction identification number or permit number in order to file the required return information.

Under this proposed rule, the application, completion, and filing processes would be electronic; however, the electronic equivalent of the current, fillable DEA paper applications and other forms for imports and exports would not be downloadable. Rather, persons would be able to securely

download approved permits and filed declarations, notices, and reports in digital image format. The DEA would enable security measures on the downloaded documents to prevent fraud, forgery, or other misuse or manipulation.

Applicants and registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. 21 CFR 1301.71(a). This includes responsibility for ensuring effective controls and procedures for which their agents and employees have access to and responsibility for completing and filing applications, notices, reports, and other filings required by DEA regulations, whether those filings be in paper format or electronic. Registrants must exercise caution in the consideration of employment of persons who 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 any application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause. 21 CFR 1309.72.

The DEA also takes this opportunity to remind registrants, those exempt from registration, and regulated persons that they may not delegate their liability away to their agents or employees. Registrants, those exempt from registration, and regulated persons remain legally liable (jointly or severally) with their agents or employees for violations of the CSA. It is unlawful for any person to knowingly or intentionally import or export controlled substances; knowingly or intentionally bring or possess on board a vessel, aircraft, or vehicle a controlled substance; or manufacture, possess with intent to distribute, or distribute a controlled substance in any means other than those authorized by the CSA. 21 U.S.C. 960(a). Except as provided in the CSA, it is unlawful for any person to knowingly import or export a listed chemical with intent to manufacture a controlled substance; export a listed chemical in violation of the laws of the country to which the chemical is exported; serve as a broker or trader for an international transaction involving a listed chemical, if the transaction is in violation of the laws of the country to which the chemical is exported; import or export a listed chemical knowing or having reasonable cause to believe that the chemical will be used to manufacture a controlled substance; export a listed chemical, or serve as a broker or trader for an international transaction involving a listed chemical

knowing or having reasonable cause to believe that the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported; import or export a listed chemical with the intent to evade the reporting or recordkeeping requirements of 21 U.S.C. 971; import a listed chemical in violation of 21 U.S.C. 952, import or export such a chemical in violation of 21 U.S.C. 957 or 971, or transfer such a chemical in violation of 21 U.S.C. 971(d); or manufacture, possess with intent to distribute, or distribute a listed chemical in violation of 21 U.S.C. 959, 21 U.S.C. 960(d). It is unlawful for applicants, registrants, those exempt from registration, regulated persons, or agents or employees thereof, to knowingly and willfully falsify, conceal, or cover up by any trick, scheme, or device a material fact. 18 U.S.C. 1001(a)(1). It is unlawful for applicants, registrants, those exempt from registration, regulated persons, or agents or employees thereof, to knowingly and willfully make false statements or representations. 18 U.S.C. 1001(a)(2). It is unlawful for applicants, registrants, those exempt from registration, regulated persons, or agents or employees thereof, to knowingly and willfully make or use any false writing or document knowing it to contain materially false, fictitious, or fraudulent statement or entry. 18 U.S.C. 1001(a)(3).

It is the position of the DEA that an employee who has knowledge of diversion of controlled substances or listed chemicals from his employer by a fellow employee has an obligation to report such information to his employer. 21 CFR 1301.91, 1309.73.

#### 3. Miscellaneous

To account for approvals by the Administration through the DEA Office of Diversion Control secure network application, DEA regulations would be amended to remove the reference to facsimile signatures found in § 1312.13 for import permits. To account for greater security and decrease opportunities for diversion, the DEA also proposes to eliminate the current requirements in §§ 1312.13 and 1312.23 that import and export permits be issued sequentially and instead assign each permit a unique, randomly-generated identifier.

Pursuant to E.O. 13659 (ITDS), the DEA would cease distributing paper copies of permits and declarations to CBP/customs services of Insular Areas. Instead, the DEA would electronically transmit pertinent data fields from the permit, declaration, or other notice to the ITDS.

To accommodate the change in practices concerning the exchange of information between the DEA and CBP/customs services of Insular Areas as part of the implementation of the ITDS, the DEA proposes to generally, globally remove current DEA regulations that address the transmission and review of import and export information between the DEA and CBP. The regulations that would be affected are §§ 1312.14, 1312.19, 1312.24, 1312.28, 1313.14, and 1313.23. The removal of these regulations will allow for increased flexibility to make adjustments regarding the transmission of information between the DEA and CBP/customs services of Insular Areas as the process is implemented. No changes or modifications in the exchange of information between the DEA and CBP/customs services of Insular Areas should have any impact on those entities that must utilize the DEA Office of Diversion Control secure network application to submit applications or filings. The DEA is not proposing to remove current operational requirements found in § 1312.15, “Shipments in greater or less amount than authorized.”

*B. Proposed Amendments Indirectly Associated With Implementation of the International Trade Data System*

1. Terminology and Definitions

For purposes of clarity and transparency, the DEA proposes to update its regulations for consistency of terminology (within DEA regulations, between DEA regulations and the CSA, and between DEA regulations and the regulations of other agencies that regulate imports and exports), to reflect name changes to referenced entities, and to add new definitions. These changes involve both technical and substantive amendments.

The DEA proposes to make technical changes to update references to certain named entities. One, all references to the “U.S. Customs Service” will be changed to “U.S. Customs and Border Protection” (CBP). In 2003, the functions of the Customs Service were transferred to the Department of Homeland Security (DHS). Its successor agency is known as U.S. Customs and Border protection (CBP). Two, the DEA is making a change in § 1310.06 to change “Federal Food and Drug Administration” to the agency’s formal name, the “U.S. Food and Drug Administration.” Three, the DEA will amend current § 1312.12(b) (proposed § 1312.12(c)) to reflect that the cities located in the Republic of India currently referenced as Calcutta and

Bombay are now recognized by the U.S. State Department as Kolkata and Mumbai. The DEA will also take this opportunity to remove any remaining incongruous references to the “Director” when referencing the head official of the DEA and alternatively insert the term “Administrator” or “Administration” as appropriate.

Additionally, the DEA proposes to make a technical change to more concisely incorporate U.S. obligations under international treaties of drug control, as statutorily codified in the CSA. The DEA will amend its regulations to consistently reference the “competent national authority” when referencing a foreign jurisdiction having authority to authorize the importation or exportation of controlled substances and listed chemicals into or out of their jurisdiction. This change is being accompanied by the addition of a definition in the regulations for “competent national authority.” A competent national authority (CNA) is an entity that has authority to authorize imports and exports of narcotic drugs and psychotropic substances and regulate or enforce national controls over precursor and essential chemicals. Generally, the only entities recognized as such by the DEA are those entities identified in the directory of “Competent National Authorities Under the International Drug Control Treaties” published by the United Nations Office on Drugs and Crime. However, for purposes of exports of narcotic drugs, such term also includes freely associated states eligible to receive exports of narcotic drugs from the United States pursuant to 48 U.S.C. 1972.

The DEA will remove “jurisdiction of the United States” as a defined term in §§ 1300.01(b) and 1300.02(b) but will add a clarification of the definition of the term “United States” in those provisions. Although the term “United States” is defined at 21 U.S.C. 802(28), the proposed definitions in the regulations will clarify the Administration’s interpretation and make the reader aware that places and waters subject to the jurisdiction of the United States, in addition to the customs territory of the United States, include (*but are not limited to*) the U.S. territories or possessions listed in the new term. The list of territories and possessions is not a catalogue of Insular Areas where the CSA is in effect. Rather, these listed territories or possessions (U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands) are ones that are permanently inhabited. Thus, they are ones from which controlled substances, listed

chemicals, and tableting or encapsulating machines might be expected to be regularly imported into the customs territory of the United States (or exported to foreign jurisdictions), as well as ones into which such materials may be imported from foreign jurisdictions, all of which would require compliance with the Administration’s import and export regulations. No substantive change is intended by this revision. Removal of the definition of “jurisdiction of the United States” and corresponding changes to remove the term in §§ 1301.12, 1301.34, and 1302.07, as well as in the definitions of “export” and “import” in 21 CFR part 1300, will make DEA regulations consistent with the CSA. The DEA proposes to remove the phrase “jurisdiction of the United States” from § 1301.12(b)(3) because it is redundant with the preceding clause referencing registration at another location in the same State, as “State” is broadly defined in 21 U.S.C. 802(26). The addition of the phrase “in which he practices” to § 1301.12(b)(3) would conform the regulation to registration requirements for practitioners as stated in 21 U.S.C. 823(f). No substantive change is intended by this amendment. Similarly, the clause “within and without the jurisdiction of the United States” would be removed from § 1301.34(c)(2) as it is superfluous with the first portion of that regulation. No substantive change is intended by this amendment. In determining whether it is in the public interest to issue a registration to import schedule I or II controlled substances, the DEA considers employment of security procedures to guard against in-transit losses both domestically and abroad and will continue to do so. The term “jurisdiction of the United States” is also found in the definition of “chemical import.” The DEA proposes to remove that definition as unnecessary and superfluous, as it is only used once in subsequent DEA regulations, in § 1313.14 in reference to “listed chemical import declarations.”

In association with the above, the DEA also proposes to amend §§ 1301.24, 1301.26, 1309.26, 1312.13, and 1312.15 to denote the responsibility of customs services of Insular Areas, and not just CBP, to enforce the import and export requirements of the CSA. When controlled substances, listed chemicals, and tableting or encapsulating machines are imported into, or exported from, a U.S. territory (or possession) or an Insular Area of the United States that is not part of the customs territory of the United States, these items are cleared by



the customs service of an Insular Area and not CBP.<sup>11</sup>

The DEA proposes to make global amendments to its import and export regulations where appropriate to reference the date of “release” by customs officers of items entering or departing the United States rather than the date of “import” or “export” where such terms are currently used in DEA regulations establishing DEA recordkeeping and reporting requirements (as compared to determining liability under the CSA as a result of items entering or leaving places and waters subject to the jurisdiction of the United States). This change will make clear that the DEA does not equate the “date of import” and “date of export” with the date that a customs officer “releases” an item that has been imported or an item intended or destined for export. As noted earlier in the document, the meaning of import and export under the CSA is much broader than how those terms may be used by other agencies exercising import or export control pursuant to organic statutes other than the CSA (*i.e.*, the actual date of import or export under the CSA may, and frequently will, occur at a date different than the date of release by a customs officer).

The DEA proposes to make a technical amendment to remove references to telex and facsimile number contact information found in various sections of 21 CFR part 1313, as telex systems and facsimile machines are now rarely utilized by registrants, regulated persons, or their agents. The DEA would add a general reference to “contact information.” This change is intended to account for contact information systems such as email now in common usage as well as other forms of communication which may be developed in the future.

The DEA proposes to make a technical amendment to replace all current references in DEA regulations to “special controlled substances invoice(s)” with “export declaration(s).” This change will conform terminology among the DEA Form 236, DEA regulations, and current practice.

The DEA is proposing global technical amendments related to plain language principles. The DEA has tried to balance the redrafting of regulatory language to better correspond with Federal Plain Language Guidelines against the knowledge that regulated persons have historical familiarity with long-standing

regulatory text which may have been the subject of previous interpretation by the Administration and court decisions. Many of the DEA’s current import and export regulations have not ever been significantly modified since the original requirements were implemented under predecessor drug control statutes (with reimplementation under authority of the CSA). The DEA has tried to balance the historical knowledge of the Administration and presently regulated individuals against the need for newly regulated persons and a broader segment of the population to be able to more easily read and comprehend applicable requirements. These proposed changes include changing the word “shall” to “must,” “desiring” to “seeking,” and “furnish” to “file,” without intending any change to the meaning of existing regulations. The DEA is proposing technical amendments throughout the revised regulations to eliminate use of passive voice in favor of the active voice. This change will make it easier for readers to identify what actions must be taken and by whom. The DEA’s proposal would also eliminate unnecessary content and unnecessary words and phrases from regulations. The proposal also includes reorganization of several regulations to group reporting requirements for specific individuals or types of reports. This change will help to reduce the need to cross-reference between multiple regulations in order to more easily understand at a glance if you must report, when you must report, what you must report, and how you must report.

The DEA also proposes to amend various import and export regulations related to the maintenance of records to add a cross reference to 21 CFR part 1304 or 1310, as applicable, which are the general parts governing recordkeeping and reporting responsibilities related to controlled substances and listed chemicals, respectively.

In addition to the above noted technical changes, the DEA proposes to define the terms “customs officer,” “port of entry,” “port of export,” “return information,” and “shipment” currently utilized in DEA regulations. Defining these terms will add clarity and transparency as to how these terms are utilized for the specific purposes of DEA regulations related to the import and export of tableting and encapsulating machines, controlled substances, and listed chemicals as compared to how these terms may be used by other federal agencies having additional authorities over import or export. The proposed DEA definitions

are substantially similar to how these terms are used by other agencies with overlapping authority over import and export. However, the definitions are not exact duplications because of the unique obligations and requirements imposed on imports and exports of controlled substances, listed chemicals, and tableting and encapsulating machines by the CSA. Most specifically, DEA regulations must take into account that the CSIEA defines “import” in broader terms than just in relation to the customs territory which is used as the basis for CBP’s definition of “date of importation” and related terms. Similarly, CBP’s definition of “port of entry” is defined narrowly to reference only the authority of CBP officials, whereas DEA regulations also need to take into account the authority of customs officials of Insular Areas of the United States to enforce the CSA.

The proposed definition of “customs officer” makes clear that for purposes of DEA regulations, the term means any person authorized to enforce the customs laws of the United States. Consistent with 21 U.S.C. 951–953 and other provisions of the CSA, the term “customs officer” includes customs officers of any commonwealth, territory, or possession of the United States. Correspondingly, in defining “port of entry,” the DEA’s goal is to improve readability and transparency, and to clarify that applicable regulations regarding the importation of tableting and encapsulating machines, controlled substances, and listed chemicals apply to all locations at which these machines and substances may potentially be imported. *See* 21 U.S.C. 951(a)(1). The proposed definition of such locations include, but are not limited to, ports of entry as defined in title 19 of the United States Code, customs stations, landing rights airports, and user fee airports. Relatedly, the DEA is proposing to add a definition for “port of export” and make technical amendments throughout the export regulations to consistently refer to the “port of export.” Current DEA regulations variously refer to the point at which goods are released by customs officers for export from the United States as both the “port of exit” and the “port of exportation.” The proposed definition of “port of export” is based on the definition of the term in the Foreign Trade Regulations. 15 CFR 30.1. The Foreign Trade Regulations are promulgated by the U.S. Census Bureau, the Federal agency responsible for collecting, compiling, and publishing trade statistics for the United States pursuant to title 13, U.S.C., chapter 9. While the proposed definition is not an

<sup>11</sup> Although the U.S. Virgin Islands are outside the customs territory of the United States, the customs laws of the U.S. Virgin Islands are enforced by U.S. Customs and Border Protection. 19 CFR 7.2(c).



exact duplication, due to the different authorities and responsibilities of the respective agencies, no significant substantive differences are intended. By basing the DEA's definition of "port of export" on 15 CFR 30.1, consistency of meaning, despite the unique requirements of the CSA, for the term will be achieved throughout the import and export process for persons who are subject to regulation by various Federal agencies.

"Shipment" is variously defined by the federal entities having authority over importation and exportation of goods. The addition of a definition of this term in DEA regulations will aid in readability and transparency on how this term is understood and utilized by the DEA in regard to the importation and exportation of tableting and encapsulating machines, controlled substances, and listed chemicals. Introduction of the proposed definition emphasizes requirements found in 21 CFR parts 1310, 1312, and 1313 that a shipment of tableting or encapsulating machines, controlled substances, or listed chemicals is not only limited to a single transaction between a single importer or exporter and a single consignee on a single loading document, but also that the shipment must occur on a single conveyance (e.g., one plane, one ship, or one freight train—but not each rail car), as opposed to multiple conveyances (e.g., two planes, two ships, two freight trains, or any combination thereof). This definition is not meant to preclude release of merchandise into the United States that has been transhipped at a location outside of the United States. This is meant to clarify that each individual shipment of tableting or encapsulating machines, controlled substances, or listed chemicals must be associated with a single filing with the DEA for such activity. Consistent with long-standing DEA policy and the proposed definition, a load of goods would be considered a "split shipment" if it is divided into multiple parts to be placed onto more than one conveyance, even if on the same commercial loading document. Under existing DEA policy and under these proposed regulations, such "split shipments" cannot be included on a single declaration or permit. Each part of such shipment constitutes a shipment in its own right and requires a separate permit or declaration pursuant to these proposed changes. This addition of the definition, as proposed, would not change the ability of registrants to include multiple line items on one permit application, declaration, or notice. Neither is the

definition meant to preclude the ability of importers and exporters to utilize multiple common carriers as intermediaries for the transportation of an entire shipment. Thus, for example, a shipment consisting of lots A and B, subject to a single valid export permit or declaration, can be reloaded *together* from one conveyance to another (such as from a freight train to a plane on its way to the port), but lots A and B cannot be separated from each other onto *separate conveyances* (such as onto separate planes or separate ships) at any time until the shipment has reached its final destination and the export transaction concluded. (The same being true in reverse for imports until delivered to the registered location.) Likewise, lot A cannot be subdivided into lots A1 and A2 unless lots A1 and A2 are subject to separate valid permits or declarations. In relation to this change, and for consistency with the existing single-shipment requirements found in 21 CFR parts 1312 and 1313, the DEA proposes to amend § 1310.05(c)(1) to specify that each shipment of tableting or encapsulating machines must be reported separately to the DEA. To further make clear this prohibition, the DEA proposes to add a definition of "split shipment" to mean an import or export shipment that is divided between two or more conveyances.

Additionally, the DEA is proposing to amend §§ 1304.21(d) and 1310.06 to clarify record keeping requirements concerning imports and exports. The current text of § 1304.21(d) states that the date of importation or exportation is the date on which the controlled substances are "actually" imported or exported. The DEA is proposing to amend these regulations to instead require that in maintaining records concerning imports and exports, the registrant needs to record the date on which the items are released by a customs officer at the port of entry or port of export. However, it should be understood that this clarification only applies for purposes of recordkeeping. For all other purposes under the CSIEA, the date of import or export is the date such activity actually occurs within the meaning of those terms under the Act. See 21 U.S.C. 951 through 953. The regulation remains unchanged with respect to recording dates of receipt and distribution, *i.e.*, the dates will remain the actual date received at the registered location and distributed from the registered location.

The DEA is additionally proposing to add a definition of "return information" to §§ 1300.01(b) and 1300.02(b) stating that such information references

information that persons are required to report to the Administration following an import or export transaction. While this term is already generally understood by the regulated community, the term is not defined, and may cause initial confusion to the general public or parties that are newly subject to DEA reporting requirements.

The DEA proposes to harmonize the return information requirements across parts 1310, 1312, and 1313, to the extent possible. This document discusses the details of each proposal in the relevant section below. In general, the DEA is proposing that return information must be reported within 30 calendar days after release by customs at the port of entry or exit, or within 10 calendar days of a written request by the Administration, whichever is sooner. All return information for applications or other initial filings that are required to be made electronically through the DEA Office of Diversion Control secure network application would likewise be required to be filed electronically through the same system. Because the secure network application can only be accessed through authenticated access that ensures the legitimacy of the reporter/filer, and because the user must know the applicable transaction identification number or permit number in order to input return information for a specific transaction, the DEA does not see a need for return information to be signed by a responsible company official. Therefore, the DEA is proposing to remove the requirement for signature by a responsible company official that currently appears in § 1312.22(c)(7).

## 2. Part 1302: Labeling and Packaging Requirements for Controlled Substances

Corresponding to the removal of "jurisdiction of the United States" and the revised definitions of "export" and "import," the DEA proposes to make a corresponding technical change to § 1302.07 to reflect those definitional changes. The sealing requirement would be separately stated for imports and exports. This change allows the import statement to clearly reflect that the sealing requirement for imported controlled substances applies regardless of whether the import occurred inside or outside of the customs territory of the United States. Separating the import and export requirements also makes clear that the distinction between the customs territory and the non-customs territory is only applicable to imports and not exports.

### 3. Part 1304: Records and Reports for Registrants

The DEA proposes to make a technical amendment to § 1304.02 to reflect that definitions found in § 1300.02, “Definitions relating to listed chemicals,” are not applicable to part 1304, that addresses the records and reports that are required of controlled substance handlers. (21 CFR part 1310 addresses records and reports of listed chemicals and certain machines.)

As discussed in section II, B, 1 of this document above, the DEA will make a technical amendment to amend § 1304.21(d) to separately state reporting requirements concerning imports and exports of controlled substances. The recording date for receipt, distribution, other transfer, or destruction would not change. The regulation would be amended to state that the recording date for imports or exports of controlled substances is the date on which the controlled substance was released by a customs officer at the port of entry or port of export.

### 4. Part 1308: Schedules of Controlled Substances

The DEA proposes to make two technical updates to part 1308. First, the DEA would amend § 1308.01 to denote that part 1308 also includes nonnarcotic substances, chemical preparations, veterinary anabolic steroid implant products, prescription products, and anabolic steroid products excluded pursuant to 21 U.S.C. 811. Second, the DEA would amend § 1308.49 to reflect the current requirements of the CSA regarding issuance of temporary scheduling orders. 21 U.S.C. 811(h) was amended by section 1153 of the Food and Drug Administration Safety and Innovation Act of 2012, Public Law 112–144, July 9, 2012, to make temporary scheduling orders effective for two years, with an option to extend for up to one year during the pendency of proceeding under 21 U.S.C. 811(a). The CFR was not updated when the law changed. The DEA also proposes to realign the subsections of § 1308.49 to properly separate the discussion of the circumstances in which a temporary scheduling order will be vacated.

### 5. Part 1309: Registration of Manufacturers, Distributors, Importers and Exporters of List I Chemicals

The DEA proposes to amend § 1309.32(d) to add “manufactured” to the list of business activities each applicant can include for each list I chemical. Adding “manufactured” would accurately reflect an “activity” that an applicant could conduct with

list I chemicals if appropriately registered. No change is required to DEA Form 510 because “manufacturer” is already listed as an option.

The DEA is proposing to correct and update the cross-reference in § 1309.46(d) by removing the reference “§ 1309.54” and replacing it with the reference “§ 1309.53.” Section 1309.46(d) currently instructs an applicant to file a request for a hearing pursuant to § 1309.54. However, § 1309.54 is entitled “Burden of Proof,” and therefore is an inaccurate cross-reference.

The DEA is proposing to correct and update the cross-reference in § 1309.51(a) by removing the cross-reference to § 1309.57 and replacing it with the cross-reference “1309.55.” Currently, § 1309.57 is a misleading cross-reference since it does not exist in Title 21, chapter II of the CFR. The “Hearings” section in part 1309 concludes at § 1309.55. The DEA is therefore changing the cross-reference in § 1309.51(a) from “1309.57” to “1309.55.” Finally, the DEA is proposing to correct two minor typographic issues in § 1309.71.

### 6. Part 1310: Records and Reports of Listed Chemicals and Certain Machines

#### a. Mail Order Reporting for Ephedrine, Pseudoephedrine, Phenylpropanolamine, and Gamma-Hydroxybutyric Acid

The DEA proposes to incorporate mandatory electronic reporting requirements into part 1310 for monthly reports of mail-order transactions involving ephedrine, pseudoephedrine, phenylpropanolamine, and gamma-hydroxybutyric acid (including drug products containing these chemicals or controlled substance) required to be filed in accordance with § 1310.03(c) pursuant to 21 U.S.C. 830(b)(3). To standardize and streamline the electronic filing requirement of these monthly mail-order reports, the DEA proposes to implement usage of a new form, DEA Form 453, which would be referenced in the revised regulations. The new form would be accessed, completed, and submitted by regulated persons entirely through the DEA Office of Diversion Control secure network application. 21 CFR 1310.03(c) would be further revised to reflect that reports would not be deemed filed until the Administration issues a transaction identification number unless they are complete upon submission. As discussed earlier in this document, transaction identification numbers would be single-use identifiers, unique to a specific communication, signifying

that a communication has been received, reviewed, and accepted by the DEA. While current DEA regulations do not require confirmation of receipt from the DEA before the report is deemed filed, the proposed change is designed to ensure that electronically submitted reports are indeed received by the DEA, are complete, and can be appropriately tracked and monitored; to streamline the report filing process; and to eliminate potential duplicate filings. The current § 1310.06(i) would be revised to reflect that the monthly mail-order information required to be submitted would now be submitted on the DEA Form 453 and would be designated as § 1310.06(k). 21 CFR 1310.03(c) would be further revised by separately listing the requirement for monthly reports to be submitted by regulated persons who engage in the specified domestic mail-order transactions and export transactions. The proposed revision also more plainly lays out the requirement that the regulated person must be engaged in a transaction with one of the specified chemicals or controlled substance and use or attempt to use the U.S. Postal Service or any private or commercial carrier for both activities in order to be required to file the monthly report. This revision is not intended to impose any different requirements than the current regulation, but only to ease understanding of the reporting requirements. 21 CFR 1310.05(e) would correspondingly be amended to reflect the implementation of the mandatory electronic filing requirement.

The DEA is also proposing technical amendments to § 1310.05(d) to revise the mailing information in the second sentence and to replace the term “shall” in three locations without changing the requirements.

#### b. Listed Chemicals and Tableting and Encapsulating Machines

The DEA proposes to amend § 1310.05 to require reports of unusual or excessive loss or disappearance of a listed chemical to be filed through the DEA Office of Diversion Control secure network application. When determining whether a loss is unusual or excessive, the DEA is proposing guidelines that the regulated person should consider: (1) The actual quantity of a listed chemical; (2) the specific listed chemical involved; (3) whether the loss or disappearance of the listed chemical can be associated with access to those listed chemical by specific individuals, or whether the loss or disappearance can be attributed to unique activities that may take place involving the listed chemical; and (4) a pattern of losses or disappearances over

a specific time period, whether the losses or disappearances appear to be random, and the result of efforts taken to resolve the losses. If known, the regulated person would also need to report whether (1) the specific listed chemical was a likely candidate for diversion and (2) local trends and other indicators of the diversion potential of the listed chemical. This language is similar to the current regulatory language relating to theft and loss of controlled substances in § 1301.74(c).

In addition, the DEA proposes to clarify in the revised § 1310.05(b)(1) that regulated persons must submit a report of unusual or excessive loss or disappearance whether or not the listed chemical is subsequently recovered. The DEA also has proposed changes in the revised § 1310.05(b)(1) to clarify which party has the responsibility for reporting during domestic and international transactions. These changes will streamline the data collection process and allow the DEA to more efficiently respond to diversion as well as to respond to reporting requests concerning these items from the United Nations.

The DEA also proposes to remove the phrase “whenever possible” from the oral reporting requirements of the current § 1310.05(b). The DEA believes that the phrase is redundant with the stated requirement that such reports be made “at the earliest practicable opportunity.” Removing this phrase would better align the reporting requirements with the statutory language of 21 U.S.C. 830(b)(1).

In response to the above discussed changes, the DEA proposes to restructure § 1310.05(a) and (b) to reflect the revised reporting structure. Paragraph (a) would address those reports made solely to the local DEA office in accordance with the current and revised § 1310.05(a)(1) and (2). Paragraph (b) would address those reports made orally to the local DEA office with written reports being submitted through the DEA Office of Diversion Control secure network application. The reporting requirements now located in § 1310.05(b) would be transferred to paragraphs (a)(1) and (2), and (b)(1) and (2), as applicable. This change consolidates the reporting requirements for each of the applicable reports into their applicable paragraphs; readers would no longer be required to look at both paragraphs to determine when and how they must initially report these transactions. In addition, the DEA proposes to clarify in § 1310.05(a)(2) that regulated persons must report orally, not in writing, any proposed regulated transaction with a person

whose description or other identifying characteristic the Administration has provided to the regulated person. Regulated persons would be required to orally report the other types of actions at the earliest practicable opportunity to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located.

21 CFR 1310.06 would be revised to reflect the various changes in §§ 1310.03 through 1310.05. Cross-citations have been amended to reflect where regulations have been moved and new forms instituted. The DEA also proposes in § 1310.06(a)(3) to require regulated persons to include the NDC number of the product containing the listed chemical, if applicable, in all records required by § 1310.03(a). If the record contains the NDC number, information about the “form of packaging” would not be necessary. The restructuring of § 1310.05(a) also corrects a long-standing typographical error in the current § 1310.06(c), which now incorrectly references § 1310.05(a)(4) instead of (a)(3). 21 CFR 1310.06(c) currently states that a report submitted pursuant to § 1310.05(a)(4), domestic regulated transactions, must include a description of the circumstances leading the regulated person to make the report. However, the corresponding example relates to an unusual loss, which is addressed in the current § 1310.05(a)(3) (proposed § 1310.05(b)(1)). The DEA also is proposing to make technical amendments in § 1310.06, including replacing the term “shall” in paragraphs (a) and (b).

The DEA would standardize submissions of domestic and import and export regulated transaction reports involving tableting and encapsulating machines through the introduction of a new form, the DEA Form 452. Under the current regulations, regulated persons who engage in a domestic regulated transaction in a tableting or encapsulating machine are required, whenever possible, to make an oral report to the DEA Divisional Office in advance of the transaction, followed by a written report. 21 CFR 1310.05 (a)(4) and (b). In the revised § 1310.05(b)(2), the DEA proposes to make the oral reporting mandatory and to mandate the electronic filing of the written report. The DEA also proposes to provide specific guidelines on when those reports must be given. The revised § 1310.05(b)(2) would require regulated persons to orally report domestic regulated transactions in a tableting machine or an encapsulating machine when an order is placed rather than at the earliest practicable opportunity after

the regulated person becomes aware of the circumstances involved. The written report (DEA Form 452) would be required to be filed within 15 calendar days after the order has been shipped by the seller. The previous standard was originally adopted for reporting of domestic regulated transactions for uniformity with the timeframe reporting standard imposed by 21 U.S.C. 830(b)(1)(A) for transactions involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or other suspicious circumstances. However, the DEA proposes to exercise its authority under 21 U.S.C. 830(b)(1) to impose a different reporting timeframe standard for machines. The revised standards are not only less ambiguous for regulated persons to follow, they also ensure the DEA receives the information in time to take appropriate action as may be necessary. The new DEA Form 452, which was discussed above in section II, A, 1, d, would cover not only import and export regulated transactions of tableting and encapsulating machines required under the current § 1310.05(c) but also the domestic regulated transactions of tableting machines or encapsulating machines required by the current § 1310.05(a)(4). The requirements for the content of domestic reports would be moved from § 1310.06(d) to a new § 1310.06(f), while the requirements for reports of importations and exportations would all be contained within § 1310.06(e). The DEA also is proposing to amend the recordkeeping requirements in § 1310.06(a) and reporting requirements in § 1310.06(e) and (f) to require the inclusion of information about whether the machine is manual or electric. Under the proposed language in §§ 1310.06(e)(1)(vi) and 1310.06(f)(3), the DEA would require reports of importations and domestic transactions to include any proposed changes to the identifying information of imported machines that will occur after the importation or other transaction.

The DEA also is proposing to amend § 1310.06 to require regulated persons who import or export a tableting or encapsulating machine to report return information to the Administration within 30 calendar days of the release of the shipment by customs at the port of entry or port of export, or within 10 calendar days after receipt of a written request by the Administration. The DEA has included the provision for the requirement to submit return information earlier than the 30 days for two reasons. First, it conforms to the changes proposed for controlled

substances and listed chemicals in parts 1312 and 1313. Uniformity of requirements should simplify procedures and ease understanding of the requirements by regulated industry. Second, the option to request advance return information allows the DEA to receive information that may be needed for time-sensitive requirements, such as investigations that may need to result in immediate action to protect the public health and safety. Return information would be required to be submitted electronically through the DEA Office of Diversion Control secure network application on the DEA Form 452. Reports would not be deemed filed until a transaction identification number has been issued by the DEA. Pursuant to the proposed § 1310.06(h), importers would be required to report specifics on their return, including dates of the transaction, quantities of machines involved, and descriptions of the machines. Consistent with the current requirements importers also would be required to report subsequent transfers of the machines under § 1310.05(b)(2). Reports of transfers after import may be submitted with the return information or separately.

The proposed revisions relating to tableting and encapsulating machines that would standardize the submission of reports of regulated transactions, whether domestic or import/export, and require return information, would enhance the monitoring of these machines and allow the DEA greater ability to detect and prevent their use for the illicit manufacture of controlled substances. While tableting machines and encapsulating machines are commonly used by legitimate companies to produce pharmaceuticals and nutritional supplements, they are also used by traffickers to produce single dosage units of illicit synthetic substances such as methylenedioxymethamphetamine (“MDMA”) aka “Molly,” “ecstasy,” and other synthetic designer drugs classified as schedule I controlled substances or analogue substances. These machines have also been known to be used by marijuana dispensaries, steroid labs, and counterfeit drug manufacturers.

Manual capsule fillers and small encapsulating machines can produce anywhere from 15 to 1,000 capsules at a time, and rotary presses can produce massive amounts of tablets in a very short period of time. The value of the machines can range anywhere from under \$100 to over \$400,000 depending on the type of machine. Importers and exporters are not required to report the value of the machine or its production capacity to the DEA. However,

sometimes the manifest will contain the weight of the shipment and will provide some indication of the machine's capacity.

During 2014, 33 machines at various points of entry were seized by CBP for mislabeling and nonidentification. Regulatory changes in the proposed rule would require importers and exporters to report to the DEA when a shipment has been denied release by a customs officer for any reason, whether or not the denial was based on a violation of DEA regulations. Likewise, by unifying the reporting format for regulated transactions in tableting machines, whether domestic, import, or export, the DEA will be able to monitor the flow of these machines through the distribution chain. This will allow the DEA to better understand and monitor the trade in these machines and to adopt more efficient means of stopping the diversion of tableting and encapsulating machines, and prevent their use in the illicit manufacture of controlled substances.

#### 7. Part 1312: Importation and Exportation of Controlled Substances

The DEA proposes to make a technical change to §§ 1312.11 and 1312.22 to insert a cross-reference to part 1301 of chapter II of title 21 of the Code of Federal Regulations when referencing the registration requirements for the importation of controlled substances.

The DEA proposes to amend § 1312.14 to account for revised distribution procedures for import permits. The DEA is retaining the requirement that an official record of the permit (a “copy” under current DEA regulatory terms) accompany the shipment of controlled substances. This is an important tool utilized by the DEA for ensuring compliance with the closed system of distribution by allowing quick initial visual indication of compliance with requirements with the CSA. However, because customs officers will be able to electronically validate the legitimacy of the import permit through ITDS, customs officers will not need to physically detach the official record of the permit for validation. An official record of the permit must instead accompany the shipment until it reaches its final destination. The DEA also proposes to amend § 1312.14 to omit the discussion of the circumstances in which customs officers will refuse entry of a shipment.

The final destination for an import must be the registered location of the importer. (The import must be received at the registered address of the importer before being moved to another location

of the importer or delivered to a customer.) The receipt of imported goods is a principal activity of registered importers. Pursuant to 21 U.S.C. 958(h), a separate registration is required at each principal place of business where applicants import or export controlled substances. Accordingly, the final destination of a shipment of imported controlled substances is the registered location of the registrant. Drop shipments, *i.e.*, deliveries made by an importer directly to a customer without passing through the registered location of the importer,<sup>12</sup> are explicitly prohibited under the proposed revisions to § 1312.19. Similarly, consistent with current requirements, deliveries may not be made directly to a warehouse exempted from registration pursuant to § 1301.12(b)(1); they must arrive first at the registered location.

A technical amendment to paragraph (a) of § 1312.15 is proposed to cross-reference § 1312.16, concerning shipments that may be in greater or lesser amount than what is authorized by the import permit.

Associated with the foregoing changes, as discussed earlier in this document, the DEA is additionally proposing to amend its regulations regarding expiration dates associated with imports and exports of controlled substances. The DEA proposes to change the current expiration period of import and export permits found in §§ 1312.16 and 1312.25 from not more than six months to not more than 180 calendar days after the date of issuance. This change will standardize expiration procedures as not all months have the same number of days. The DEA also proposes to amend §§ 1312.18 and 1312.27 to specify an expiration date for import and export declarations for controlled substances. Such declarations do not currently have an expiration date assigned to them; however, permits to import and export controlled substances expire not more than six months after approved under the current regulation. 21 CFR 1312.16 and 1312.25. Similar to permits, at times declarations filed with the DEA are never actually utilized. The DEA is concerned that absence of an expiration date for these declarations may lead to incomplete or inaccurate records in the ITDS. Therefore, the DEA is proposing that declarations expire 180 calendar days after the date the declaration is deemed filed with the Administration.

The DEA proposes to modify the condition currently found in § 1312.22(a) that requires an application

<sup>12</sup> See definition of “drop shipment,” *e.g.*, <http://www.businessdictionary.com> (accessed 05.24.2015).

for a permit to export controlled substances to contain an affidavit that the packages of controlled substances for export are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols “in effect on May 1, 1971.” The regulation will be amended to instead require that such affidavit state that packages of controlled substances for export are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols which are in effect at the time of export or reexport. The DEA does not believe that this change will have any current effect on the regulated community because it is not a new requirement. However, the DEA is taking this opportunity in revising its other import and export regulations to propose this change to account for any changes in international treaties, conventions, or protocols which might be made in the future.

As discussed above, this proposal includes changes to harmonize, to the extent possible, return information requirements for import and export regulations throughout parts 1310, 1312, and 1313 for tableting and encapsulating machines, controlled substances, and listed chemicals. Although these provisions are similarly structured, the actual content of the return information varies across the regulations to account for international reporting requirements for machines, controlled substances, and listed chemicals. Variations in return reporting requirements also vary among controlled substances, listed chemicals, and tableting and encapsulating machines to maximize the detection, investigation, and prevention of diversion. The DEA has reviewed the return information currently collected for imported and exported controlled substances and is proposing changes.

The DEA is proposing amendments to §§ 1312.12, 1312.18, 1312.22, and 1312.27 to require registrants and those exempt from registration to report return information to the Administration following imports and exports of controlled substances authorized by permits and conducted pursuant to filed declarations. The DEA is proposing to require this information to be submitted within 30 calendar days, or within 10 calendar days after a request from the Administration, whichever is sooner. This regulatory text change is consistent with existing business practice, as importers and exporters generally submit such information to the DEA at the conclusion of transactions. The submission of such reports will allow

the United States to meet its obligations under article 19 (*Estimates of drug requirements*) and article 20 (*Statistical returns to be furnished to the Board*) of the Single Convention on Narcotic Drugs, 1961, and article 16 (*Reports to be furnished by the Parties*) of the Convention on Psychotropic Substances, 1971. The DEA will continue to independently collect such return information outside of the single window as the ITDS does not capture all elements of the return information that the DEA needs to submit under those treaty obligations and otherwise adequately monitor the closed system of distribution of imports and exports to detect and prevent diversion. 21 U.S.C. 871(b). Additionally, the timing and frequency of required return information reporting is outside the scope of the single window. Requirements for return information to be submitted to the DEA are already specifically included in § 1312.22(d)(6) for reexported controlled substances pursuant to 21 U.S.C. 953(f)(6).

For imported and exported controlled substances there are four principal pieces of information that the DEA is proposing importers and exporters supply to the DEA in the returns: The date on which the controlled substances arrived/departed the registered location, the date on which a customs officer released the shipment, the actual quantity of controlled substances that arrived/left the registered location, and the actual quantity of controlled substances that a customs officer actually released. The current text in 21 CFR 1312.22 relating to controlled substances exported for subsequent reexportation requires the reporting of the “date shipped.” This requirement has been interpreted differently, sometimes as the date it left the facility and sometimes as the date the import/export transaction occurred. Both dates are needed to adequately monitor the closed system of distribution for import and export transactions. For example, an analysis of the amount of time it takes a shipment to complete an import or export transaction could be compared with the rate of theft and loss and could potentially lead to corresponding changes to DEA security regulations being proposed. Likewise both the actual amount of controlled substances that customs released and the actual amount of controlled substances that arrived or left the registered facility are needed to adequately monitor the closed system of distribution and allow precise accountability of all substances within a registrant’s inventory. These figures allow a base level against which to

cross-check reports for in-transit losses for imported and exported controlled substances.

The DEA proposes to revise §§ 1312.12, 1312.18, 1312.22, and 1312.27 to prohibit the importation/exportation of any shipment of controlled substances denied release by customs at the port of entry or port of export for any reason without resubmission of the permit application or declaration and issuance of a new permit or transaction identification number by the DEA. For example, if a customs officer denied release of controlled substances at the port of entry because of a violation of another agency’s regulation (*e.g.*, U.S. Food and Drug Administration), customs officials would not allow entry until after the reason for denial was adequately addressed and the DEA has issued a new permit or transaction identification number. This change is needed to strengthen the DEA’s ability to monitor and detect practices that may render an importer’s or exporter’s registration inconsistent with the public safety, especially in relation to the DEA’s statutory obligation to take into consideration an applicant’s compliance with applicable State and local laws and other relevant factors. 21 U.S.C. 823(a), 958(a).

The DEA proposes to amend § 1312.22 to reflect that the Administration has discretion whether to issue a permit for reexport pursuant to 21 U.S.C. 953(f). The proposed revision to § 1312.22(g)(8), like the current regulation, specifies that the exporter must provide “a brief summary of the facts that warrant the return” of an export that has been refused or is otherwise unacceptable or undeliverable. The DEA Office of Diversion Control secure network application contains a field appropriate for this information within the DEA Form 357. Likewise, the “written request for reexport” of a controlled substance subject to declaration requirements, currently required in § 1312.27(b)(5)(iv), can be submitted in a field of the DEA Form 236 in the DEA Office of Diversion Control secure network application. As in the current regulations, a refused or otherwise unacceptable or undeliverable controlled substance subject to the declaration requirements could be imported only after the DEA issues “affirmative authorization in writing.” A transaction identification number does not serve as such “affirmative authorization in writing.”

The DEA proposes to amend §§ 1312.22, 1312.31, and 1312.32 to require a certified translation of

authorizations issued by foreign competent national authorities that are not issued either entirely in English or bilingual with English. If the foreign authorization, or the certified copy of such, is not written in English or bilingual with another language and English, the registrant must submit with their application or notice a certified translation of the permit or license. The DEA proposes that for purposes of this requirement, certified translation will mean that the translator has signed the translation legally attesting to the accuracy of the translation and the attestation has been notarized. This change is meant to ensure that these foreign authorizations are complete and accurate, and that the information that they contain are accurately understood and applied to DEA import/export policies and procedures.

#### 8. Reexportation of Controlled Substances—Including Implementation of Section 4 of the Improving Regulatory Transparency for New Medical Therapies Act

This proposal contains amendments that would implement section 4, Re-exportation Among Members of the European Economic Area, of the Improving Regulatory Transparency for New Medical Therapies Act, Public Law 114–89 (hereinafter “the 2015 Act”), which was signed into law on November 25, 2015. Section 4 of the 2015 Act amended section 1003 of the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 953) by making changes to paragraph (f) and adding paragraph (g), changes that allow for expanded reexportation of certain controlled substances among members of the European Economic Area (EEA). Prior to passage of the 2015 Act, the CSIEA (21 U.S.C. 953(f)) provided, with respect to controlled substances in schedule I or II and narcotic drugs in schedule III or IV, that such substances could be exported from the United States for subsequent reexport from the recipient country (the “first country”) to another country (the “second country”)—but *with no further reexports from the second country*. The 2015 Act removed this latter limitation provided that every country involved is an EEA country. As a result, unlimited further reexports may now occur among EEA countries, provided the conditions specified in the 2015 Act are met.

Beyond the new allowance for unlimited reexports among EEA countries, most of the statutory requirements that applied to all reexports prior to the 2015 Act remain in effect under the 2015 Act with respect to reexports among EEA

countries. For example, it remains a requirement that first, second, and subsequent countries within the EEA must be parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971. 21 U.S.C. 953(f)(1). Also consistent with pre-enactment statutory requirements, each such EEA country must have instituted and maintain, in conformity with such Conventions, a system of controls of imports which the Attorney General deems adequate, the importer and exporter must be properly permitted or licensed, and the controlled substance must be applied exclusively to medical, scientific, or other legitimate uses. 21 U.S.C. 953(f)(2).

However, in contrast to the reexport requirements that apply where the reexport involves any non-EEA countries, the 2015 Act provides that reexportation from the first EEA country to a second EEA country may not be constrained to any specific time period. 21 U.S.C. 953(g)(1). This notice proposes revisions to DEA regulations to incorporate this and other changes mandated by the 2015 Act.

In drafting the proposed regulatory changes to implement the statutory changes made by the 2015 Act, the DEA carefully took into consideration the new subsection, 21 U.S.C. 953(g)(2), which prohibits the Attorney General from promulgating or enforcing any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation of any controlled substance among European Economic Area countries, including by promulgating or enforcing any requirement that information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States or prior to each re-exportation among members of the European Economic Area.

In interpreting the foregoing provision of the 2015 Act, given that the term “impedes” is somewhat vague, the DEA took the following factors into account. First, the CSIEA itself continues to impose various requirements that some might characterize as “impeding” reexports among EEA countries. Specifically, as described above, the 2015 Act retained, with respect to such reexports, most of the preexisting requirements in 21 U.S.C. 953(f). Second, for the United States to continue to meet its reporting and other obligations under the Single Convention and Psychotropic Convention, the DEA must continue to obtain certain information from persons involved in reexport transactions. For these reasons,

the DEA does not interpret the term “impedes” in the 2015 Act to prohibit the DEA from imposing any requirement that goes beyond the explicit requirements of 21 U.S.C. 953(f) and (g). Rather, the DEA interprets the “impedes” clause as follows: (i) The DEA may not promulgate or enforce any regulation of the specific nature described in paragraphs (1) and (2) of 21 U.S.C. 953(g) and (ii) beyond the type of restrictions referred to in paragraphs (1) and (2), the DEA must avoid promulgating or enforcing any unduly burdensome regulations on such reexports.

Consistent with the foregoing interpretation of the 2015 Act, in the proposed revised regulations, the DEA would no longer require bulk substances to undergo further manufacturing process within the first EEA country if the substance is to be reexported within the EEA. Also consistent with this interpretation of the 2015 Act, the DEA proposes to remove the requirement that the exporter must provide product and consignee information beyond the first country in advance of (prior to) export from the United States. Exporters who submit an application for reexport among members of the EEA will continue to be required to supply information of the consignee in the first country, including the consignee’s contact information and business—but (as mandated by the 2015 Act) information concerning the second or subsequent consignee, country, and product will not be required to be provided *prior to* exportation of the controlled substance from the United States or prior to each reexportation among members of the EEA. The DEA’s continued collection of this information will help ensure that the DEA has sufficient information to uphold U.S. treaty obligations.

Also consistent with the retained requirements of 21 U.S.C. 953(f), DEA registered exporters seeking to export controlled substances to the EEA for such reexport will continue to be required to submit an affidavit that the consignee in the second country and any country of subsequent reexport within the EEA is authorized under the laws and regulations of the recipient country to receive the controlled substances, that the packages are labeled in conformance with U.S. treaty obligations that the controlled substances are to be applied exclusively for medical or scientific uses, that the controlled substances will not be reexported outside of the EEA, and that there is an actual need for the controlled substances for medical or scientific uses within the recipient country. Consistent

with past practice, this affidavit will constitute “substantial evidence” for purposes of 21 U.S.C. 953(f)(4) for reexports of controlled substances among members of the European Economic Area. *See* 71 FR 61436, 61438, Oct. 18, 2006.

Presently, under the current § 1312.22(d)(7), the DEA requires that controlled substances must be reexported from the first country to the second country, or countries, within 180 days after the controlled substances have been exported from the United States. As discussed in the notice of proposed rulemaking for *Reexportation of Controlled Substances*, for which the associated final rule added this provision to § 1312.22, the justification behind this requirement is to minimize the likelihood of uncertainties regarding the status of reexport shipments and thereby minimize the likelihood of diversion. 71 FR 61436, 61437, Oct. 18, 2006. However, as previously stated above, the 2015 Act specifically provides that reexportation among members of the EEA may not be constrained to any specific time period. 21 U.S.C. 953(g)(1). Therefore, the DEA proposes to eliminate application of this provision to reexports of controlled substances among members of the EEA.

While, as just discussed, the DEA is proposing to eliminate certain requirements for EEA reexports in order to bring DEA regulations into accordance with the 2015 Act, the DEA continues to believe that those requirements serve an important purpose in safeguarding against international diversion and promoting compliance with international treaty obligations. Therefore, the DEA is not proposing to change or exclude those requirements as they apply outside of the EEA reexport context, as Congress did not require the DEA to do so.

Persons who export controlled substances for reexport among members of the EEA are required by the law to provide return information to the Attorney General within 30 days after each re-exportation, including certification that the reexportation has occurred and “information concerning the consignee, country, and product.” 21 U.S.C. 953(f)(6)(B). This return information is in addition to the return information that the exporter must provide related to the export of the controlled substance from the United States to the first country. Because of the constraints imposed by the statutory language in the 2015 Act, the DEA is proposing a straightforward 30-calendar-day reporting limit for reexports of controlled substances without the caveat that the

Administration may request such information sooner, as is generally contained in this proposal for other return information. Although the DEA is without authority to require such information to be submitted in advance of the 30-day statutory deadline, the DEA continues to encourage return information on reexports to be submitted as soon as possible so as to allow the DEA to meet its treaty reporting deadlines.<sup>13</sup>

To effectuate and efficiently implement the different reexport requirements between those controlled substances intended for reexport outside the EEA and those intended for reexport within the EEA, the DEA is proposing to restructure § 1312.22. The DEA proposes to restructure § 1312.22 to generally align with the three types of exports covered by the regulation—export not for reexport, export for reexport outside of the EEA, and export for reexport within the EEA. The requirements for export/reexport and return information would be addressed separately under the corresponding header for each type of transaction. Of particular note, this reorganization would allow readers to easily understand the return reporting information for each type of transaction: Return on an export from the United States (not for reexport); for reexports outside the EEA—the return on the initial export from the United States to the first country and a return on the export from the first country to the second country; and for reexports among members of the EEA—the return on the initial export from the United States to the first country and return on the export from the first country to the second country/subsequent export(s) to other EEA member countries.

The DEA is proposing to establish a new Form 161R–EEA for the reporting of reexports among members of the EEA. The DEA Form 161R–EEA would be

<sup>13</sup> “Under the Single Convention, each country that is a party to the treaty is required to furnish the International Narcotics Control Board (INCB) with annual estimates of, among other things, the quantities of narcotic drugs on hand, the anticipated amounts that will be consumed by the party for legitimate purposes, and the anticipated production quantities. The Single Convention also requires parties to furnish the INCB with statistical returns for the prior year, indicating the amounts of drugs produced, utilized, consumed, imported, exported, seized, disposed of, and in stock. The Psychotropic Convention requires the parties to provide the INCB with statistical reports and assessments containing similar information with respect to psychotropic substances. Through the collection of this information, the INCB provides exporting countries with information on the legitimate requirements of the importing countries and can take steps to reduce the likelihood of international diversion.” 71 FR 61436, 61438, Oct. 18, 2006.

accessed, completed, and submitted through the DEA Office of Diversion Control secure network application. The DEA considered, but ultimately did not choose to propose, that such applications would be made electronically on the DEA Form 161R based on the fact that there are different application requirements for the two types of transactions required by the CSA. Most important of these distinctions for tracking purposes are that reexports among members of the European Economic Area do not have a time period for which such transactions will “close” (*i.e.*, all return information submitted). While under current § 1312.22(d)(7) (proposed § 1312.22(h)(6)), other reexports must be completed no later than 180 days after initial export from the United States, the 2015 Act specifies that controlled substances may continue to be reexported within the European Economic Area indefinitely, so long as the statutory conditions are met. Use of a new form should not impose a burden on registrants, however. Because the system is electronic the experience for the registrant will be the same regardless of whether they are entering the required application information on a new electronic form or being redirected to a different portion of the electronic DEA Form 161R.

While the new law did not have a direct impact on reexports for nonnarcotic controlled substances in schedules III and IV or controlled substances in schedule V, the DEA is proposing to make corresponding changes to its reexport of controlled substances under declaration procedures found in § 1312.27. If such conforming amendments were not made, there would be stricter requirements for controlled substances exported for reexport within the European Economic Area under declaration procedures than under permit procedures. *See also* DEA final rule, *Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances; Registration of Importers and Exporters of Controlled Substances; Importation and Exportation of Controlled Substances; updating Requirements*, 52 FR 17286, 17287, May 7, 1987 (“One of the stated purposes for the Diversion Control Amendments is to decrease the disparity of control between narcotic and non-narcotic controlled substances.”).



### 9. Part 1313: Importation and Exportation of List I and List II Chemicals

The DEA proposes to add a new § 1313.03 that would consolidate the DEA Form information applicable to part 1313 in a corresponding change to that proposed for the new § 1312.03. The new § 1313.03 would consist of a table referencing the DEA Form number, form name, information about where the form may be accessed, and where the completed form should be submitted.

The DEA proposes to amend § 1313.12(b) to require that all declarations (DEA Form 486/486A) must be complete and accurate when submitted. Under § 1304.21, registrants must maintain complete and accurate records for controlled substances. That requirement applies to import and export declarations for controlled substances. This proposed revision would impose the same requirement for import/export declarations as for listed chemicals.

Declarations (DEA Forms 486/486A) would not be deemed filed until the transaction identification number has been issued by the DEA. Upon receipt and review, the DEA would assign each declaration a transaction identification number (a unique identifier). Once the declaration has been accepted and assigned a transaction identification number, registrants would be able to use the assigned transaction identification number to access the official record of the declaration. While current DEA regulations do not require confirmation of receipt from the DEA prior to importation or exportation pursuant to a declaration, the proposed change is consistent with current practices. Currently, the DEA assigns a Web Tracking Number to each declaration when it is submitted and accepted. The proposed regulatory codification of the issuance of a transaction identification number is designed to ensure that electronically submitted declarations are indeed received by the DEA, are completed, and can be appropriately tracked and monitored; to streamline the declaration filing process; and to eliminate duplicate filings. The fact that the DEA issues a transaction identification number after reviewing the filing does not waive the Administration's right to suspend a shipment under § 1313.41.

The DEA is proposing to make changes in the regulatory text to reflect that 21 U.S.C. 830 has been changed to require official records of import declarations involving listed chemicals to be retained for two years.

As discussed above, return information requirements have been harmonized across parts 1310, 1312, and 1313, to the extent possible. The DEA is proposing that return information must be reported within 30 calendar days after release by a customs officer at the port of entry or export, or reexport. All return information for applications or other initial filings that are required to be made electronically through the DEA Office of Diversion Control secure network application would likewise be required to be filed electronically through the same system. As with controlled substance return information, the DEA is proposing to require listed chemical importers and exporters to include both the date a customs officer releases an imported item or releases an item for export and the date that the shipment arrived at the location of the importer or exporter, the actual quantities of product both when released by a customs officer and at the time of shipment from the exporter's location or arrival at the importer's location, and the actual port of entry or export. These revised reporting requirements will better allow the DEA to track the flow of listed chemicals, and detect and prevent diversion. For example, by tracking and comparing diversion of listed chemicals against the actual port of entry or exit, the DEA will be better able to detect potential weak spots in the import/export system and direct more resources to that region. The DEA also is proposing to revise the regulatory text to clarify that the references to "chemical" and "container" apply to the reporting of subsequent transfers.

The final destination for an import of a list I chemical must be the registered location of the registered importer. The import must be received at the registered address of the importer before being moved to another location of the importer or delivered to a customer. The receipt of imported goods is a principal activity of registered list I chemical importers. Pursuant to 21 U.S.C. 958(h), a separate registration is required at each principal place of business where applicants import or export list I chemicals. Accordingly, the final destination of a shipment of an imported list I chemical is the registered location of the registrant. Drop shipments, *i.e.*, deliveries made by an importer directly to a customer without passing through the registered location of the importer,<sup>14</sup> are explicitly prohibited under the proposed revisions to § 1313.14. Similarly, consistent with

<sup>14</sup> See definition of "drop shipment", *e.g.*, <http://www.businessdictionary.com> (accessed 05.24.2015).

current requirements, deliveries may not be made directly to a warehouse exempted from registration pursuant to § 1309.23(b)(1); they must arrive first at the registered location.

The DEA is proposing to amend § 1313.22(a) to add a cross-reference to § 1310.04(g) relating to listed chemicals that may be exported. This change would harmonize § 1313.22(a) with § 1313.21(a).

### 10. Part 1316: Administrative Functions, Practices, and Procedures

The DEA proposes to amend § 1316.47(a) to align with the DEA's current practice referenced in all recent **Federal Register** publications that requests for a hearing are to be sent directly to the Hearing Clerk. Specifically, this amendment would remove "Attention: DEA Federal Register Representative" from the template letter. Since the paragraph before the template letter states that persons requesting a hearing should refer to § 1321.01 for current mailing addresses, the DEA is not adding an "Attention" field in the template letter.

The DEA is proposing to amend § 1316.48 so that the filing of notices of appearance corresponds with the DEA's practice that requests for hearing shall be sent to the Hearing Clerk. Specifically, the DEA would remove "Attention: Federal Register Representative" from the template letter. Since the paragraph before the template letter states that persons requesting a hearing should see § 1321.01 for current mailing addresses, the DEA is not adding an "Attention" field in the template letter.

#### C. DEA Mailing Addresses

The DEA proposes to amend the Table of DEA Mailing Addresses found in § 1321.01 to account for changes proposed in this rule as part of the implementation of ITDS. The DEA is also taking this opportunity to propose various technical amendments to the Table of DEA Mailing Addresses.

Pursuant to this proposed action all import and export applications and filings would be submitted through the DEA Office of Diversion Control secure network application. The DEA proposes to amend the Table of DEA Mailing Addresses to retain a reference to the notifications that, prior to this rule, could be made by mail, but note with an asterisk that those filings must now be made electronically. The CFR sections listed under the DEA Import/Export Unit would be merged with those under the DEA Regulatory Section and placed under the header of "DEA Regulatory Section."



The mailing addresses for §§ 1308.21(a), 1308.23(b), 1308.25(a), 1308.31(a), 1308.33(b), and 1310.13(b) will be transferred from the DEA Office of Diversion Control to the DEA Drug & Chemical Evaluation Section (ODE), the subject matter experts on excluded and exempted products. This change will allow these matters to be processed in a more efficient manner. The reference to § 1307.22, “Disposal of Controlled substances by the Administration delivery application,” will be revised to “Delivery of surrendered and forfeited controlled substances” in conformity with the final rule, *Disposal of Controlled Substances*, 79 FR 53520, Sept. 9, 2014. Corresponding to recent internal DEA reorganization, the mailing addresses for §§ 1303.12(b), 1303.12(d), 1303.22, 1304.31(a), 1304.32(a), 1315.22, 1315.32(e) and (g), 1315.34(d), and 1315.36(b), regarding quota applications and reporting, will be moved from the DEA Drug & Chemical Evaluation Section to the UN Reporting & Quota Section under a new corresponding header.

The DEA proposes to amend § 1316.48 to provide that notices of appearance should be sent to the DEA Hearing Clerk instead of the DEA Administrator so that notices of appearance will be filed in a more efficient manner. The DEA also proposes to amend § 1316.47 to provide that requests for hearing should be sent to the DEA Hearing Clerk instead of the DEA Federal Register Representative so that such requests will be filed in a more efficient manner. In the Table of DEA Mailing Addresses in § 1321.01, DEA proposes to make the corresponding change, and to add §§ 1301.43, 1303.34, 1308.44, and 1316.47(a), regarding requests for hearing or appearance and/or waivers, under the DEA Hearing Clerk heading. These items are being directed to the DEA Hearing Clerk to expedite the hearing process and will lead to fewer delays. The DEA is additionally revising this portion of the table to correct the attention line of the mailing address for the DEA Hearing Clerk. The address will be changed from “Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, VA 22152” to “Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, VA 22152.”

The DEA is adding the following citations to be directed to the DEA Federal Register Representative: § 1301.34(a)—Filing of written comments regarding application for importation of Schedule I and II substances; § 1303.11(c)—Filing of

written comments regarding notice of an aggregate production quota; and § 1303.13(c)—Filing of written comments regarding adjustments of aggregate production quotas. These topics have been added so that comments corresponding to **Federal Register** publications can be sent directly to the Federal Register Representative whose responsibility it is to review comments and make them publicly available, as appropriate. The DEA is additionally amending this portion of the table to revise the attention line of the mailing address for the DEA Federal Register Representative. The address will be changed from “Drug Enforcement Administration, Attn: Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152” to “Drug Enforcement Administration, Attn: Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, VA 22152.” Additionally, this rule adds the Web address for the Federal eRulemaking Portal, <http://www.regulations.gov>, under the heading “DEA Federal Register Representative.” This Web address provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. This change conforms to the DEA’s current practice, referenced in the DEA’s recent **Federal Register** publications, which requires that comments either be submitted through <http://www.regulations.gov> or be directed to the DEA Federal Register Representative.

### III. Regulatory Analyses

#### *Executive Orders 12866 and 13563*

This proposed rule was developed in accordance with the principles of Executive Orders 12866 and 13563. The DEA has determined that this proposed rule is a significant regulatory action, and accordingly this rule has been submitted to the Office of Management and Budget for review.

By business activity, the DEA estimates this rule will result in a combined annual savings of \$424,640 for controlled substances importers, exporters, researchers, and analytical labs; a combined annual cost of \$5,011 for listed chemical importers and exporters and tableting and encapsulating machine importers and exporters; and no economic impact for brokers, domestic transactions in tableting and encapsulating machines, and mail order transactions of ephedrine (EPH), pseudoephedrine (PSE), phenylpropanolamine (PPA), or gamma-hydroxybutyric acid (GHB).

Therefore, the estimated net annual impact of this rule is a cost savings of \$419,629 and the estimated combined annual economic effect is \$429,650. The DEA does not anticipate that this rulemaking will have an annual effect on the economy of \$100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. An economic analysis of the proposed rule can be found in the rulemaking docket at <http://www.regulations.gov>.

#### *Executive Order 12988*

The proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

#### *Executive Order 13132*

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

#### *Executive Order 13175*

This proposed rule is in accordance with the February 19, 2014, Executive Order 13659, “Streamlining the Export/Import Process for America’s Businesses,” 79 FR 10657, Feb. 25, 2014. It does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### *Regulatory Flexibility Act*

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

Below is a summary of the threshold analyses conducted by the DEA to support the certification statement above. The complete threshold analysis is available at <http://www.regulations.gov> for easy reference. The DEA specifically solicits written comments regarding the DEA’s economic threshold analysis of the impact of these proposed changes. The

DEA requests that commenters provide detailed descriptions in their comment of any expected economic impacts, especially to small entities. Commenters should provide empirical data to illustrate the nature and scope of such impact.

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. This proposed rule affects all entities who import or export, or seek to import or export, controlled substances, listed chemicals, tableting and encapsulating machines, or who broker international transactions (from foreign country to another foreign country while in the United States). Additionally, this proposed rule affects all persons who would be required to report unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person in accordance with proposed revised § 1310.05(b)(1), all persons who are required to report domestic regulated transactions in tableting or encapsulating machines in accordance with proposed revised 21 CFR 1310.05(b)(2), and all persons who are required to report mail order transactions of ephedrine (EPH), pseudoephedrine (PSE), phenylpropanolamine (PPA), or gamma-hydroxybutyric acid (GHB) in accordance with 21 CFR 1310.03(c). The affected entities include DEA registrants and non-registrants. A DEA registration is required to import or export any controlled substance and most list I chemicals. A DEA registration is not required to import or export some list I chemicals or any list II chemical, to import or export tableting and encapsulating machines, or to broker international transactions. Also, a DEA registration is not required to conduct domestic transactions in tableting and encapsulating machines or mail order transactions of EPH, PSE, or PPA. (Registration is required for mail order transactions of GHB as GHB is a schedule I controlled substance.) The affected entities (DEA registrants and non-registrants) are grouped into "business activities," based on types of activities performed by the entities. The business activities described in this analysis that are required to have DEA registrations are importers/exporters, researchers, analytical labs, and chemical importers/exporters that deal in the list I chemicals requiring registration (referred to as "DEA-registered listed chemical importers/exporters"). The business activities described in this analysis that are not required to have DEA registrations are chemical importers/exporters that deal

in list I chemicals not requiring registration and list II chemicals (referred to as "non-registered listed chemical importers/exporters"), tableting/encapsulating machine importers/exporters, brokers of international transactions, tableting/encapsulating machine domestic suppliers, and entities selling EPH, PSE, and/or PPA by mail order.

The DEA estimates that 7,840 entities are affected by this rule, which consist of 331 controlled substances importers/exporters; 5,884 researchers; 1,200 analytical labs; 231 DEA-registered listed chemical importers/exporters; 76 non-registered listed chemical importers/exporter; 56 tableting/encapsulating machine importers/exporters; 12 brokers of international transactions; 46 tableting/encapsulating machine domestic suppliers; and 4 entities selling EPH, PSE, PPA, and/or GHB by mail order. Regulated persons potentially reporting unusual or excessive loss or disappearance of a listed chemical would be included in one of the business activities above.

The DEA estimates 7,321 (93.4%) of total 7,840 affected entities are small entities. Specifically, the DEA examined the impact of the proposed changes regarding (1) mandatory electronic permit applications and filings, and (2) 180-calendar-day expiration for all declarations for the 7,321 small entities affected by the proposed rule, which consist of 310 controlled substances importers/exporters; 5,474 researchers; 1,134 analytical labs; 218 DEA-registered listed chemical importers/exporters; 72 non-registered listed chemical importers/exporters; 54 tableting/encapsulating machine importers/exporters; 11 brokers of international transactions; 44 tableting/encapsulating machine domestic suppliers; and 4 entities selling EPH, PSE, PPA, and/or GHB by mail order.

The DEA is proposing to mandate the electronic submission of all permit applications and other required filings and reports associated with the importation or exportation of tableting and encapsulating machines, controlled substances, and listed chemicals. Additionally, the DEA is proposing to mandate the electronic submission of all reports associated with the unusual or excessive loss or disappearance of a listed chemical, domestic regulated transactions in tableting or encapsulating machines, and mail order transactions of EPH, PSE, PPA, and GHB. The DEA would cease to accept paper filing of controlled substances import/export permit applications (other than transshipments), controlled substances import/export declarations,

listed chemicals import/export declarations, and certain filings and reports specified as discussed previously in this document. Currently, some electronic forms associated with these activities are available online and in use. Usage rates vary for each form and also vary by business activities. However, as virtually all paper submissions of permit applications and declarations are currently delivered via express common carrier with pre-paid return envelope or account information, savings are anticipated because of this change.

The DEA estimates that each conversion to electronic filing from paper controlled substances import/export permit application and controlled substances import/export declaration will result in an estimated cost savings of \$58.75 and \$9.75, respectively. Based on DEA's registration data, the DEA assumes all affected entities have information systems capable of completing and submitting online forms and downloading, printing, and transmitting electronic documents at nominal additional cost. Among the affected establishments that hold DEA registrations, 92% of previous applications for registration or renewal of registration were made online. Furthermore, even though the email address is an optional data field, 99% of the registrations have an email address on record. Based on these facts and the high rate of internet penetration in the general U.S. population,<sup>15</sup> it is reasonable to assume virtually all regulated establishments, registrants and non-registrants, have information systems capable of completing and submitting online forms and downloading, printing, and transmitting electronic documents at minimal additional cost. No special software or equipment will be needed to access the DEA Office of Diversion Control secure network application.

There are no anticipated cost savings for the conversion to electronic filing from paper for the listed chemicals import/export declarations and tableting and encapsulating machine import/export notifications since virtually all are currently submitted via online, facsimile, or email, without the use of a common carrier. However, the DEA anticipates an additional cost associated

<sup>15</sup> See note 15 of the accompanying Economic Impact Analysis ("An estimated 78.1 percent of people in U.S. households had a high-speed Internet connection in 2013. "Computer and Internet Use in the United States: 2013," U.S. Census Bureau, <http://www.census.gov/content/dam/Census/library/publications/2014/acs/acs-28.pdf>.").

with the new requirement for tableting/encapsulating machine importers/exporters to submit return information within 30 calendar days after the release by a customs officer has taken place or within 10 calendar days after receipt of a written request by the Administration to the exporter/importer, whichever is sooner.

The DEA estimates there will be no economic impact associated with the electronic submission of all reports associated with the unusual or excessive loss or disappearance of a listed chemical, domestic regulated transactions in tableting or encapsulating machines, and mail order transactions of EPH, PSE, PPA, and GHB. While the written reports would be required to be made online, the labor cost of making the report is expected to be the same, whether on paper or online.

Based on the varying number of annual occurrences estimated for each of the business activities, the DEA estimates importers/exporters as a group would save \$383,857, researchers as a group would save \$4,316, and analytical labs as a group would save \$37,567. The DEA estimates tableting/encapsulating machine importers/exporters as a group would have an additional cost of \$3,978, for a total net savings of \$421,761 for the electronic submissions requirement. (Figures are rounded.) Based on the number of affected entities and the cost savings to the business activities as a group, the DEA estimated the average annual cost savings for each affected entity. The DEA estimates importers/exporters, researchers, and analytical labs will save on average \$1,160, \$1, and \$31 per year, respectively, and tableting/encapsulating machine importers/exporters would have a cost of \$71 per year.

In addition, the DEA is proposing to specify that all controlled substance and listed chemical declarations expire in 180 calendar days, consistent with the controlled substance import/export permits. If release by a customs officer will occur more than 180 calendar days after the declaration is deemed filed, the declarant must submit a new declaration for the transaction. The 180-calendar-day expiration provision for all controlled substance and listed chemical declarations is estimated to cause a small increase in the number of re-submissions of the declarations. The DEA estimates approximately 1% of all declarations would require re-submissions to replace the expiring declaration, requiring a total of an additional 85 controlled substance declarations and 132 listed chemical declarations per year. The estimated

cost of each re-submission of controlled substance declarations and listed chemical declarations, based on estimated labor rates and time to complete the forms, is \$13.02 and \$7.81, respectively. There is no cost to tableting/encapsulating machine importers/exporters and brokers of international transactions, as this provision does not apply to these business activities. Based on the varying number of annual re-submissions estimated for each of the business activities, the DEA estimates this provision, if promulgated, would cost importers/exporters as a group \$1,023, researchers as a group \$24, analytical labs as a group \$54, chemical importers/exporters as a group \$689, and non-registered chemical importers/exporters as a group \$344, for a total of \$2,132. Based on the number of affected entities and the cost to the business activities as a group, the DEA estimated the average annual cost for each affected entity. The DEA estimates importers/exporters, researchers, analytical labs, chemical importers/exporters, and non-registered chemical importers/exporters will have an average cost impact of \$3; \$0; \$0; \$3; and \$5 per year, respectively. (Figures are rounded.)

In summary, the DEA combined the impact of the two provisions to estimate the net impact to the affected small entities. The DEA estimates an average annual net savings of \$1,157 for the 310 controlled substance importers/exporters, an average annual net savings of \$1 for the 5,474 researchers, an average annual net savings of \$31 for the 1,134 analytical labs, an average annual net cost of \$3 for the 218 DEA-registered listed chemical importers/exporters, an average annual net cost of \$5 for the 72 non-registered listed chemicals importers/exporters, an annual net cost of \$71 for the 54 tableting/encapsulating machine importers/exporters, no economic impact for the 11 brokers of international transactions, no economic impact for the 44 tableting/encapsulating machine domestic suppliers, and no economic impact for 4 entities selling EPH, PSE, PPA, and GHB by mail order.

The DEA evaluated the net economic impact by size category for each of the business activities. The DEA estimates that the average annual cost savings of \$1,157 for controlled substance importers/exporters is economically significant, cost savings greater than 1% of annual revenue, for 32 of 310 small importer/exporter entities. None of the remaining 7,011 small entities of the remaining business activities are estimated to be significantly impacted by this proposed rule. If the proposed

rule were finalized, it would have a significant economic impact, in form of cost savings, on 32 (0.4%) of the 7,321 affected small entities. It is the DEA's assessment that 0.4% of small entities does not constitute a substantial number. The DEA's evaluation of economic impact by size category indicates that the proposed rule will not have a significant effect on a substantial number of these small entities.

#### *Unfunded Mandates Reform Act of 1995*

The estimated annual impact of this rule is \$429,650; thus, the DEA has determined in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

#### *Paperwork Reduction Act of 1995*

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), the DEA has identified the following collections of information related to this proposed rule and has submitted this collection request to the Office of Management and Budget (OMB) for review and approval. This proposed rule updates the DEA regulations for import and export of controlled substances, listed chemicals, and tableting and encapsulating machines. The proposal also clarifies certain policies and reflects current procedures and technological advancements. It allows for the implementation of the President's Executive Order on streamlining the export/import process, requiring the government-wide utilization of the International Trade Data System (ITDS). The DEA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if one is required. Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

#### *A. Collections of Information Associated With the Proposed Rule*

The DEA is proposing to revise existing information collections 1117-0004, 1117-0009 and 1117-0013 by establishing mandatory filing of return information for imports and exports of controlled substances.

Additionally, the DEA is also proposing to revise existing information collection 1117-0024 by establishing two new forms for the reporting of transactions with listed chemicals, tableting machines, and encapsulating machines. Specifically, the DEA is creating new DEA Form 452, "Reports for Regulated Machines." The DEA Form 452 will be used by regulated persons to report both domestic regulated transactions as well as import and export regulated transactions of tableting and encapsulating machines. The DEA is also establishing mandatory filing of return information for the importing and exporting of tableting and encapsulating machines that would be incorporated into the DEA Form 452. Additionally, the DEA is proposing to revise existing information collection 1117-0024 by establishing a new form for the reporting of unusual or excessive loss or disappearance of a listed chemical. Regulated persons would report this information on new DEA Form 107, "Reports of Loss or Disappearance of Listed Chemicals."

The DEA is proposing to revise existing information collection 1117-0033 by establishing a new form for reporting mail-order transactions involving specified listed chemicals. Specifically, the DEA is creating new DEA Form 453, "Report of Mail Order Transactions." The DEA Form 453 will be used by regulated persons required to file monthly reports of transactions with nonregulated persons with ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid (including drug products containing these chemicals or controlled substance) and use or attempt to use the U.S. Postal Service or any private or commercial carrier as well as regulated persons required to file monthly reports of export transactions with ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid (including drug products containing these chemicals or controlled substance) and use or attempt to use the U.S. Postal Service or any private or commercial carrier.

1. Title: Application for Permit to Export Controlled Substances—DEA Form 161/Application for Permit to Export Controlled Substances for Subsequent Reexport—DEA Form 161R/Application for Permit to Export Controlled Substances for Subsequent Reexport Among Members of the European Economic Area—DEA Form 161R-EEA

*OMB Control Number:* 1117-0004.

*Form Number:* DEA Form 161, 161R, 161R-EEA.

As part of the implementation of the ITDS, the DEA is proposing mandatory electronic filing of return information for any person who desires to export or reexport controlled substances listed in schedule I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule II which the Administrator has specifically designated by regulation in § 1312.30, or any non-narcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, 1971.

The DEA is proposing amendments to § 1312.22 in the ITDS proposed rule to provide clear instructions on the process of return information for controlled substances subject to export permit requirements, which will be submitted electronically as part of the DEA Form 161. Specifically, the DEA is proposing to require in § 1312.22 that within 30 calendar days after a controlled substance is released by a customs officer at the port of export from the United States in accordance with the permitting process, or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application (available on the DEA Office of Diversion Control Web site) that such export has occurred and the specifics of the transaction.

As part of the implementation of ITDS, the DEA is proposing to establish a new DEA Form 161R-EEA, discussed in greater detail below, to be used by registrants who export controlled substances for reexport among members of the European Economic Area. The existing DEA Form 161R would remain in use for exports of controlled substances that will be reexported to countries that are not members of the European Economic Area. The DEA is proposing amendments to § 1312.22 in the ITDS proposed rule to provide clear instructions on the process of return information for controlled substances subject to reexport permit requirements that will be reexported outside of the European Economic Area, which will be submitted electronically as part of the DEA Form 161R. Consistent with current requirements, the amended § 1312.22 would require that within 30 calendar days after a controlled substance is released by a customs officer at the port of export the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application (available on the DEA Office of Diversion Control Web site) that such

export has occurred and the specifics of the transaction. Also consistent with current requirements, the amended text would require that the exporter must additionally electronically file a similar report of return information within 30 calendar days of the controlled substances being exported from the first country to the second country. As noted, the DEA Form 161R, and associated return information, would be required to be accessed, completed, and submitted to the DEA through the DEA Office of Diversion Control secure network application.

This proposal contains amendments that would implement section 4, Re-exportation Among Members of the European Economic Area, of the Improving Regulatory Transparency for New Medical Therapies Act, Public Law 114-89, which was signed into law on November 25, 2015. Section 4 amended section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) by making changes to paragraph (f) and adding paragraph (g) that allows for reexportation of controlled substances among members of the European Economic Area. While other reexports must be completed no later than 180 days after initial export from the United States, controlled substances may continue to be reexported among members of the European Economic Area indefinitely, so long as the statutory conditions are met. As part of the implementation, the DEA is proposing to establish a new DEA Form 161R-EEA, "Application for Permit to Export Controlled Substances for Subsequent Reexport Among Members of the European Economic Area," to be used by registrants who export controlled substances for reexport among members of the European Economic Area. Specifically, the DEA is proposing to require in § 1312.22 that within 30 calendar days after the controlled substance is released by a customs officer at the port of export the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application of the particulars of the transaction. The exporter must additionally file similar return information within 30 days of the controlled substances being exported from the first country to the second country and for each subsequent reexport among members of the European Economic Area. The DEA considered but ultimately did not choose to propose that such applications would be made electronically on the DEA Form 161R based on the fact that there are different

application requirements for the two types of transactions required by the CSA. Most important of these distinctions for tracking purposes are that reexports among members of the European Economic Area do not have a time period for which such transactions will “close” (*i.e.*, all return information submitted). While under current § 1312.22(d)(7) (proposed § 1312.22(h)(6)), other reexports must be completed no later than 180 days after release by a customs officer at the port of export from the United States, the 2015 Act specifies that controlled substances may continue to be reexported among members of the European Economic Area indefinitely, so long as the statutory conditions are met. As noted, the DEA Form 161R–EEA, and associated return information, would be required to be accessed, completed, and submitted to the DEA through the DEA Office of Diversion Control secure network application.

The DEA estimates that there will be 125 respondents to this information collection. The DEA estimates that the frequency of response will vary as DEA Form 161 is required to be completed by each respondent per each occurrence. The DEA estimates there will be a total of 5,386 responses. The DEA estimates, based on data from an already approved collection containing return information, that it will take 5 minutes (online) to provide return information electronically and that the total annual burden will be 449 hours. The DEA estimates that the frequency of response will vary as DEA Form 161R and DEA Form 161R–EEA are required to be completed by each respondent per each occurrence. The DEA estimates there will be a combined total of 789 responses for DEA Form 161R and DEA Form 161R–EEA. Since the distinction between DEA Form 161R and DEA Form 161R–EEA does not currently exist, the DEA does not have an estimated number of responses for the two forms separately. Actual responses will be used for future information collection requests. Since return information is currently required for reexports, the proposed rule does not create a new information collection burden for reexports.

2. Title: Controlled Substances Import/Export Declaration—DEA Form 236

*OMB Control Number:* 1117–0009.

*Form Number:* DEA Form 236.

As part of the implementation of the ITDS, the DEA is proposing mandatory electronic filing of return information for any person who desires to import non-narcotic substances in schedules III, IV, and V or to export non-narcotic

substances in schedules III and IV and any other substance in schedule V.

The DEA is proposing amendments to § 1312.18(e) in the proposed rule to provide clear instructions on the process of return information for controlled substances imported under declaration procedures, which will be submitted electronically as part of the DEA Form 236 (Import declaration). The amended regulation would state that within 30 calendar days after actual receipt of a controlled substance at the importer’s registered location, or within 10 calendar days after the receipt of a written request by the Administration to the importer, whichever is sooner, the importer must report to the Administration utilizing the secure network application available on the DEA Office of Diversion Control Web site certifying that such import occurred and the details of the transaction.

The DEA is proposing to amend § 1312.27(d) in the proposed rule to provide clear instructions on the process of return information for controlled substances exported and reexported under declaration procedures, which will be submitted electronically as part of the DEA Form 236 (Export declaration). The amended regulation would state that within 30 calendar days after the controlled substance is released by a customs officer at the port of export or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must report to the Administration through the DEA Office of Diversion Control secure network application (available on the DEA Office of Diversion Control Web site) certifying that such export has occurred and the details of the transaction. For reexports under declaration procedures, the amended regulation states that within 30 calendar days after the controlled substance is exported from the first country to the second country, or within 10 calendar days after the receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must report to the Administration through the DEA Office of Diversion Control secure network application (available on the DEA Office of Diversion Control Web site) certifying that such export from the first country has occurred and the details of the transaction.

The DEA estimates that there will be 341 respondents to this information collection. The DEA estimates that the frequency of response will vary as DEA Form 236 is required to be completed by each respondent per each occurrence. The DEA estimates there will be a total

of 6,026 responses. The DEA estimates, based on data from an already approved collection containing return information, that it will take 5 minutes (online) to provide return information electronically and that the total annual burden will be 502 hours.

3. Title: Application for Permit To Import Controlled Substances for Domestic and/or Scientific Purposes Pursuant to 21 U.S.C. 952

*OMB Control Number:* 1117–0013.

*Form Number:* DEA Form 357.

As part of the implementation of the ITDS, the DEA is proposing mandatory electronic filing of return information for any person who desires to import any controlled substance listed in schedule I or II or any narcotic controlled substance listed in schedule III, IV, or V or any non-narcotic controlled substance in schedule III which the Administrator has specifically designed by regulation in 21 CFR 1312.30 or any non-narcotic controlled substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances.

The DEA is proposing amendments to current § 1312.12(c) in the proposed rule to provide clear instructions on the process of return information for controlled substances imported under permit procedures, which will be submitted electronically as part of the DEA Form 357. Specifically, the DEA is proposing to require in proposed § 1312.12(d) that within 30 calendar days of actual receipt of a controlled substance at the importer’s registered location, or within 10 calendar days after receipt of a written request by the Administration, whichever is sooner, the importer must report to the Administration through the DEA Office of Diversion Control secure network application (available on the DEA Office of Diversion Control Web site) that such import occurred and the details of the transaction.

The DEA estimates that there will be 148 respondents to this information collection. The DEA estimates that the frequency of response will vary as DEA Form 357 is required to be completed by each respondent per each occurrence. The DEA estimates there will be a total of 1,024 responses. The DEA estimates, based on data from an already approved collection containing return information, that it will take 5 minutes (online) to provide return information electronically and that the total annual burden will be 85 hours.

4. Title: Reports of Loss or Disappearance of Listed Chemicals—DEA Form 107, and Regulated Transactions in Tableting/Encapsulating Machines—DEA Form 452

*OMB Control Number:* 1117–0024.

*Form Number:* DEA Form 107 and DEA Form 452.

As part of the implementation of the ITDS, the DEA is proposing to establish a new DEA Form 452 to be used by regulated persons involved in regulated transactions in tableting or encapsulating machines. The DEA would standardize the current report required in the current § 1310.05(a)(4) for domestic regulated transactions in a tableting or encapsulating machine as well as the report required in the current § 1310.05(c) for import and export of tableting and encapsulating machines. DEA Form 452 would be required to be accessed, completed, and submitted to the DEA through the DEA Office of Diversion Control secure network application.

Moreover, under both the current and revised regulation, each regulated person must orally report any domestic regulated transaction in a tableting machine or an encapsulating machine to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, although the DEA now proposes to clarify that the report must be made when the order is placed with the seller. The regulated person must subsequently file a written report of the domestic regulated transaction (on DEA Form 452) with the Administration through the DEA Office of Diversion Control secure network application within 15 calendar days after the order has been shipped by the seller. A report (on DEA Form 452) may contain multiple line entries for more than one transaction.

Additionally, the DEA is proposing mandatory filing of return information for the import and export of tableting and encapsulating machines which will be electronically submitted as part of the DEA Form 452. The amended regulation states that within 30 calendar days of the the shipment being released by a customs officer at the port of entry or port of export, or within 10 calendar days after the receipt of a written request by the Administration to the importer/exporter, whichever is sooner, the importer/exporter must report to the Administration through the DEA Office of Diversion Control secure network application (available on the DEA Office of Diversion Control Web site) certifying that such import/export occurred and the details of the transaction.

Previously, § 1310.05(c) instructed that regulated persons needed to provide notification of the import or export of a tableting machine or encapsulating machine on or before the date of exportation. However, the DEA has amended § 1310.05(c) in order for DEA Form 452 to be submitted to the DEA at least 15 calendar days before the date of release by a customs officer at the port of entry or port of export in order to allow time for the DEA to review the information and transmit it into the ITDS prior to the actual import or export. 21 CFR 1310.05(c).

As part of the implementation of the ITDS, the DEA is proposing to establish a new DEA Form 107 to be used by regulated persons involved in reporting unusual or excessive loss or disappearance of a listed chemical. The DEA would standardize the current report required to be filed in the current § 1310.05(a)(3). Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person will orally report to the Special Agent in Charge of the DEA Divisional Office at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. The regulated person must also file a complete and accurate DEA Form 107 with the Administration through the DEA Office of Diversion Control secure network application within 15 calendar days after becoming aware of the circumstances requiring the report. Unusual or excessive losses or disappearances must be reported whether or not the listed chemical is subsequently recovered or the responsible parties are identified and action taken against them. DEA Form 107 would be required to be accessed, completed, and submitted to the DEA through the DEA Office of Diversion Control secure network application. While the report would be electronic, the filing requirements are essentially unchanged. The DEA estimates that the reporting burden would continue to be 20 minutes for each report.

Specifically, based on publicly available information and historical data, the DEA estimates that there will be 130 respondents to this information collection, 60 for domestic transactions and 70 for imports or exports. The DEA estimates that the frequency of response will vary as DEA Form 452 is required to be completed by each respondent per each occurrence. As the DEA does not

have a strong basis to estimate the number of responses for domestic transactions, the DEA makes an initial estimate (to be refined later) of 52 responses per week for each of 60 respondents, or a total of 3,120 domestic transaction related responses. Based on historical data, the DEA estimates there will be 917 import or export related responses for a grand total of 4,037 responses for domestic transactions, imports, and exports. Because of the information required on the DEA Form 452, the DEA estimates that this form will take 20 minutes to complete, including the oral report for domestic transactions and return information for imports and exports, and that the total annual burden will be 1,346 hours.

5. Title: Report of Mail Order Transactions—DEA Form 453

*OMB Control Number:* 1117–0033.

*Form Number:* DEA Form 453.

As part of the implementation of the ITDS, the DEA is proposing to establish a new DEA Form 453, “Report of Mail Order Transactions,” to be used by regulated persons required to file monthly reports of transactions with nonregulated persons with ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid (including drug products containing these chemicals or controlled substance) and use or attempt to use the U.S. Postal Service or a private or commercial carrier as well as regulated persons required to file monthly reports of export transactions with ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid (including drug products containing these chemicals or controlled substance) and use or attempt to use the U.S. Postal Service or a private or commercial carrier. The DEA would require reports under the current §§ 1310.03(c) and 1310.06(i) to be submitted on a new DEA Form 453 which would be required to be accessed and submitted to the DEA through the DEA Office of Diversion Control secure network application.

Additionally, the form would require the following information: The mail order transaction supplier name and registration number; the purchaser’s name and address; the name and address shipped to (if different from purchaser’s name and address); the name of the chemical contained in the scheduled listed chemical product and total quantity shipped (e.g., pseudoephedrine, 3 grams); the date of shipment; the product name; the dosage form (e.g., tablet, liquid, powder); the dosage strength; the number of dosage unites; the package type; the number of

packages; and the lot number.

Previously, § 1310.05(e) instructed that regulated persons submit a written report, containing the information listed above, on or before the 15th day of each month following the month in which the distributions took place. However, the DEA proposes to amend part 1310 in order for DEA Form 453 to be submitted to the DEA electronically on or before the 15th day of each month following the month in which the distributions took place.

Specifically, based on historical data, the DEA estimates that there will be 7 respondents to this information collection. The respondents will provide 12 responses per year. The DEA estimates there will be a total of 84 responses per year. The DEA estimates that this form will take 15 minutes to complete and that the total annual burden will be 21 hours.

#### *B. Request for Comments Regarding the Proposed Information Collections*

Under the PRA, the DEA is required to provide a notice regarding the proposed collections of information in the **Federal Register** with the notice of proposed rulemaking and solicit public comment. Section 3506(c)(2)(A) and (B) of the PRA (44 U.S.C. 3506(c)(2)(A) and (B)) requires that the DEA solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the DEA.
- The accuracy of the DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Written comments and suggestions from the public and affected agencies concerning the proposed collections of information are encouraged. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB41/Docket No. DEA-403.

All comments must be submitted to OMB on or before October 17, 2016. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

#### **List of Subjects**

##### *21 CFR Part 1300*

Chemicals, Drug traffic control.

##### *21 CFR Part 1301*

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

##### *21 CFR Part 1302*

Drug traffic control, Exports, Imports, Labeling, Packaging and containers.

##### *21 CFR Part 1303*

Administrative practice and procedure, Drug traffic control.

##### *21 CFR Part 1304*

Drug traffic control, Reporting and recordkeeping requirements.

##### *21 CFR Part 1308*

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

##### *21 CFR Part 1309*

Administrative practice and procedure, Drug traffic control, Exports, Imports.

##### *21 CFR Part 1310*

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

##### *21 CFR Part 1312*

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

##### *21 CFR Part 1313*

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

##### *21 CFR Part 1314*

Drug traffic control, Reporting and recordkeeping requirements.

##### *21 CFR Part 1315*

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

##### *21 CFR Part 1316*

Administrative practice and procedure, Authority delegations (Government agencies), Drug traffic control, Research, Seizures and forfeitures.

##### *21 CFR Part 1321*

Administrative practice and procedure.

For the reasons stated in the preamble, the DEA proposes to amend 21 CFR parts 1300, 1301, 1302, 1303, 1304, 1308, 1309, 1310, 1312, 1313, 1314, 1315, 1316, and 1321 as follows:

## **PART 1300—DEFINITIONS**

- 1. The authority citation for part 1300 continues to read as follows:

**Authority:** 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

- 2. In § 1300.01(b):

- a. Add definitions for “Competent national authority” and “Customs officer” in alphabetical order;
- b. Revise the definitions of “Export” and “Import”;
- c. Remove the definition of “Jurisdiction of the United States”;
- d. Add definitions for “Port of entry”, “Port of export”, “Return information”, “Shipment”, “Split shipment”, and “United States” in alphabetical order.

The additions and revisions read as follows:

### **§ 1300.01 Definitions relating to controlled substances.**

\* \* \* \* \*

*Competent national authority*, for purposes of importation and exportation of controlled substances and listed chemicals, means an entity lawfully entitled to authorize the import and export of controlled substances, and to regulate or enforce national controls over listed chemicals, and included as such in the directory of “Competent National Authorities Under the International Drug Control Treaties” published by the United Nations Office on Drugs and Crime. For purposes of exports of narcotic drugs, the term also includes freely associated states authorized to receive such exports pursuant to 48 U.S.C. 1972.

\* \* \* \* \*

*Customs officer* means either an Officer of the Customs as defined in 19 U.S.C. 1401(h), or any individual duly authorized to accept entries of merchandise, to collect duties, and to enforce the customs laws of any commonwealth, territory, or possession of the United States.

\* \* \* \* \*

*Export* means, with respect to any article, any taking out or removal of such article from the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs laws, export control laws enforced by other agencies, or related laws of the United States).

\* \* \* \* \*

*Import* means, with respect to any article, any bringing in or introduction of such article into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof (whether or



not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

\* \* \* \* \*

Port of entry means, unless distinguished as being a foreign port of entry, any place at which a customs officer is duly authorized to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs laws of the United States (whether or not such place is a port of entry as defined in title 19 of the United States Code or its associated implementing regulations). Examples of ports of entry include, but are not limited to, places designated as ports of entry or customs stations in title 19 of the Code of Federal Regulations or by the governing customs authority of that area. When shipments are transported under U.S. Customs and Border Protection immediate transportation procedures, the port of entry shall be the port of final destination.

Port of export means, unless distinguished as being a foreign port of export, any place under the control of a customs officer where goods are loaded on an aircraft, vessel or other conveyance for export outside of the United States. For goods loaded aboard an aircraft or vessel in the United States, that stops at several ports before departing the United States, the port of export is the first port where the goods were actually loaded. For goods off-loaded from the original conveyance to another conveyance (even if the aircraft or vessel belongs to the same carrier) at any port subsequent to the port where the first on-loading occurred in the United States, the port where the goods were loaded onto the last conveyance before departing the United States is the port of export.

\* \* \* \* \*

Return information means supplemental information required to be reported to the Administration following an import or export transaction containing the particulars of the transaction and any other information as the Administration may specify.

\* \* \* \* \*

Shipment means a quantity of goods or merchandise imported or exported at one place, at one time, for delivery to one consignee, on a single conveyance, at one place, on one bill of lading, air waybill, or other commercial loading document.

Split shipment means a single import or export that is divided onto two or more conveyances.

\* \* \* \* \*

United States, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States, which, in addition to the customs territory of the United States, include but are not limited to the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

\* \* \* \* \*

- 3. In § 1300.02(b):
- a. Remove the definition of “Chemical import”;
- b. Add definitions for “Competent national authority”, “Customs officer”, “Export”, and “Import” in alphabetical order;
- c. Remove the definition of “Jurisdiction of the United States”; and
- d. Add definitions for “Port of entry”, “Port of export”, “Return information”, “Shipment”, “Split shipment”, and “United States” in alphabetical order.

The additions and revisions read as follows:

**§ 1300.02 Definitions relating to listed chemicals.**

\* \* \* \* \*

Competent national authority, for purposes of importation and exportation of controlled substances and listed chemicals, means an entity lawfully entitled to authorize the import and export of controlled substances, and to regulate or enforce national controls over listed chemicals, and included as such in the directory of “Competent National Authorities Under the International Drug Control Treaties” published by the United Nations Office on Drugs and Crime.

Customs officer means either an Officer of the Customs as defined in 19 U.S.C. 1401(h), or any individual duly authorized to accept entries of merchandise, to collect duties, and to enforce the customs laws of any commonwealth, territory, or possession of the United States.

\* \* \* \* \*

Export means, with respect to any article, any taking out or removal of such article from the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs laws, export control laws enforced by other agencies, or related laws of the United States).

\* \* \* \* \*

Import means, with respect to any article, any bringing in or introduction of such article into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof (whether or

not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

\* \* \* \* \*

Port of entry, unless distinguished as being a foreign port of entry, means any place at which a customs officer is duly authorized to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs laws of the United States (whether or not such place is a port of entry as defined in title 19 of the United States Code or its associated implementing regulations). Examples of ports of entry include, but are not limited to, places designated as ports of entry or customs stations in title 19 of the Code of Federal Regulations or by the governing customs authority of that area. When shipments are transported under U.S. Customs and Border Protection immediate transportation procedures, the port of entry shall be the port of final destination.

Port of export means, unless distinguished as being a foreign port of export, any place under the control of a customs officer where goods are loaded on an aircraft, vessel or other conveyance for export outside of the United States. For goods loaded aboard an aircraft or vessel in the United States that stops at several ports before departing the United States, the port of export is the first port where the goods were loaded. For goods off-loaded from the original conveyance to another conveyance (even if the aircraft or vessel belongs to the same carrier) at any port subsequent to the port where the first on-loading occurred in the United States, the port where the goods were loaded onto the last conveyance before departing the United States is the port of export. For reporting purposes, in the case of an otherwise lawful export occurring by mail, the port of export is the place of mailing.

\* \* \* \* \*

Return information means supplemental information required to be reported to the Administration following an import or export transaction containing the particulars of the transaction and any other information as the Administration may specify.

\* \* \* \* \*

Shipment means a quantity of goods or merchandise imported or exported at one place, at one time, for delivery to one consignee, on a single conveyance, at one place, on one bill of lading, air waybill, or other commercial loading document.



*Split shipment* means a single import or export that is divided onto two or more conveyances.

\* \* \* \* \*

*United States*, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States, which, in addition to the customs territory of the United States, include but are not limited to the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

\* \* \* \* \*

#### **PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES**

■ 4. The authority citation for part 1301 continues to read as follows:

**Authority:** 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965.

■ 5. Revise § 1301.12(b)(3) to read as follows:

##### **§ 1301.12 Separate registrations for separate locations.**

\* \* \* \* \*

(b) \* \* \*

(3) An office used by a practitioner (who is registered at another location in the same State in which he or she practices) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

\* \* \* \* \*

■ 6. Revise § 1301.24(a)(1) to read as follows:

##### **§ 1301.24 Exemption of law enforcement officials.**

(a) \* \* \*

(1) Any officer or employee of the Administration, any customs officer, any officer or employee of the U.S. Food and Drug Administration, and any other Federal or Insular officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs, or customs, and is duly authorized to possess or to import or export controlled substances in the course of his/her official duties; and

\* \* \* \* \*

■ 7. Revise § 1301.26(b) introductory text to read as follows:

##### **§ 1301.26 Exemption from import or export requirements for personal medical use.**

\* \* \* \* \*

(b) The individual makes a declaration to an appropriate customs officer stating:

\* \* \* \* \*

■ 8. Revise § 1301.34(c)(2) to read as follows:

##### **§ 1301.34 Application for importation of Schedule I and II substances.**

\* \* \* \* \*

(c) \* \* \*

(2) Employment of security procedures to guard against in-transit losses.

\* \* \* \* \*

■ 9. Revise § 1301.74(c) introductory text to read as follows:

##### **§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.**

\* \* \* \* \*

(c) The registrant must notify the Field Division Office of the Administration in his or her area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. Unless the theft or loss occurs during an import or export transaction, the supplier is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. In an import transaction, once a shipment has been released by the customs officer at the port of entry, the importer is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. In an export transaction, the exporter is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section within one business day of discovery of such theft or loss, until the shipment has been released by the customs officer at the port of export. The registrant must also complete, and submit to the Field Division Office in his or her area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

\* \* \* \* \*

#### **PART 1302—LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES**

■ 10. The authority citation for part 1302 continues to read as follows:

**Authority:** 21 U.S.C. 821, 825, 871(b), 958(e).

■ 11. Revise § 1302.07 to read as follows:

##### **§ 1302.07 Labeling and packaging requirements for imported and exported substances.**

(a) The symbol requirements of §§ 1302.03 through 1302.05 apply to every commercial container containing, and to all labeling of, controlled substances imported into the customs territory of the United States from any place outside thereof (but within the United States), or imported into the United States from any place outside thereof. These sealing and labeling requirements are in addition to any sealing requirements required under applicable customs laws.

(b) The symbol requirements of §§ 1302.03 through 1302.05 do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export.

(c) The sealing requirements of § 1302.06 apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or any narcotic controlled substance listed in schedule III or IV imported into the customs territory of the United States from any place outside thereof (but within the United States), or imported into the United States from any place outside thereof. The sealing requirements of § 1302.06 apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or any narcotic controlled substance listed in schedule III or IV, exported or intended for export from the United States.

#### **PART 1303—QUOTAS**

■ 12. The authority citation for part 1303 continues to read as follows:

**Authority:** 21 U.S.C. 821, 826, 871(b).

##### **§ 1303.12 [Amended]**

■ 13. Amend § 1303.12 as follows:

■ a. In paragraph (b) by removing “Drug and Chemical Evaluation Section, Drug Enforcement Administration” from the last sentence and adding in its place “UN Reporting and Quota Section, Office of Diversion Control”; and

■ b. In paragraph (d) by removing “Drug & Chemical Evaluation Section, Drug

Enforcement Administration” from the second sentence and adding in its place “UN Reporting and Quota Section, Office of Diversion Control”.

§ 1303.22 [Amended]

■ 14. In the introductory text to 1303.22, remove “Drug & Chemical Evaluation Section, Drug Enforcement Administration” and add in its place “UN Reporting and Quota Section, Office of Diversion Control”.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 15. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 831, 871(b), 958 (e)–(g), and 965, unless otherwise noted.

■ 16. Revise § 1304.02 to read as follows:

§ 1304.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or § 1300.01, § 1300.03, § 1300.04, or § 1300.05 of this chapter.

■ 17. Revise § 1304.21(d) to read as follows:

§ 1304.21 General requirements for continuing records.

\* \* \* \* \*

(d) In recording dates of receipt, distribution, other transfers, or destruction, the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed will be used as the date of receipt, distribution, transfer, or destruction (e.g., invoices or packing slips, or DEA Form 41). In maintaining records concerning imports and exports, the registrant must record the date on which the controlled substances are released by a customs officer at the port of entry or port of export.

\* \* \* \* \*

§ 1304.31 [Amended]

■ 18. In § 1304.31(a), remove “Drug and Chemical Evaluation Section, Drug Enforcement Administration” from the second sentence and add in its place “UN Reporting and Quota Section, Office of Diversion Control”.

§ 1304.32 [Amended]

■ 19. In § 1304.32(a), remove “Drug and Chemical Evaluation Section, Drug Enforcement Administration” from the second sentence and add in its place “UN Reporting and Quota Section, Office of Diversion Control”.

■ 20. Revise § 1304.33(a) and (f)(1) to read as follows:

§ 1304.33 Reports to Automation of Reports and Consolidated Orders System (ARCOS).

(a) Reports generally. All reports required by this section shall be filed with the Pharmaceutical Investigations Section, Office of Diversion Control, Drug Enforcement Administration on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

\* \* \* \* \*

(f) \* \* \*

(1) A registered institutional practitioner that repackages or relabels exclusively for distribution or that distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the Pharmaceutical Investigations Section, Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

\* \* \* \* \*

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 21. The authority citation for part 1308 is revised to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 22. Revise § 1308.01 to read as follows:

§ 1308.01 Scope of part 1308.

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812) and nonnarcotic substances, chemical preparations, veterinary anabolic steroid implant products, prescription products, anabolic steroid products, and cannabis plant material and products made therefrom that contain tetrahydrocannabinols excluded pursuant to section 201 of the Act (21 U.S.C. 811), as they are changed, updated, and republished from time to time, are set forth in this part.

§ 1308.21 [Amended]

■ 23. In § 1308.21(a), remove “Office of Diversion Control, Drug Enforcement Administration” and add in its place “Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration”.

§ 1308.23 [Amended]

■ 24. In § 1308.23(b), remove “Office of Diversion Control, Drug Enforcement Administration” and add in its place

“Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration”.

§ 1308.25 [Amended]

■ 25. In § 1308.25(a), remove “Office of Diversion Control, Drug Enforcement Administration” and add in its place “Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration”.

§ 1308.31 [Amended]

■ 26. In § 1308.31(a), remove “Office of Diversion Control, Drug Enforcement Administration” and add in its place “Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration”.

§ 1308.33 [Amended]

■ 27. In § 1308.33(b), remove “Office of Diversion Control, Drug Enforcement Administration” and add in its place “Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration”.

■ 28. Revise § 1308.49 to read as follows:

§ 1308.49 Temporary scheduling.

(a) Pursuant to 21 U.S.C. 811(h) and without regard to the requirements of 21 U.S.C. 811(b) relating to the scientific and medical evaluation of the Secretary of Health and Human Services, the Drug Enforcement Administration may place a substance into Schedule I on a temporary basis, if it determines that such action is necessary to avoid an imminent hazard to the public safety. An order issued under this section may not be effective before the expiration of 30 calendar days from:

(1) The date of publication by the Administration of a notice in the Federal Register of its intention to issue such order and the grounds upon which such order is to be issued, and

(2) The date the Administration has transmitted notification to the Secretary of Health and Human Services of the Administration’s intention to issue such order.

(b) An order issued under this section will be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under section 201(a) (21 U.S.C. 811(a)) with respect to such substance or at the end of two years from the effective date of the order scheduling the substance, except that during the pendency of proceedings under section 201(a) (21 U.S.C. 811(a)) with respect to the substance, the Administration may extend the temporary scheduling for up to one year.

**PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS**

■ 29. The authority citation for part 1309 continues to read as follows:

**Authority:** 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

■ 30. Revise § 1309.26(a)(1) to read as follows:

**§ 1309.26 Exemption of law enforcement officials.**

(a) \* \* \*

(1) Any officer or employee of the Administration, any customs officer, any officer or employee of the U.S. Food and Drug Administration, and any Federal or Insular officer who is lawfully engaged in the enforcement of any federal law relating to listed chemicals, controlled substances, drugs, or customs, and is duly authorized to possess and distribute List I chemicals in the course of his/her official duties; and

\* \* \* \* \*

■ 31. Revise § 1309.32(d) to read as follows:

**§ 1309.32 Application forms; contents; signature.**

\* \* \* \* \*

(d) Each application for registration must include the Administration Chemical Code Number, as set forth in § 1310.02 of this chapter, for each List I chemical to be manufactured, distributed, imported, or exported.

\* \* \* \* \*

**§ 1309.46 [Amended]**

■ 32. In § 1309.46(d), remove “§ 1309.54” and add in its place “§ 1309.53”.

**§ 1309.51 [Amended]**

■ 33. In § 1309.51(a), remove “1309.57” and add in its place “1309.55”.

■ 34. Revise § 1309.71(b)(5) and (7) to read as follows:

**§ 1309.71 General security requirements.**

\* \* \* \* \*

(b) \* \* \*

(5) The extent of unsupervised public access to the facility;

\* \* \* \* \*

(7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored; and

\* \* \* \* \*

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

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

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

■ 36. Revise the heading of part 1310 to read as set forth above.

■ 37. Amend § 1310.03 as follows:

■ a. In paragraph (b) by removing “Section 1310.05” and adding in its place “§ 1310.05”; and

■ b. Revising paragraph (c) to read as follows:

**§ 1310.03 Persons required to keep records and file reports.**

\* \* \* \* \*

(c) Each regulated person who engages in a transaction with a nonregulated person which involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma hydroxybutyric acid (including drug products containing these chemicals or controlled substance), and uses or attempts to use the U.S. Postal Service or any private or commercial carrier must, on a monthly basis, report to the Administration each such transaction conducted during the previous month as specified in §§ 1310.05(e) and 1310.06(k) on DEA Form 453 through the DEA Office of Diversion Control secure network application. Each regulated person who engages in an export transaction which involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma hydroxybutyric acid (including drug products containing these chemicals or controlled substance), and uses or attempts to use the U.S. Postal Service or any private or commercial carrier must, on a monthly basis, report each such transaction conducted during the previous month as specified in §§ 1310.05(e) and 1310.06(k) on DEA Form 453 through the DEA Office of Diversion Control secure network application.

\* \* \* \* \*

■ 38. Revise § 1310.05(a) through (e) to read as follows:

**§ 1310.05 Reports.**

(a)(1) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located 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 this part. The regulated person will orally report to the Special Agent in Charge of the DEA Divisional 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. The regulated person must file a written report of the transaction(s) with the Special Agent in Charge of the DEA Divisional Office as set forth in § 1310.06 within 15 calendar days after the regulated person becomes aware of the circumstances of the event.

(2) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person. The regulated person will orally report to the Special Agent in Charge of the DEA Divisional Office at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(b)(1) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person will orally report to the Special Agent in Charge of the DEA Divisional Office at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. Unless the loss or disappearance occurs during an import or export transaction, the supplier is responsible for reporting all in-transit losses of any listed chemical by their agent or the common or contract carrier. In an import transaction, once a shipment has been released by the customs officer at the port of entry, the importer is responsible for reporting all in-transit losses of any listed chemical by their agent or the common or contract carrier. In an export transaction, the exporter is responsible for reporting all in-transit losses of any listed chemical by their agent or the common or contract carrier until the shipment has been released by the customs officer at the port of export.

The regulated person must also file a complete and accurate DEA Form 107, in accordance with § 1310.06(d), with the Administration through the DEA Office of Diversion Control secure network application within 15 calendar days after becoming aware of the circumstances requiring the report. Unusual or excessive losses or disappearances must be reported whether or not the listed chemical is subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss or disappearance of a listed chemical was unusual or excessive, the regulated persons should consider, among others, the following factors:

- (i) The actual quantity of a listed chemical;
- (ii) The specific listed chemical involved;
- (iii) Whether the loss or disappearance of the listed chemical can be associated with access to those listed chemicals by specific individuals, or whether the loss or disappearance can be attributed to unique activities that may take place involving the listed chemical;
- (iv) A pattern of losses or disappearances over a specific time period, whether the losses or disappearances appear to be random, and the result of efforts taken to resolve the losses.
- (v) If known, the regulated person should also consider whether the specific listed chemical was a likely candidate for diversion as well as local trends and other indicators of the diversion potential of the listed chemical.

(2) Each regulated person must orally report any domestic regulated transaction in a tableting machine or an encapsulating machine to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located when the order is placed with the seller. The regulated person also must file a report of the transaction (on DEA Form 452) with the Administration through the DEA Office of Diversion Control secure network application within 15 calendar days after the order has been shipped by the seller. A report (DEA Form 452) may list more than one machine for a single transaction. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until a transaction identification number has been issued by the Administration.

(c) *Imports and exports of tableting machines and encapsulating machines.*

(1) Each regulated person who imports or exports a tableting machine, or encapsulating machine, must file a report of such importation or exportation on DEA Form 452 with the Administration through the DEA Office of Diversion Control secure network application, at least 15 calendar days before the anticipated arrival at the port of entry or port of export. In order to facilitate the importation or exportation of any tableting machine or encapsulating machine and implement the purpose of the Act, regulated persons may report to the Administration as far in advance as possible. A separate report (DEA Form 452) must be filed for each shipment, in accordance with § 1310.06(e). Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until a transaction identification number has been issued by the Administration. The importer or exporter may only proceed with the transaction once the transaction identification number has been issued. Any tableting machine 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 machine or encapsulating machine may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(2) *Denied release at the port of entry.* In the event that a shipment of tableting or encapsulating machine(s) has been denied release by a customs officer at the port of entry for any reason, the importer who attempted to import the shipment must, within 24 hours of the denial, report to the Administration that the shipment was denied, the basis for denial, and such other information as is required by § 1310.06(g). Such report must be transmitted to the Administration through the DEA Office of Diversion Control secure network application. Upon the importer's report of a denied entry, DEA will assign the report a transaction identification number and the original import notification will be void and of no effect. No shipment of tableting machines or encapsulating machines denied entry for any reason will be allowed entry without a subsequent refiling of an amended DEA Form 452 by the regulated person. In such circumstances, the regulated person may proceed with the release of the

tableting machines or encapsulating machines upon receipt of a transaction identification number for the refilled and amended DEA Form 452 without regard to the 15-day advance filing requirement in paragraph (c)(1) of this section, so long as the article is otherwise cleared for entry under U.S. customs laws.

(d) Each regulated bulk manufacturer of a listed chemical must submit manufacturing, inventory and use data on an annual basis as set forth in § 1310.06(j). This data must be submitted annually to the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, on or before the 15th day of March of the year immediately following the calendar year for which submitted. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A business entity which manufactures a listed chemical may elect to report separately by individual location or report as an aggregate amount for the entire business entity provided that they inform the DEA of which method they will use. This reporting requirement does not apply to drugs or other products that are exempted under paragraph (1)(iv) or (v) of the definition of regulated transaction in § 1300.02 of this chapter except as set forth in § 1310.06(j)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption are not required to report for that listed chemical. For purposes of these reporting requirements, internal consumption consists of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption includes (but is not limited to) quantities used for quality control testing, quantities consumed in-house, or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. If an existing standard industry report contains the information required in § 1310.06(j) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report must be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph only, the term regulated bulk manufacturer of a listed chemical means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or

relabeling of listed chemical products or the manufacture of drug dosage forms of products which contain a listed chemical.

(e) Each regulated person required to report pursuant to § 1310.03(c) must file a report containing the transaction identification number for each such transaction (if the regulated person is required to obtain a transaction identification number under part 1313 of this chapter) and information set forth in § 1310.06(k), on or before the 15th day of each month following the month in which the distributions took place.

\* \* \* \* \*  
 ■ 39. Revise § 1310.06 to read as follows:

**§ 1310.06 Content of records and reports.**

(a) Each record required by § 1310.03(a) must include the following:

(1) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.), and, if required, DEA registration number of each party to the regulated transaction.

(2) The date of the regulated transaction.

(3) The quantity, chemical name, and, if applicable, National Drug Code (NDC) number. If NDC number is not applicable, the form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine (including make, model serial number, if any, and whether the machine is manual or electric).

(4) The method of transfer (company truck, picked up by customer, etc.).

(5) The type of identification used by the purchaser and any unique number on that identification.

(b) For purposes of this section, normal business records will be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person. For prescription drug products, prescription and hospital records kept in the normal course of medical treatment will be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to dispensing to patients, and records required to be maintained pursuant to the U.S. Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, will be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to distributions.

(c)(1) Each report required by § 1310.05(a) must include the information as specified by § 1310.06(a),

the basis for making the report, and, where obtainable, the registration number of the other party, if such party is registered. A report of an uncommon method of payment or delivery submitted in accordance with § 1310.05(a)(1) must also include a reason why the method of payment or delivery was uncommon.

(2) A suggested format for the reports in § 1310.05(a)(1) is provided below:

Supplier:  
 Registration Number (if registered) \_\_\_\_\_  
 Name \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_  
 State \_\_\_\_\_  
 Zip \_\_\_\_\_  
 Contact Information: \_\_\_\_\_

Purchaser:  
 Registration Number (if registered) \_\_\_\_\_  
 Name \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_  
 State \_\_\_\_\_  
 Zip \_\_\_\_\_  
 Contact Information \_\_\_\_\_  
 Identification \_\_\_\_\_

Shipping Address (if different than purchaser Address):  
 Street \_\_\_\_\_  
 City \_\_\_\_\_  
 State \_\_\_\_\_  
 Zip \_\_\_\_\_  
 Date of Shipment \_\_\_\_\_

Description of Listed Chemical:  
 Chemical Name \_\_\_\_\_  
 Quantity \_\_\_\_\_  
 National Drug Code (NDC) Number(s), or Form(s) of Packaging \_\_\_\_\_

Other:  
 The basis (i.e., reason) for making the report: \_\_\_\_\_

Any additional pertinent information: \_\_\_\_\_

(d) Each report of an unusual or excessive loss or disappearance of a listed chemical required by § 1310.05(b)(1) (on DEA Form 107), must include the following information:

(1) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.), and, if applicable, DEA registration number of each party to the regulated transaction.

(2) The date (or estimated date) on which unusual or excessive loss or disappearance occurred, and the actual date on which the unusual or excessive loss or disappearance was discovered by the regulated person.

(3) The quantity, chemical name, and National Drug Code (NDC) number, if applicable or if not the form of packaging of the listed chemical.

(4) The type of business conducted by the regulated person, (e.g., grocery store,

pharmacy/drug store, discount department store, warehouse club or superstore, convenience store, specialty food store, gas station, mobile retail vendor, mail-order, etc.) if the regulated person is not a DEA registrant.

(e)(1) Each report of an importation of a tableting machine or an encapsulating machine required by § 1310.05(c)(1) (on DEA Form 452) must include the following information:

(i) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the import broker or forwarding agent, if any;

(ii) A description of each machine (including make, model, serial number, if any, and whether the machine is manual or electric) and the number of machines being received;

(iii) The anticipated date of arrival at the port of entry, and the anticipated port of entry; and

(iv) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignor in the foreign country of exportation.

(v) The intended medical, commercial, scientific, or other legitimate use of the machine.

(vi) Any proposed changes in identifying information of the imported machines (e.g., name, brand, serial number, if any, etc.) that will take place after importation.

(2) Each report of an exportation of a tableting machine or an encapsulating machine required by § 1310.05(c)(1) (on DEA Form 452) must include the following information:

(i) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the export broker (if applicable);

(ii) A description of each machine (including make, model, serial number, if any, and whether the machine is manual or electric) and the number of machines being received;

(iii) The anticipated date of arrival at the port of export, the foreign port and country of entry; and

(iv) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignee in the country where the shipment is destined; the name(s)/business name(s)

and address(es)/business address(es), and contact information (e.g., telephone number(s), email address(es), etc.) of the intermediate consignee(s) (if any).

(f) Each report of a domestic regulated transaction in a tableting machine or encapsulating machine required by § 1310.05(b)(2) (on DEA Form 452) must include the following information:

(1) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the purchaser;

(2) A description of each machine (including make, model, serial number, if any, and whether the machine is manual or electric) and the number of machines being received;

(3) Any changes made by the regulated person in identifying information of the machines (e.g., name, brand, serial number, etc.).

(g) Each report of a denied release by a customs officer at the port of entry of a tableting machine or an encapsulating machine required by § 1310.05(c)(2) must include the following information: The quantity of machines denied release; a concise description of the machines denied release; the date on which release was denied; the port where the denial of release was issued from; and the basis for the denial.

(h) *Return information.* (1) Within 30 calendar days after actual receipt of a tableting or encapsulating machine, or within 10 calendar days after receipt of a written request by the Administration to the importer, whichever is sooner, the importer must file a report with the Administration (on DEA Form 452) specifying the particulars of the transaction utilizing the DEA Office of Diversion Control secure network application. This report must include the following information: The date on which a customs officer at the port of entry released the machine(s); the date on which the machine(s) arrived at the final destination; the port of entry where the machine(s) were actually released by a customs officer; the actual quantity of machines released by a customs officer; the actual quantity of machines that arrived at the final destination; a description of each tableting or encapsulating machine imported (including make, model, and serial number, if any); any changes in identifying information of the imported machines (e.g., name, brand, serial number, if any, etc.) that will take place after importation; and any other information as the Administration may from time to time specify. Upon receipt

and review, the Administration will assign a transaction identification number to a completed report. The report will not be deemed filed until the Administration has issued a transaction identification number. A single return declaration may include the particulars of both the importation and distribution. For DEA reporting purposes, import responsibilities are concluded upon the receipt of the machines by the importer. Once machines are received by the importer, domestic transaction reporting requirements commence. Distributions of tableting and encapsulating machines from the importer to their customers must be reported as domestic regulated transactions in accordance with § 1310.05(b)(2).

(2) Within 30 calendar days after the tableting or encapsulating machine is released by a customs officer at the port of export, or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must file a report with the Administration (on DEA Form 452) through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: The date on which the machine(s) was(were) released by a customs officer at the port of export; the actual quantity of machines released; a description of each tableting or encapsulating machine released (including make, model, serial number, if any, and whether the machine is manual or electric); and any other information as the Administration may from time to time specify.

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

(j) Each annual report required by § 1310.05(d) must provide the following information for each listed chemical manufactured:

(1) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) and chemical registration number (if any) of the manufacturer.

(2) The aggregate quantity of each listed chemical that the company manufactured during the preceding calendar year.

(3) The year-end inventory of each listed chemical as of the close of business on the 31st day of December of each year. (For each listed chemical, if the prior period's ending inventory has not previously been reported to DEA, this report should also detail the beginning inventory for the period.) For purposes of this requirement, inventory shall reflect the quantity of listed chemicals, whether in bulk or non-exempt product form, held in storage for later distribution. Inventory does not include waste material for destruction, material stored as an in-process intermediate or other in-process material.

(4) The aggregate quantity of each listed chemical used for internal consumption during the preceding calendar year, unless the chemical is produced solely for internal consumption.

(5) The aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted from paragraph (1)(iv) or (v) of the definition of regulated transaction in § 1300.02 of this chapter during the preceding calendar year.

(6) Data shall identify the specific isomer, salt or ester when applicable but quantitative data shall be reported as anhydrous base or acid in kilogram units of measure.

(k) Each monthly report required by §§ 1310.03(c) and 1310.05(e) (on DEA Form 453) must provide the following information for each transaction:

(1) Supplier name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) and registration number.

(2) Purchaser's name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.).

(3) Name/business name, address/business address shipped to (if different from purchaser's name/address).

(4) Chemical name, National Drug Code (NDC) number, if applicable, and total amount shipped.

(5) Date of shipment.

(6) Product name (if drug product).

(7) Dosage form (if drug product) (e.g., pill, tablet, liquid).

(8) Dosage strength (if drug product) (e.g., 30mg, 60mg, per dose etc.).

(9) Number of dosage units (if drug product) (e.g., 100 doses per package).

(10) Package type (if drug product) (e.g., bottle, blister pack, etc.).

(11) Number of packages (if drug product) (e.g., 10 bottles).

(12) Lot number (if drug product).

(l) Information provided in reports required by § 1310.05(e) which is exempt from disclosure under 5 U.S.C. 552(a), by reason of 5 U.S.C. 552(b)(6), will be provided the same protections from disclosure as are provided in section 310(c) of the Act (21 U.S.C. 830(c)) for confidential business information.

**§ 1310.13 [Amended]**

■ 40. In § 1310.13(b), remove “Office of Diversion Control, Drug Enforcement Administration” and add in its place “Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration”.

**PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES**

■ 41. The authority citation for part 1312 continues to read as follows:

**Authority:** 21 U.S.C. 952, 953, 954, 957, 958.

■ 42. Add § 1312.03 to precede the undesignated center heading Importation of Controlled Substances to read as follows:

**§ 1312.03 Forms applicable to this part.**

Form	Access/ submission
DEA Form 35, Permit to Import .....	electronic.
DEA Form 36, Permit to Export .....	electronic.
DEA Form 161, Application for Permit to Export Controlled Substances .....	electronic.
DEA Form 161R, Application for Permit to Export Controlled Substances For Subsequent Reexport .....	electronic.
DEA Form 161R—EEA, Application for Permit to Export Controlled Substances for Subsequent Reexport among members of the European Economic Area.	electronic.
DEA Form 236, Controlled Substances Import/Export Declaration .....	electronic.
DEA Form 357, Application for Permit to Import Controlled Substances for Domestic And/Or Scientific Purposes .....	electronic.

■ 43. Revise § 1312.11 to read as follows:

**§ 1312.11 Requirement of authorization to import.**

(a) No person shall import, or cause to be imported, into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof, any controlled substances listed in Schedule I or II, or any narcotic controlled substance listed in Schedule III, IV, or V, or any non-narcotic controlled substance listed in Schedule III which the Administrator has specifically designated by regulation in § 1312.30 or any non-narcotic controlled substance listed in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances, 1971, unless and until such person is properly registered under the Act (or, in accordance with part 1301 of this chapter, exempt from registration) and the Administration has issued him or her a permit to do so in accordance with § 1312.13.

(b) No person shall import, or cause to be imported, into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof, any non-narcotic controlled substance listed in Schedule III, IV, or V, excluding those described in paragraph (a) of this section, unless and until such person is properly registered under the Act (or, in accordance with part 1301 of this chapter, exempt from registration) and

has filed an import declaration to do so in accordance with § 1312.18.

(c) A separate permit or declaration is required for each shipment of a controlled substance to be imported.

■ 44. Revise § 1312.12 to read as follows:

**§ 1312.12 Application for import permit; return information.**

(a) Registered importers, other registrants authorized to import as a coincident activity of their registrations, and persons who in accordance with part 1301 of this chapter are exempt from registration, seeking to import a controlled substance in schedule I or II; any narcotic drug in schedule III, IV, or V; any non-narcotic drug in schedule III that has been specifically designated by regulation in § 1312.30 of this part; or any non-narcotic substance listed in schedule IV or V that is also listed in schedule I or II of the Convention on Psychotropic Substances, 1971, must submit an application for a permit to import controlled substances on DEA Form 357. All applications and supporting materials must be submitted to the Administration through the DEA Office of Diversion Control secure network application. The application must be signed and dated by the importer and must contain the importer’s registered address to which the controlled substances will be imported.

(b) The applicant must include on the DEA Form 357 the registration number of the importer and a detailed description of each controlled substance to be imported including the drug name,

dosage form, National Drug Code (NDC) number, the Administration Controlled Substance Code Number as set forth in part 1308 of this chapter, the number and size of the packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid, base or alkaloid) given in kilograms or parts thereof. The application must also include the following:

(1) The name/business name, address/business address, contact information (e.g., telephone number(s), email address(es), etc.), and business of the consignor, if known at the time the application is submitted, but if unknown at that time, the fact should be indicated and the name and address afterwards furnished to the Administration as soon as ascertained by the importer;

(2) The foreign port and country of initial exportation (i.e., the place where the article will begin its journey of exportation to the United States);

(3) The port of entry into the United States;

(4) The latest date said shipment will leave said foreign port or country;

(5) The stock on hand of the controlled substance desired to be imported;

(6) The name of the importing carrier or vessel (if known, or if unknown it should be stated whether the shipment will be made by express, freight, or otherwise, imports of controlled substances in Schedules I or II and



narcotic drugs in Schedules III, IV, or V by mail being prohibited);

(7) The total tentative allotment to the importer of such controlled substance for the current calendar year;

(8) The total number of kilograms of said allotment for which permits have previously been issued and the total quantity of controlled substance actually imported during the current year to date.

(c) If desired, alternative foreign ports of exportation within the same country may be indicated upon the application (e.g., 1. Kolkata, 2. Mumbai). If a permit is issued pursuant to such application, it will bear the names of the two ports in the order given in the application and will authorize shipment from either port. Alternative ports in different countries will not be authorized in the same permit.

(d) *Return information.* Within 30 calendar days after actual receipt of a controlled substance at the importer's registered location, or within 10 calendar days after receipt of a written request by the Administration to the importer, whichever is sooner, the importer must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: The date the controlled substance was released by a customs officer at the port of entry); the date on which the controlled substance arrived at the registered location; the actual quantity of the controlled substance released by a customs officer at the port of entry; and the actual quantity of the controlled substance that arrived at the registered location. Upon receipt and review, the Administration will assign a transaction identification number to a completed report. The report will not be deemed filed until the Administration has issued a transaction identification number.

(e) *Denied release at the port of entry.* In the event that a shipment of controlled substances has been denied release by a customs officer at the port of entry for any reason, the importer who attempted to have the shipment released must, within 24-hours of the denial, report to the Administration that the shipment was denied and the reason for denial. Such report must be transmitted to the Administration through the DEA Office of Diversion Control secure network application. This report must include the following information: The quantity of the controlled substance denied release; the date on which release was denied; and the basis for the denied release. Upon

the importer's report of a denied release at the port of entry, the DEA will assign the report a transaction identification number and the import permit will be void and of no effect. No shipment of controlled substances denied release for any reason will be allowed to be released into the United States unless the importer submits a new DEA Form 357 and the Administration issues a new import permit.

■ 45. Revise § 1312.13(e) to read as follows:

**§ 1312.13 Issuance of import permit.**

\* \* \* \* \*

(e) If an importation is approved, the Administrator will issue an import permit bearing his or her signature or that of his or her delegate. Each permit will be assigned a unique permit number. A permit must not be altered or changed by any person after being signed. Any change or alteration upon the face of any permit after it has been signed renders it void and of no effect. Permits are not transferable. The Administrator or his/her delegate will date and certify on each permit that the importer named therein is thereby permitted as a registrant under the Act, to import, through the port of entry named, one shipment of not to exceed the specified quantity of the named controlled substances, shipment to be made before a specified date. Only one shipment may be made on a single import permit. Split shipments are prohibited. The permit must state that the Administration is satisfied that the requirement proposed to be imported is required for legitimate purposes.

\* \* \* \* \*

■ 46. Revise § 1312.14 to read as follows:

**§ 1312.14 Distribution of import permits.**

The Administration shall transmit the import permit to the competent national authority of the exporting country and shall make an official record of the import permit available to the importer through secure electronic means. The importer, or their agent, must submit an official record of the import permit and/or required data concerning the import transaction to a customs officer at the port of entry in compliance with all import control requirements of agencies with import control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. The importer must maintain an official record of the import permit (available from the DEA Office of Diversion Control secure network application after issuance) in accordance with part 1304 of this chapter as the record of authority for the

importation and shall transmit an official record of the permit to the foreign exporter. If required by the foreign competent national authority, the importer shall ensure that an official record of the import permit is provided (e.g., by transmitting an official record of the permit to the foreign exporter who shall transmit such record to the competent national authority of the exporting country). The importer must ensure that an official record of the permit accompanies the shipment of controlled substances to its final destination, the registered location of the importer (i.e., drop shipments are prohibited).

**§ 1312.15 [Amended].**

■ 47. Amend § 1312.15 as follows:

■ a. In paragraph (a), remove “the U.S. Customs Service” and add in its place “the U.S. Customs and Border Protection or customs service of an Insular Area”, and add “, in accordance with § 1312.16(a)” to the end of the first sentence; and

■ b. In paragraph (b), remove “the U.S. Customs Service” and add in its place “the U.S. Customs and Border Protection or customs service of an Insular Area”, and remove “Director of the Administration” from the last sentence and add in its place “Administrator”.

■ 48. Revise § 1312.16 to read as follows:

**§ 1312.16 Amendment, cancellation, expiration of import permit.**

(a) Importers may only request that an import permit or application for an import permit be amended in accordance with paragraphs (a)(1) through (7) of this section. Requests for an amendment must be submitted through the DEA Office of Diversion Control secure network application. Except as provided in paragraph (a)(5) of this section and § 1312.15(a), importers must submit all requests for an amendment at least one full business day in advance of the date of release by a customs officer. Importers must specifically request that an amendment be made; supplementary information submitted by an importer through the DEA Office of Diversion Control secure network application will not automatically trigger the amendment process. While the request for an amendment is being reviewed by the Administration, the original permit will be temporarily stayed and may not be used to authorize entry of a shipment of controlled substances. If the importer's request for an amendment to an issued permit is granted by the Administration, the Administration will immediately



cancel the original permit and re-issue the permit, as amended, with a revised permit number. The DEA and importer will distribute the amended permit in accordance with § 1312.14. If a request for an amendment is denied by the Administration, the temporary stay will be lifted; once lifted, the originally issued permit may immediately be used to authorize entry of a shipment in accordance with the terms of the permit, subject to the shipment being compliant with all other applicable laws.

(1) An importer may request that an import permit or application for a permit be amended to change the National Drug Control number, description of the packaging, or trade name of the product, so long as the description is for the same basic class of controlled substance as in the original permit.

(2) An importer may request that an import permit or application for a permit be amended to change the proposed port of entry, the date of release by a customs officer, or the method of transport.

(3) An importer may request that an import permit or application for a permit be amended to change the justification provided as to why an import shipment is needed to meet the legitimate scientific or medical needs of the United States.

(4) An importer may request that an import permit or application for a permit be amended to change any registrant notes.

(5) Prior to departure of the shipment from its original foreign location, an importer may request that an import permit or application for a permit be amended to increase the total base weight of a controlled substance. At the U.S. port of entry, an importer may request that an import permit be amended in accordance with § 1312.15(a). Importers are not required to amend an import permit for the sole purpose of decreasing the total base weight of a controlled substance authorized to be imported. However, the balance of any unimported authorized quantity of controlled substances on an import permit is void upon entry of a shipment on the issued permit or upon expiration of the unused permit in accordance with paragraph (b) of this section, whichever is sooner. Other than for an amendment to an import permit under § 1312.15(a), importers must submit a request for an amendment to increase the total base weight of a controlled substance at least three business days in advance of the date of release by a customs officer.

(6) An importer may request that an import permit be amended to remove a

controlled substance from the permit. However, an importer may not amend an import permit to add or replace a controlled substance/Administration controlled substance code number to the item(s) to be imported. Importers who desire to import a different controlled substance than that contained on their issued import permit or permit application must submit a request for the permit or permit application to be canceled and request a new permit in accordance with § 1312.12.

(7) An importer may not amend the importer's name (as it appears on their DEA certificate of registration) or the name of the foreign exporter as provided in the DEA Form 357. Importers who need to make any changes to any of these fields must submit a request for the permit or permit application to be canceled and request a new permit in accordance with § 1312.12.

(b) An import permit will be void and of no effect after the expiration date specified therein, and in no event will the date be more than 180 calendar days after the date the permit is issued. Amended import permits will retain the original expiration date.

(c) An import permit may be canceled after being issued, at the request of the importer submitted to the Administration through the DEA Office of Diversion Control secure network application, provided that no shipment has been made thereunder. Nothing in this part will affect the right, hereby reserved by the Administration, to cancel a permit at any time for proper cause.

■ 49. In § 1312.18:

- a. Revise the section heading;
- b. Revise paragraphs (b), (c) introductory text, and (c)(3); and
- c. Add paragraphs (e) through (h);

The revisions and additions read as follows:

**§ 1312.18 Import declaration.**

\* \* \* \* \*

(b) Any person registered or authorized to import and seeking to import any non-narcotic controlled substance listed in Schedules III, IV, or V which is not subject to the requirement of an import permit as described in paragraph (a) of this section, must file a controlled substances import declaration (DEA Form 236) with the Administration through the DEA Office of Diversion Control secure network application not later than 15 calendar days prior to the anticipated date of release by a customs officer and distribute an official record of the declaration as hereinafter directed in § 1312.19. The declaration must be signed and dated by the importer and

must specify the address of the final destination for the shipment, which must be the importer's registered location. Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The import declaration is not deemed filed, and therefore is not valid, until the Administration has issued a transaction identification number. The importer may only proceed with the import transaction once the transaction identification number has been issued.

(c) DEA Form 236 must include the following information:

\* \* \* \* \*

(3) The anticipated date of release by a customs officer at the port of entry, the foreign port and country of exportation to the United States, the port of entry, and the name, address, and registration number of the recipient in the United States; and

\* \* \* \* \*

(e) *Return information.* Within 30 calendar days after actual receipt of a controlled substance at the importer's registered location, or within 10 calendar days after receipt of a written request by the Administration to the importer, whichever is sooner, the importer must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: The date on which the controlled substance was released by a customs officer at the port of entry; the date on which the controlled substance arrived at the registered location; the actual quantity of the controlled substance released by a customs officer at the port of entry; the actual quantity of the controlled substance that arrived at the registered location; and the actual port of entry. Upon receipt and review, the Administration will assign a transaction identification number to a completed report. The report will not be deemed filed until the Administration has issued a transaction identification number.

(f) An importer may amend an import declaration in the same circumstances in which an importer may request amendment to an import permit, as set forth in § 1312.16(a)(1) through (7). Amendments to declarations must be submitted through the DEA Office of Diversion Control secure network application. Except as provided in § 1312.16(a)(5) and § 1312.15(a), importers must submit all amendments at least one full business day in advance of the date of release by a customs

officer. Importers must specifically note that an amendment is being made; supplementary information submitted by an importer through the DEA Office of Diversion Control secure network application will not automatically be considered an amendment. While the amendment is being processed by the Administration, the original declaration will be temporarily stayed and may not be used to authorize release of a shipment of controlled substances. Upon receipt and review, the Administration will assign each completed amendment a transaction identification number. The amendment will not be deemed filed until the Administration issues a transaction identification number. The DEA and importer will distribute the amended declaration in accordance with § 1312.19. A filed amendment will not change the date that the declaration becomes void and of no effect pursuant to § 1312.18(g).

(g) An import declaration may be canceled after being filed with the Administration, at the request of the importer by the importer submitting to the Administration the request through the DEA Office of Diversion Control secure network application, provided that no shipment has been made thereunder. Import declarations shall become void and of no effect 180 calendar days after the date the declaration is deemed filed with the Administration.

(h) *Denied release at the port of entry.* In the event that a shipment of controlled substances has been denied release by a customs officer at the port of entry for any reason, the importer who attempted to have the shipment released, within 24-hours of the denial, report to the Administration that the shipment was denied release and the reason for denial. Such report must be transmitted to the Administration through the DEA Office of Diversion Control secure network application. This report must include the following information: The quantity of the controlled substance denied release; the date on which release was denied; and the basis for the denied release. Upon the importer's report of a denied release, the DEA will assign the report a transaction identification number and the import declaration will become void and of no effect. No shipment of controlled substances denied release for any reason will be allowed to be released into the United States until the importer has filed a new import declaration and the Administration has issued a new transaction identification number.

■ 50. Revise § 1312.19 to read as follows:

**§ 1312.19 Distribution of import declaration.**

The importer must furnish an official record of the declaration (available through the DEA Office of Diversion Control secure network application after the Administration issues a transaction identification number) to the foreign shipper. The foreign shipper must submit an official record of the declaration to the competent national authority of the exporting country, if required as a prerequisite to export authorization. The importer, or their agent, must submit an official record of the declaration and/or required data concerning the import transaction to a customs officer at the port of entry in compliance with all import control requirements of agencies with import control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. The importer must ensure that an official record of the declaration accompanies the shipment to its final destination, which must only be the registered location of the importer (*i.e.*, drop shipments are prohibited). The importer must maintain an official record of the declaration in accordance with part 1304 of this chapter.

■ 51. Revise § 1312.21 to read as follows:

**§ 1312.21 Requirement of authorization to export.**

(a) No person shall in any manner export, or cause to be exported, from the United States any controlled substance listed in Schedule I or II, or any narcotic controlled substance listed in Schedule III or IV, or any non-narcotic controlled substance in Schedule III which the Administrator has specifically designated by regulation in § 1312.30 or any non-narcotic controlled substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances, 1971, unless and until such person is properly registered under the Act (or, in accordance with part 1301 of this chapter, exempt from registration) and the Administrator has issued him or her a permit to do so in accordance with § 1312.23.

(b) No person shall in any manner export, or cause to be exported, from the United States any non-narcotic controlled substance listed in Schedule III, IV, or V, excluding those described in paragraph (a) of this section, or any narcotic controlled substance listed in Schedule V, unless and until such person is properly registered under the

Act (or, in accordance with part 1301 of this chapter, exempt from registration) and has furnished an export declaration as provided by section 1003 of the Act (21 U.S.C. 953(e)) to the Administration in accordance with § 1312.28.

(c) A separate permit or declaration is required for each shipment of controlled substance to be exported.

■ 52. Revise § 1312.22 to read as follows:

**§ 1312.22 Application for export or reexport permit; return information.**

(a) Registered exporters, and persons who in accordance with part 1301 of this chapter are exempt from registration, seeking to export controlled substances must submit an application for a permit to export controlled substances on DEA Form 161. Registered exporters, and persons who in accordance with part 1301 of this chapter are exempt from registration, seeking to reexport controlled substances must submit an application for a permit to reexport controlled substances on DEA Form 161R or DEA Form 161R-EEA, whichever applies. All applications and supporting materials must be submitted to the Administration through the DEA Office of Diversion Control secure network application. The application must be signed and dated by the exporter and contain the exporter's registered address from which the controlled substances will be exported. Controlled substances may not be exported until a permit number has been issued.

(b) Exports of controlled substances by mail are prohibited.

(c) *Applications.* (1) Except as provided in paragraph (c)(2) of this section, each application for a permit to export or reexport must include the following information:

(i) The exporter's name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.);

(ii) The exporter's registration number, address, and contact information (*e.g.*, telephone number(s), etc.) from which the controlled substances will be exported;

(iii) A detailed description of each controlled substance to be exported including the drug name, dosage form, National Drug Code (NDC) number, Administration Controlled Substance Code Number as set forth in part 1308 of this chapter, the number and size of the packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid,

base, or alkaloid) given in kilograms or parts thereof;

(iv) The name/business name, address/business address, contact information (e.g., telephone number(s), email address(es), etc.) and business of the consignee in the first country (the country to which the controlled substance is exported from the United States), foreign port and country of entry/first country of entry, the port of export, the anticipated date of release by a customs officer at the port of export, the name of the exporting carrier or vessel (if known, or if unknown it should be stated whether the shipment will be made by express, freight, or otherwise), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued;

(v) An affidavit that the packages or containers are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols in effect at the time of the export or reexport. The affidavit shall further state that to the best of the affiant's knowledge and belief, the controlled substances therein are to be applied exclusively to medical or scientific uses within the country to which exported, will not be reexported therefrom and that there is an actual need for the controlled substance for medical or scientific uses within such country, unless the application is submitted for reexport in accordance with paragraphs (f) through (h) of this section. In the case of exportation of crude cocaine, the affidavit may state that to the best of affiant's knowledge and belief, the controlled substances will be processed within the country to which exported, either for medical or scientific use within that country or for reexportation in accordance with the laws of that country to another for medical or scientific use within that country;

(2) With respect to reexports among members of the European Economic Area in accordance with section 1003(f) of the Act (21 U.S.C. 953(f)), the requirements of paragraph (c)(1) of this section shall apply only with respect to the export from the United States to the first country and not to any subsequent export from that country to another country of the European Economic Area.

(d)(1) Except as provided in paragraph (d)(2) of this section, the applicant must also submit with the application any import license or permit or a certified copy of any such license or permit issued by the competent national authority in the country of destination,

or other documentary evidence deemed adequate by the Administration, showing: that the merchandise is consigned to an authorized permittee; that it is to be applied exclusively to medical or scientific use within the country of destination; that it will not be reexported from such country (unless the application is submitted for reexport in accordance with paragraphs (f) through (h) of this section); and that there is an actual need for the controlled substance for medical or scientific use within such country or countries. If the import license or permit, or the certified copy of such, is not written in English or bilingual with another language and English, the registrant must also submit with their application a certified translation of the permit or license. For purposes of this requirement, certified translation means that the translator has signed the translation legally attesting the accuracy of the translation and the attestation has been notarized. (In the case of exportation of bulk coca leaf alkaloid, the applicant need only include with the application the material outlined in paragraph (c) of this section.)

(2) With respect to reexports among members of the European Economic Area in accordance with section 1003(f) of the Act (21 U.S.C. 953(f)), the requirements of paragraph (d)(1) of this section shall apply only with respect to the export from the United States to the first country and not to any subsequent export from that country to another country of the European Economic Area.

(e) *Return information for exports (on a DEA Form 161)*. Within 30 calendar days after the controlled substance is released by a customs officer at the port of export, or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must report to the Administration through the DEA Office of Diversion Control secure network application the particulars of the transaction. This report must include the following information: the date on which the controlled substance left the registered location; the date on which the controlled substance was released by a customs officer at the port of export; the actual quantity of controlled substance that left the registered location; and the actual quantity of the controlled substance released by a customs officer at the port of export; the actual port of export, and any other information as the Administration may from time to time specify. Upon receipt and review, the Administration will assign a transaction identification number to a completed report. The report will not be deemed

filed until the Administration has issued a transaction identification number.

(f) *Reexports outside of the European Economic Area*. Except as provided in paragraph (g), the Administration may authorize any controlled substance listed in Schedule I or II, or any narcotic drug listed in Schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met, in accordance with section 1003(f) of the Act (21 U.S.C. 953(f)):

(1) Both the country to which the controlled substance is exported from the United States (referred to in this section as the "first country") and the country to which the controlled substance is exported from the first country (referred to in this section as the "second country") are parties to the Single Convention on Narcotic Drugs, 1954, and the Convention on Psychotropic Substances, 1971;

(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Administration deems adequate;

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country;

(4) With respect to the second country, substantial evidence is furnished to the Administration by the applicant for the export permit that—

(i) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

(ii) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country;

(5) The controlled substance will not be exported from the second country;

(6) The exporter has complied with paragraph (h) of this section and a permit to export the controlled substance from the United States has been issued by the Administration; and

(7) *Return information for reexports outside of the European Economic Area (on DEA Form 161R)*—(i) *Return information for export from the United States, for reexport*. Within 30 calendar days after the controlled substance is released by a customs officer at the port of export the exporter must file a report

with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: the date on which the controlled substance left the registered location; the date on which the controlled substance was released by a customs officer at the port of export; the actual quantity of controlled substance released by a customs officer at the port of export; and the actual port of export. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number. In determining whether the exporter has complied with the requirement to file within 30 calendar days, the report shall be deemed filed on the first date on which a complete report is filed.

(ii) *Return information for export from a first country that is or is not a member of the European Economic Area to a country outside of the European Economic Area; return information for export from a first country that is not a member of the European Economic Area to a member of the European Economic Area.* Within 30 calendar days after the controlled substance is exported from the first country to the second country the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the export from the first country. If the permit issued by the Administration authorized the reexport of a controlled substance from the first country to more than one second country, a report for each individual reexport is required. These reports must include the following information: name of second country; actual quantity of controlled substance shipped; and the date shipped from the first country, the actual port from which the controlled substances were shipped from the first country. Upon receipt and review, the Administration will assign each completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

(g) *Reexports among members of the European Economic Area (on DEA Form 161R-EEA).* The Administration may authorize any controlled substance listed in Schedule I or II, or any narcotic drug listed in Schedule III or IV, to be exported from the United States to a country of the European Economic Area for subsequent export from that country

to another country of the European Economic Area, if the following conditions and the conditions of (f)(1), (2), (3) (4), and (6) are met, in accordance with section 1003(f) of the Act (21 U.S.C. 953(f)):

(1)(i) The controlled substance will not be exported from the second country, except that the controlled substance may be exported from a second country that is a member of the European Economic Area to another country that is a member of the European Economic Area, provided that the first country is also a member of the European Economic Area; and

(ii) Subsequent to any reexportation described in paragraph (g)(1)(i) of this section, a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, if—

(A) The conditions applicable with respect to the first country under paragraphs (f)(1), (2), (3), (4), and (6) of this section and paragraph (g)(2) of this section are met with respect to each subsequent country from which the controlled substance is exported pursuant to this paragraph; and

(B) The conditions applicable with respect to the second country under paragraphs (f)(1), (2), (3), (4), and (6) of this section and paragraph (g)(2) of this section are met with respect to each subsequent country to which the controlled substance is exported pursuant to this paragraph.

(2) *Return information for reexports among members of the European Economic Area—(i) Return information for export from the United States, for reexport among members of the European Economic Area.* Exporters must comply with the return reporting requirements of paragraph (f)(7)(i) of this section.

(ii) *Reexports among members of the European Economic Area.* Within 30 calendar days after the controlled substance is exported from the first country to the second country, and within 30 calendar days of each subsequent reexport within the European Economic Area, if any, the U.S. exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the export. These reports must include the name of country to which the controlled substance was reexported, *i.e.*, another member of the European Economic Area; the actual quantity of controlled substance shipped; the date shipped from the first country, the name/business name, address/business address, contact information (*e.g.*,

telephone number(s), email address(es), etc.) and business of the consignee; and the name/business name, address/business address, contact information (*e.g.*, telephone number(s), email address(es), etc.) and business of the exporter. Upon receipt and review, the Administration will assign each completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

(h) Where a person is seeking to export a controlled substance for reexport outside of the European Economic Area in accordance with paragraph (f) of this section, the requirements of paragraphs (h)(1) through (7) of this section shall apply in addition to (and not in lieu of) the requirements of paragraphs (a) through (d) of this section. Where a person is seeking to export a controlled substance for reexport among members of the European Economic Area in accordance with paragraph (g) of this section, the requirements of paragraph (h)(4) of this section shall apply in addition to (and not in lieu of) the requirements of paragraphs (a) through (d) of this section.

(1) Bulk substances will not be reexported in the same form as exported from the United States, *i.e.*, the material must undergo further manufacturing process. This further manufactured material may only be reexported to a second country.

(2) Finished dosage units, if reexported, must be in a commercial package, properly sealed and labeled for legitimate medical use in the second country.

(3) Any proposed reexportation must be made known to the Administration at the time the initial DEA Form 161R is submitted. In addition, the following information must also be provided where indicated on the form:

(i) Whether the drug or preparation will be reexported in bulk or finished dosage units;

(ii) The product name, dosage strength, commercial package size, and quantity;

(iii) The name of consignee, complete address, and expected shipment date, as well as the name and address of the ultimate consignee in the second country.

(4) The application must contain an affidavit that the consignee in the second country, and any country of subsequent reexport within the European Economic Area, is authorized under the laws and regulations of the second and/or subsequent country to receive the controlled substances. The

affidavit must also contain the following statements, in addition to the statements required under paragraph (c) of this section:

(i) That the packages are labeled in conformance with the obligations of the United States under the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and any amendments to such treaties in effect;

(ii) That the controlled substances are to be applied exclusively to medical or scientific uses within the second country, or country of subsequent reexport within the European Economic Area;

(iii) That the controlled substances will not be further reexported from the second country except as provided by paragraph (f) of section 1003 of the Act (21 U.S.C. 953(f)); and

(iv) That there is an actual need for the controlled substances for medical or scientific uses within the second country, or country of subsequent reexport within the European Economic Area.

(5) If the applicant proposes that the shipment of controlled substances will be separated into parts after it arrives in the first country and then reexported to more than one second country, the applicant must so indicate on the DEA Form 161R and provide all the information required in this section for each second country.

(6) Except in the case of reexports among countries of the European Economic Area in accordance with section 1003(f) of the Act (21 U.S.C. 953(f)), the controlled substance will be reexported from the first country to the second country (or second countries) no later than 180 calendar days after the controlled substance was released by a customs officer from the United States.

(7) Shipments that have been exported from the United States and are refused by the consignee in either the first or second country, or subsequent member of the European Economic Area, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Administration. In these circumstances, the exporter in the United States must submit a written request for the return of the controlled substances to the United States with a brief summary of the facts that warrant the return, along with a completed DEA Form 357 through the DEA Office of Diversion Control secure network application. The Administration will evaluate the request after considering all the facts as well as the exporter's registration status with the Administration. If the exporter

provides sufficient justification, the Administration may issue an import permit for the return of these drugs, and the exporter may then obtain an export permit from the country of original importation. The substance may not be returned to the United States until after a permit has been issued by the Administration.

(i) In considering whether to grant an application for a permit under paragraphs (f) through (h) of this section, the Administration shall consider whether the applicant has previously obtained such a permit and, if so, whether the applicant complied fully with the requirements of this section with respect to that previous permit.

(j) *Denied release at the port of export.* In the event that a shipment of controlled substances has been denied release by a customs officer at the port export from the United States for any reason, the exporter who attempted to have the shipment released must, within 24-hours of the denial, report to the Administration that the shipment was denied release and the reason for denial. Such report must be transmitted to the Administration through the DEA Office of Diversion Control secure network application. This report must include the following information: The quantity of the controlled substance denied release; the date on which release was denied; the basis for the denied release, the port from which the denial was issued, and any other information as the Administration may from time to time specify. Upon the exporter's report of a denied release, DEA will assign the report a transaction identification number and the export permit will be void and of no effect. No shipment of controlled substances denied release for any reason will be allowed to be released from the United States unless the exporter submits a new DEA Form 161, 161R, or 161R-EEA, as appropriate, and the Administration issues a new export permit.

■ 53. Revise § 1312.23(e) to read as follows:

**§ 1312.23 Issuance of export permit.**

\* \* \* \* \*

(e) If an exportation is approved, the Administrator shall issue an export permit bearing his or her signature or that of his or her delegate. Each permit will be assigned a permit number that is a unique, randomly generated identifier. A permit shall not be altered or changed by any person after being signed. Any change or alteration upon the face of any permit after it has been signed renders it void and of no effect. Permits are not transferable. The

Administrator or his/her delegate shall date and certify on each permit that the exporter named therein is thereby permitted as a registrant under the Act, to export, through the port of export named, one shipment of not to exceed the specified quantity of the named controlled substances, shipment to be made before a specified date. Only one shipment may be made on a single export permit. Split shipments are prohibited. Each export permit shall be predicated upon, *inter alia*, an import certificate or other documentary evidence issued by a foreign competent national authority.

\* \* \* \* \*

■ 54. Revise § 1312.24 to read as follows:

**§ 1312.24 Distribution of export permit.**

The Administration shall transmit the export permit to the competent national authority of the importing country and shall make available to the exporter an official record of the export permit through secure electronic means. The exporter, or their agent, must submit an official record of the export permit and/or required data concerning the export transaction to a customs officer at the port of export in compliance with all export control requirements of agencies with export control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. The exporter must maintain an official record of the export permit (available from the secure network application on the DEA Office of Diversion Control Web site after the Administration issues a transaction identification number) in accordance with part 1304 of this chapter as the record of authority for the exportation and shall transmit an official record of the export permit to the foreign importer. The exporter must ensure that an official record of the permit accompanies the shipment to its final destination. No shipment of controlled substances denied release for any reason shall be allowed to be released from the United States without subsequent authorization from the Administration.

■ 55. Revise § 1312.25 to read as follows:

**§ 1312.25 Amendment, cancellation, expiration of export permit.**

(a) Exporters may only request that an export permit or application for an export permit be amended in accordance with paragraphs (a)(1) through (7) of this section. Requests for an amendment must be submitted through the DEA Office of Diversion Control secure network application. Except as provided in paragraph (a)(5)

of this section exporters must submit all requests for an amendment at least one full business day in advance of the date of release from the port of export. Exporters must specifically request that an amendment be made; supplementary information submitted by an exporter through the DEA Office of Diversion Control secure network application will not automatically trigger the amendment process. While the request for an amendment is being reviewed by the Administration, the original permit will be temporarily stayed and may not be used to authorize release of a shipment of controlled substances. If the exporter's request for an amendment to an issued permit is granted by the Administration, the Administration will immediately cancel the original permit and re-issue the permit, as amended, with a revised permit number. The DEA and exporter will distribute the amended permit in accordance with § 1312.24. If a request for an amendment is denied by the Administration, the temporary stay will be lifted; once lifted, the originally issued permit may immediately be used to authorize release of a shipment in accordance with the terms of the permit.

(1) An exporter may request that an export permit or application for a permit be amended to change the National Drug Control number, description of the packaging, or trade name of the product, so long as the description is for the same basic class of controlled substance as in the original permit.

(2) An exporter may request that an export permit or application for a permit be amended to change the proposed port of export, the anticipated date of release by a customs officer, or the method of transport.

(3) An exporter may request that an export permit or application for a permit be amended to change the justification provided as to why an export shipment is needed to meet the legitimate scientific or medical needs of the country of import.

(4) An exporter may request that an export permit or application for a permit be amended to change any registrant notes.

(5) Prior to departure of the shipment from the exporter's registered location, an exporter may request that an export permit or application for a permit be amended to increase the total base weight of a controlled substance. However, the total base weight or the strength of the product (if listed) of a controlled substance may not exceed that permitted for import as indicated on the import permit from the foreign competent national authority. Exporters are not required to amend an export

permit for the sole purpose of decreasing the total base weight of a controlled substance authorized to be exported. However, the balance of any unexported authorized quantity of controlled substances on an export permit is void upon release of a shipment on the issued permit or upon expiration of the unused permit in accordance with paragraph (b) of this section, whichever is sooner. Exporters must submit a request for an amendment to increase the total base weight of a controlled substance at least three business days in advance of the date of release from the port of export.

(6) An exporter may request that an export permit be amended to remove a controlled substance from the permit. However, an exporter may not amend an export permit to add or replace a controlled substance to the item(s) to be exported. Exporters who desire to export a different controlled substance than that contained on their issued export permit or permit application must submit a request for the permit or permit application to be canceled and request a new permit in accordance with § 1312.22.

(7) An exporter may not amend the exporter's name (as it appears on their DEA certificate of registration), the name of the foreign importer(s), or the foreign permit information as provided in the DEA Form 161, 161R, or 161R-EEA. Exporters who need to make any changes to any of these fields must submit a request for the permit or permit application to be canceled and request a new permit in accordance with § 1312.22.

(b) An export permit will be void and of no effect after the date specified therein, which date must conform to the expiration date specified in the supporting import certificate or other documentary evidence upon which the export permit is founded, but in no event will the date be more than 180 calendar days after the date the permit is issued.

(c) An export permit may be canceled after being issued, at the request of the exporter submitted to the Administration through the DEA Office of Diversion Control secure network application, provided that no shipment has been made thereunder. Nothing in this part will affect the right, hereby reserved by the Administration, to cancel an export permit at any time for proper cause.

■ 56. Revise § 1312.26 to read as follows:

**§ 1312.26 Records required of exporter.**

In addition to any other records required by this chapter, the exporter

must keep a record of any serial numbers that might appear on packages of narcotic drugs in quantities of one ounce or more in such a manner as will identify the foreign consignee, along with an official record of the export permit, in accordance with part 1304 of this chapter.

■ 57. In § 1312.27:

■ a. Revise the section heading and paragraphs (a) and (b); and

■ b. Add paragraphs (d) through (g);

The revisions and additions read as follows:

**§ 1312.27 Export/reexport declaration.**

(a) Any person registered or authorized to export and seeking to export any non-narcotic controlled substance listed in Schedule III, IV, or V, which is not subject to the requirement of an export permit pursuant to § 1312.23(b) or (c), or any person registered or authorized to export and seeking to export any controlled substance in Schedule V, must file a controlled substances export declaration (DEA Form 236) with the Administration through the DEA Office of Diversion Control secure network application not less than 15 calendar days prior to the anticipated date of release by a customs officer at the port of export, and distribute an official record of the declaration as hereinafter directed in § 1312.28. The declaration must be signed and dated by the exporter and must contain the address of the registered location from which the substances will be shipped for exportation. Upon receipt and review, the Administration will issue a completed declaration a transaction identification number. The export declaration is not deemed filed, and therefore not valid, until the Administration has issued a transaction identification number. The exporter may only proceed with the export transaction once the transaction identification number has been issued.

(b)(1) DEA Form 236 must include the following information:

(i) The name/business name, address/business address, contact information (e.g., telephone number(s), email address(es), etc.), and registration number, if any, of the exporter; and the name/business name, address/business address, contact information (e.g., telephone number(s), email address(es), etc.), and registration number of the export broker, if any;

(ii) A detailed description of each controlled substance to be exported including the drug name, dosage form, National Drug Code (NDC) number, Administration Controlled Substance Code Number as set forth in part 1308

of this chapter, the number and size of the packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof; and

(iii) The anticipated date of release by a customs officer at the port of export, the port of export, the foreign port and country of entry, the carriers and shippers involved, method of shipment, the name of the vessel if applicable, and the name, address, and registration number, if any, of any forwarding agent utilized; and

(iv) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignee in the country of destination, and any registration or license number if the consignee is required to have such numbers either by the country of destination or under United States law. In addition, documentation must be provided to show that:

(A) The consignee is authorized under the laws and regulations of the country of destination to receive the controlled substances, and that

(B) The substance is being imported for consumption within the importing country to satisfy medical, scientific or other legitimate purposes, and that

(v) The reexport of non-narcotic controlled substances in Schedules III and IV, and controlled substances in Schedule V is not permitted under the authority of 21 U.S.C. 953(e), except as provided below and in paragraph (b)(1)(vi) of this section:

(A) Bulk substances will not be reexported in the same form as exported from the United States, i.e. the material must undergo further manufacturing process. This further manufactured material may only be reexported to a country of ultimate consumption.

(B) Finished dosage units, if reexported, will be in a commercial package, properly sealed and labeled for legitimate medical use in the country of destination.

(C) Any reexportation be made known to DEA at the time the initial DEA Form 236, Controlled Substances Import/Export Declaration is completed, by checking the box marked "other" on the certification. The following information will be furnished in the remarks section:

(1) Indicate "for reexport".

(2) Indicate if reexport is bulk or finished dosage units.

(3) Indicate product name, dosage strength, commercial package size, and quantity.

(4) Indicate name of consignee, complete address, and expected shipment date, as well as, the name and address of the ultimate consignee in the country to where the substances will be reexported.

(5) A statement that the consignee in the country of ultimate destination is authorized under the laws and regulations of the country of ultimate destination to receive the controlled substances.

(D) Shipments that have been exported from the United States and are refused by the consignee in either the first or second country, or subsequent member of the European Economic Area, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Administration. In this circumstance, the exporter in the United States must file a written request for reexport, along with a completed DEA Form 236, with the Administration through the DEA Office of Diversion Control secure network application. A brief summary of the facts that warrant the return of the substance to the United States along with an authorization from the country of export must be included with the request. DEA will evaluate the request after considering all the facts as well as the exporter's registration status with DEA. The substance may be returned to the United States only after affirmative authorization is issued in writing by DEA.

(vi) The reexport of non-narcotic controlled substances in Schedules III and IV, and controlled substances in Schedule V is permitted among members of the European Economic Area only as provided below:

(A) The controlled substance will not be exported from the second country or a subsequent country, except that the controlled substance may be exported from a second country or a subsequent country that is a member of the European Economic Area to another country that is a member of the European Economic Area, provided that the first country is also a member of the European Economic Area; each country is a party to the Convention on Psychotropic Substances, 1971, as amended; and each country has instituted and maintains, in conformity with such Convention, a system of controls of imports of controlled substances which the Attorney General deems adequate.

(B) Each shipment of finished dosage units, if reexported, must be in a commercial package, properly sealed and labeled for legitimate medical use in the country of destination.

(C) Any reexportation must be made known to DEA at the time the initial DEA Form 236, Controlled Substances Import/Export Declaration is completed, by checking the box marked "other" on the certification. In addition to the requirements of paragraph (b) of this section, the following information will be furnished in the remarks section:

(1) Indicate "for reexport among members of the European Economic Area".

(2) Indicate if reexport is bulk or finished dosage units.

(3) Indicate product name, dosage strength, commercial package size, and quantity.

(4) Indicate the name/business name, address/business address, contact information (e.g., telephone number(s), email address(es) and business of the consignee in the first country.

(5) A statement that the consignee in the second country, and any subsequent consignee within the European Economic Area, is authorized under the laws and regulations of the second and/or subsequent country to receive the controlled substances.

(2) With respect to reexports among members of the European Economic Area, the requirements of paragraph (b)(1) of this section shall apply only with respect to the export from the United States to the first country and not to any subsequent export from that country to another country of the European Economic Area.

\* \* \* \* \*

(d) *Return information*—(i) *Return information for exports*. Within 30 calendar days after the controlled substance is released by a customs officer at the port of export, or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: The date on which the controlled substance left the registered location; the date on which the controlled substance was released by a customs officer; the actual quantity of the controlled substance that left the registered location; and the actual quantity of the controlled substance released by a customs officer at the port of export; the actual port of export. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.



(ii) *Return information for reexports outside of the European Economic Area*—(A) *Return information for export from the United States, for reexport.*

Within 30 calendar days after the controlled substance is released by a customs officer at the port of export the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: The date on which the controlled substance left the registered location; the date on which the controlled substance was released by a customs officer at the port of export; the actual quantity of controlled substance released by a customs officer at the port of export; and the actual port of export. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

(B) *Return information for export from a first country that is or is not a member of the European Economic Area to a country outside of the European Economic Area; return information for export from a first country that is not a member of the European Economic Area to a member of the European Economic Area.* Within 30 calendar days after the controlled substance is exported from the first country to the second country the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the export from the first country. If the permit issued by the Administration authorized the reexport of a controlled substance from the first country to more than one second country, a report for each individual reexport is required. These reports must include the following information: Name of second country; actual quantity of controlled substance shipped; the date shipped from the first country; and the actual port from which the controlled substances were shipped from the first country. Upon receipt and review, the Administration will assign each completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

(iii) *Reexports among members of the European Economic Area*—(A) *Return information for exports from the United States, for reexport among members of the European Economic Area.* Exporters must comply with the return reporting

requirements of paragraph (d)(ii)(A) of this section.

(B) *Reexports among members of the European Economic Area.* Within 30 calendar days after the controlled substance is exported from the first country to the second country, and within 30 calendar days of each subsequent reexport within the European Economic Area, if any, the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the export. These reports must include the name of country to which the controlled substance was reexported to another member of the European Economic Area; the actual quantity of controlled substance shipped; the date shipped from the first country, the name/business name, address/business address, contact information (e.g., telephone number(s), email address(es), etc.) and business of the consignee; and the name/business name, address/business address, contact information (e.g., telephone number(s), email address(es), etc.) and business of the exporter. Upon receipt and review, the Administration will assign each completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

(e) An exporter may amend an export declaration in the same circumstances in which an exporter may request amendment to an export permit, as set forth in § 1312.25(a)(1) through (7). Amendments to declarations must be submitted through the DEA Office of Diversion Control secure network application. Except as provided in § 1312.25(a)(5) exporters must submit all amendments at least one full business day in advance of the date of release by a customs officer. Exporters must specifically note that an amendment is being made; supplementary information submitted by an exporter through the DEA Office of Diversion Control secure network application will not automatically be considered an amendment. Upon receipt and review, the Administration will assign each completed amendment a transaction identification number. The amendment will not be deemed filed until the Administration issues a transaction identification number. The DEA and the exporter will distribute the amended declaration in accordance with § 1312.28. A filed amendment will not change the date that the declaration becomes void and of no effect in accordance with § 1312.27(f).

(f) An export declaration may be canceled after being filed with the Administration, at the request of the exporter, provided no shipment has been made thereunder. Export declarations shall become void and of no effect 180 calendar days after the date the declaration is deemed filed with the Administration.

(g) *Denied release at the port of export.* In the event that a shipment of controlled substances has been denied release by a customs officer at the port of export for any reason, the exporter who attempted to have the shipment released must, within 24-hours of the denial, report to the Administration that the shipment was denied release and the reason for denial. Such report must be transmitted to the Administration through the DEA Office of Diversion Control secure network application. This report must include the following information: The quantity of the controlled substance denied release; the date on which release was denied; and the basis for the denied release. Upon the exporter's report of a denied release, DEA will assign the report a transaction identification number and the export declaration will be void and of no effect. No shipment of controlled substances denied release for any reason will be allowed to be released unless the exporter files a new declaration and the Administration issues a new transaction identification number.

■ 58. Revise § 1312.28 to read as follows:

**§ 1312.28 Distribution of export declaration.**

(a) The exporter must ensure that an official record of the export declaration (available from the DEA Office of Diversion Control secure network application after the Administration issues a transaction identification number) accompanies the shipment of controlled substances to its destination.

(b) The exporter, or their agent, must submit an official record of the export declaration and/or required data concerning the export transaction to a customs officer at the port of export in compliance with all export control requirements of agencies with export control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act.

(c) The exporter must maintain an official record of the export declaration and return information (both available from the Office of Diversion Control secure network application after the Administration issues a transaction identification number) required pursuant to § 1312.27(d) as his or her

record of authority for the exportation, in accordance with part 1304 of this chapter.

■ 59. In § 1312.31, revise introductory text of paragraph (b) and add paragraph (d)(4) to read as follows:

**§ 1312.31 Schedule I: Application for prior written approval.**

\* \* \* \* \*

(b) An application for a transshipment permit must be submitted to the Regulatory Section, Office of Diversion Control, Drug Enforcement Administration, at least 30 calendar days, or in the case of an emergency as soon as is practicable, prior to the expected date of arrival at the first port in the United States. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A separate permit is required for each shipment of controlled substance to be imported, transferred, or transshipped. Each application must contain the following:

\* \* \* \* \*

(d) \* \* \*

(4) If the import license or permit, or the certified copy of such, is not written in English or bilingual with another language and English, the application must include a certified translation of the permit or license. For purposes of this requirement, certified translation means that the translator has signed the translation legally attesting the accuracy of the translation and the attestation has been notarized.

\* \* \* \* \*

■ 60. Revise § 1312.32 to read as follows:

**§ 1312.32 Schedules II, III, IV: Advance notice.**

(a) A controlled substance listed in Schedules II, III, or IV 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 Regulatory Section, Office of Diversion Control, Drug Enforcement Administration, at least 15 calendar days prior to the expected date of date of arrival at the first port in the United States. See the Table of DEA mailing Addresses in § 1321.01 of this chapter for the current mailing addresses.

(b) A separate advance notice is required for each shipment of controlled substance to be imported, transferred, or transshipped. Each advance notice must contain those items required by § 1312.31(b) and (c). If the export license, permit, or other authorization, issued by a competent national authority of the country of origin, is not

written in English or bilingual with another language and English, the notice must be accompanied by a certified translation of the export license, permit, or other authorization. For purposes of this requirement, certified translation means that the translator has signed the translation legally attesting the accuracy of the translation and the attestation has been notarized.

**PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II CHEMICALS**

■ 61. The authority citation for part 1313 continues to read as follows:

**Authority:** 21 U.S.C. 802, 830, 871(b), 971.

■ 62. Add § 1313.03 to read as follows:

**§ 1313.03 Forms applicable to this part.**

Form	Access/ submission
DEA Form 486, Import/Export Declaration for List I and List II Chemicals.	electronic.
DEA Form 486A Import Declaration for ephedrine, pseudoephedrine, and phenylpropanolamine (including drug products containing these chemicals).	electronic.

■ 63. In § 1313.12, revise the section heading, paragraphs (a), (b), (c) introductory text (d), and (e) introductory text to read as follows:

**§ 1313.12 Notification prior to import.**

(a) Each regulated person who seeks to import a listed chemical that meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, must notify the Administration of the intended import by filing an import declaration (on DEA Form 486/486A) not later than 15 calendar days before the date of release by a customs officer at the port of entry. Regulated persons who seek to import a listed chemical below the threshold quantities identified in § 1310.04(f) of this chapter are not required to file an import declaration in advance of the release by a customs officer.

(b) A complete and accurate declaration (DEA Form 486/486A) must be filed with the Administration through the DEA Office of Diversion Control secure network application not later than 15 calendar days prior to the date of release by a customs officer at the port of entry. The declaration must be signed and dated by the importer and must contain the address of the final destination for the shipment, which for

List I chemicals must be a registered location of the importer. Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The 15 calendar days shall begin on the date that the regulated person submits a completed declaration, without regard to the date that the Administration assigns a transaction identification number. Listed chemicals meeting or exceeding the threshold quantities identified in § 1310.04(f) of this chapter or for which no threshold has been established may not be imported until a transaction identification number has been issued.

(c) The 15-calendar-day advance notification requirement for listed chemical imports may be waived, in whole or in part, for the following:

\* \* \* \* \*

(d) For imports meeting the requirements of paragraph (c)(1) of this section, the declaration (DEA Form 486/486A) must be filed with the Administration through the DEA Office of Diversion Control secure network application at least three business days before the date of release by a customs officer at the port of entry. The declaration must be signed and dated by the importer and must contain the address of the final destination for the shipment, which must be a registered location of the importer (for List I chemicals). Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The importer may proceed with the import transaction only once the transaction identification number has been issued.

(e) For importations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required; however, the regulated person must submit quarterly reports to the Regulatory Section, Office of Diversion Control, Drug Enforcement Administration, not later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The report shall contain the following information regarding each individual importation:

\* \* \* \* \*

■ 64. Revise § 1313.13 to read as follows:

**§ 1313.13 Requirements of import declaration.**

(a) Any List I or List II chemical listed in § 1310.02 of this chapter may be imported if that chemical is necessary for medical, commercial, scientific, or other legitimate uses within the United

States. Chemical importations into the United States for immediate transfer/transshipment outside the United States must comply with the procedures set forth in § 1313.31 and all other applicable laws.

(b) The DEA Form 486/486A must include the following information:

(1) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical importer; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the broker or forwarding agent (if any); and

(2) The name and description of each listed chemical as it appears on the label or container, the name of each chemical as it is designated in § 1310.02 of this chapter, 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; and

(3) The date of release by a customs officer at the port of entry, the foreign port and country of export, and the port of entry; and

(4) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignor in the foreign country of exportation; and

(5) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the person or persons to whom the importer intends to transfer the listed chemical and the quantity to be transferred to each transferee.

(c) Any regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine must submit, on the import declaration (DEA Form 486A), all information known to the importer on the chain of distribution of the chemical from the manufacturer to the importer. Ephedrine, pseudoephedrine, or phenylpropanolamine include each of the salts, optical isomers, and salts of optical isomers of the chemical.

(d) Import declarations shall become void and of no effect 180 calendar days after the date the declaration is deemed filed with the Administration.

■ 65. Revise § 1313.14 to read as follows:

**§ 1313.14 Disposition of import declaration.**

The importer, or their agent, must submit an official record of the import declaration and/or required data

concerning the import transaction to a customs officer at the port of entry in compliance with all import control requirements of agencies with import control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. The final destination of the import transaction must only be the registered location of the importer (i.e., drop shipments are prohibited). A regulated person must maintain an official record of the declaration (available from the DEA Office of Diversion Control secure network application after the Administration issues a transaction identification number) in accordance with part 1310 of this chapter as the record of the import. Official records of import declarations involving listed chemicals must be retained for two years.

■ 66. In § 1313.15, revise the section heading and paragraph (b) to read as follows:

**§ 1313.15 Qualification of regular importers.**

\* \* \* \* \*

(b) Each regulated person making application under paragraph (a) of this section shall be considered a “regular importer” 30 calendar days after receipt of the application by the Administration, as indicated on the return receipt, unless the regulated person is otherwise notified in writing by the Administration.

\* \* \* \* \*

■ 67. In § 1313.16, revise the section heading and paragraph (b) to read as follows:

**§ 1313.16 Updated notice for change in circumstances.**

\* \* \* \* \*

(b) After a notice under § 1313.12(a) or (d) is submitted to the Administration, if circumstances change and the importer will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the importer must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-calendar-day period beginning on the date on which the update is filed with the Administration, or, if the import is being made by a regular importer or intended for transfer to a regular customer, 3 business days. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an

update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under § 1313.12(a) or (d). Amended declarations must be submitted to the Administration through the DEA Office of Diversion Control secure network application. The amendment must be signed and dated by the importer. Upon receipt and review, the Administration will assign each completed amendment a transaction identification number. Such shipment of listed chemicals may not be imported into the United States until the transaction identification number has been issued.

\* \* \* \* \*

■ 68. Revise § 1313.17 to read as follows:

**§ 1313.17 Return declaration for imports.**

(a) *Return information.* Within 30 calendar days after actual receipt of a listed chemical at the importer’s registered location or place of business if not required to be registered, the importer must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: The date on which the the listed chemical was released by a customs officer at the port of entry; the date on which the listed chemical arrived at the importer’s registered location or place of business; the actual quantity of the listed chemical released; the actual quantity of the listed chemical that arrived at the importer’s location; the date of any subsequent transfer; a description of the subsequent transfer, including the actual quantity transferred, chemical, container, and name of transferees; the actual port of entry; and any other information as the Administration may specify. A single report may include the particulars of both the importation and distribution. If the importer has not distributed all chemicals imported by the end of the initial 30-calendar-day period, the importer must file supplemental reports not later than 30 calendar days from the date of any further distribution, until the distribution or other disposition of all chemicals imported under the import declaration or any amendment or other update is accounted for. Upon receipt and review, the Administration will assign each completed report a transaction identification number. In determining whether the importer has complied with the requirement to file within 30 calendar days, the report shall

be deemed filed on the first date on which a complete report is filed.

(b) If an importation for which a DEA Form 486/486A has been filed fails to take place, the importer must report to the Administration that the importation did not occur through the DEA Office of Diversion Control secure network application.

(c) *Denied release at the port of entry.* In the event that a shipment of listed chemicals has been denied release by a customs officer at the port of entry for any reason, the importer who attempted to have the shipment released, within 24-hours of the denial, report to the Administration that the shipment was denied release and the reason for denial. Such report must be transmitted to the Administration through the DEA Office of Diversion Control secure network application. This report must include the following information: the quantity of the listed chemical denied release; the date on which release was denied; and the basis for the denied release. Upon the importer's report of a denied release, the DEA will assign the report a transaction identification number and the import declaration will be void and of no effect. No shipment of listed chemicals denied release for any reason will be allowed entry into the United States without a subsequent refiling of an import declaration. Following such refiling the importer may request release of the listed chemicals immediately after receipt of a transaction identification number without regard to the 15 day advance filing requirement in § 1313.12(b).

■ 69. In § 1313.21, revise the section heading, paragraphs (a), (b), (c) introductory text, (d), and (e) introductory text, and add paragraph (h) to read as follows:

**§ 1313.21 Notification prior to export.**

(a) Each regulated person who seeks to export a listed chemical that meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter, or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, must notify the Administration of the intended export by filing an export declaration (DEA Form 486) not later than 15 calendar days before the date of release by a customs officer at the port of export. Regulated persons who seek to export a listed chemical below the threshold quantities identified in § 1310.04(f) of this chapter are not required to file an export declaration in advance of the export.

(b) A complete and accurate declaration (DEA Form 486) must be filed with the Administration through

the DEA Office of Diversion Control secure network application not later than 15 calendar days prior to the date of release by a customs officer at the port of export. The declaration must be signed and dated by the exporter and must contain the address from which the listed chemicals will be shipped for exportation. Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The 15 calendar days shall begin on the date that the regulated person files a completed declaration without regard to the date that the Administration assigns a transaction identification number. Exporters may not request release of a listed chemical until a transaction identification number has been issued.

(c) The 15-calendar-day advance notification requirement for listed chemical exports may be waived, in whole or in part, for:

\* \* \* \* \*

(d) For exports meeting the requirements of paragraph (c)(1) of this section, the declaration (DEA Form 486) must be filed with the Administration through the DEA Office of Diversion Control secure network application at least three business days before the date of release by a customs officer. The declaration must be signed and dated by the exporter and must contain the address from which the listed chemicals will be shipped for exportation. Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The exporter may only proceed with the export transaction once the transaction identification number has been issued.

(e) For exportations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required; however, the regulated person must submit quarterly reports with the Regulatory Section, Office of Diversion Control, Drug Enforcement Administration, not later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Such report shall contain the following information regarding each individual exportation:

\* \* \* \* \*

(h) Export declarations shall become void and of no effect 180 calendar days after the date the declaration is deemed filed with the Administration.

■ 70. Revise § 1313.22 to read as follows:

**§ 1313.22 Export declaration.**

(a) Any List I or List II chemical listed in § 1310.02 of this chapter which meets

or exceeds the quantitative threshold criteria established in § 1310.04(f) of this chapter or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, may be exported if that chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) The export declaration (DEA Form 486) must include all the following information:

(1) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical exporter; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the export broker, if any;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The anticipated date of release by a customs officer at the port of export, the port of export, and the foreign port and country of entry; and

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

(c) Declared exports of listed chemicals which are refused, rejected, or otherwise deemed undeliverable by the foreign competent national authority may be returned to the U.S. chemical exporter of record. The regulated person must provide notification through the DEA Office of Diversion Control secure network application (this does not require a DEA Form 486) outlining the circumstances within a reasonable time following the return. Upon receipt and review, the Administration will assign the completed notice a transaction identification number. The notice will not be deemed filed until the Administration issues a transaction identification number. Listed chemicals so returned may not be reexported until the exporter has filed a new DEA Form 486 and the Administration has issued a new transaction identification

number. 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 will be regarded as imports.

■ 71. Revise § 1313.23 to read as follows:

**§ 1313.23 Disposition of export declaration.**

The exporter, or their agent, must submit an official record of the export declaration and/or required data concerning the export transaction to a customs officer at the port of export in compliance with all export control requirements of agencies with export control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. An official record of the declaration (available from the DEA Office of Diversion Control secure network application after the Administration issues a transaction identification number) must be maintained by the chemical exporter as the official record of the export in accordance with part 1310 of this chapter. Export declarations involving a listed chemical must be retained for two years.

■ 72. In § 1313.26, revise the section heading and paragraph (b) to read as follows:

**§ 1313.26 Updated notice for change in circumstances.**

\* \* \* \* \*

(b) After a notice under § 1313.21(a) is submitted to the Administration, if circumstances change and the exporter will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the exporter must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be). The exporter may not transfer the listed chemical until after the expiration of the 15-calendar-day period beginning on the date on which the update is filed with the Administration. Except, if the listed chemical is intended for transfer to a regular customer, the exporter may not transfer the listed chemical until after the expiration of three business days. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under

paragraph (a) of this section. Amended declarations must be submitted to the Administration through the DEA Office of Diversion Control secure network application. The amendment must be signed and dated by the exporter. Upon receipt and review, the Administration will assign each completed amendment a transaction identification number. The amendment will not be deemed filed until the Administration issues a transaction identification number.

\* \* \* \* \*

■ 73. Revise § 1313.27 to read as follows:

**§ 1313.27 Return declaration for exports.**

(a) *Return information.* Within 30 calendar days after a listed chemical is released by a customs officer at the port of export, the exporter must file a report with the Administration through the DEA Office of Diversion Control secure network application specifying the particulars of the transaction. This report must include the following information: the date on which the listed chemical left the registered location or place of business; the date on which the listed chemical was released by a customs officer at the port of export; the actual quantity of listed chemical that left the registered location or place of business; the actual quantity of the listed chemical released by a customs officer at the port of export; chemical; container; name of transferees; and any other information as the Administration may specify. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number. In determining whether the exporter has complied with the requirement to file within 30 calendar days, the report shall be deemed filed on the first date on which a complete report is filed.

(b) If an exportation for which a DEA Form 486 has been filed fails to take place, the exporter must report to the Administration that the exportation did not occur through the DEA Office of Diversion Control secure network application.

(c) *Denied release at the port of export.* In the event that a shipment of listed chemicals has been denied release by a customs officer at the port of export for any reason, the exporter who attempted to have the shipment released must, within 24-hours of the denial, report to the Administration that the shipment was denied release and the reason for denial. Such report must be transmitted to the Administration

through the DEA Office of Diversion Control secure network application. This report must include the following information: the quantity of the listed chemicals denied release; the date on which release was denied; and the basis for the denied release. Upon the exporter's report of a denied release, DEA will assign the report a transaction identification number and the export declaration will be void and of no effect. No shipment of listed chemicals denied release for any reason will be allowed to be released from the United States without a subsequent refiling of a complete and accurate export declaration. Following such refiling, the exporter may request the release of the listed chemicals immediately after receipt of a transaction identification number without regard to the 15 day advance filing required by paragraph § 1313.21(b).

■ 74. In § 1313.31, revise paragraph (b) introductory text and paragraphs (b)(7), (b)(8), (b)(14), and (b)(15) to read as follows:

**§ 1313.31 Advance notice of importation for transshipment or transfer.**

\* \* \* \* \*

(b) Advance notification must be provided to the Regulatory Section, Office of Diversion Control, Drug Enforcement Administration, not later than 15 calendar days prior to the proposed date the listed chemical will transship or transfer through the United States. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A separate notification is required for each shipment of listed chemicals to be transferred or transshipped. The written notification (not a DEA Form 486) must contain the following information:

\* \* \* \* \*

(7) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) and type of business of the foreign exporter;

(8) The foreign port and country of export;

\* \* \* \* \*

(14) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) and type of business of the consignee at the foreign port or country of entry;

(15) The shipping route from the U.S. port of export to the foreign port or country of entry at final destination;

\* \* \* \* \*

■ 75. Revise § 1313.32 to read as follows:

**§ 1313.32 Notification of international transactions.**

(a) A broker or trader must notify the Administration prior to an international transaction involving a listed chemical which meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, in which the broker or trader participates. Notification must be made not later than 15 calendar days before the transaction is to take place. In order to facilitate an international transaction involving listed chemicals and implement the purpose of the Act, regulated persons may wish to provide advance notification to the Administration as far in advance of the 15 calendar days as possible.

(b) A completed DEA Form 486 must be submitted to the Administration through the DEA Office of Diversion Control secure network application, not later than 15 calendar days prior to the international transaction. The DEA Form 486 must be signed and dated by the broker or trader. Upon receipt and review, the Administration will assign a transaction identification number to each completed notification. A notification is not deemed filed, and therefore is not valid, until the Administration assigns the notification a transaction identification number. An international transaction may not take place until after a transaction identification number has been assigned and the expiration of the 15-calendar-day period beginning on the date on which the broker or trader submits a complete notification to the Administration.

(c) No person shall serve as a broker or trader for an international transaction involving a listed chemical knowing or having reasonable cause to believe that the transaction is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in § 1313.25.

(d) After a notice under paragraph (a) of this section is submitted to the Administration, if circumstances change and the broker or trader will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the broker or trader must amend the notice through the DEA Office of

Diversion Control secure network application to identify the most recent prospective transferee or the most recent quantity or both (as applicable) and may not transfer the listed chemical until after the expiration of the 15-calendar-day period beginning on the date on which the update is submitted to the Administration. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an amendment to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under paragraph (a) of this section.

(e) For purposes of this section:

(1) The term transfer, with respect to a listed chemical, includes the sale of the chemical.

(2) The term transferee means a person to whom an exporter transfers a listed chemical.

■ 76. Revise § 1313.33(b) and (c) to read as follows:

**§ 1313.33 Contents of an international transaction declaration.**

\* \* \* \* \*

(b) Any broker or trader who desires to arrange an international transaction, defined in 21 U.S.C. 802(42), involving a listed chemical which meets the threshold criteria set forth in § 1310.04 of this chapter must notify the Administration through the procedures outlined in § 1313.32(b).

(c) The DEA Form 486 must include:

(1) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical exporter; the name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the chemical importer;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The anticipated date of release at the foreign port of export, the anticipated foreign port and country of export, and the foreign port and country of entry; and

(4) The name/business name, address/business address, and contact information (e.g., telephone number(s), email address(es), etc.) of the consignee in the country where the chemical

shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

■ 77. Revise § 1313.34 to read as follows:

**§ 1313.34 Disposition of the international transaction declaration.**

The broker or trader must retain an official record of the declaration (DEA Form 486) (available from the DEA Office of Diversion Control secure network application after the Administration issues a transaction identification number) as the official record of the international transaction. In accordance with part 1310 of this chapter, declarations involving listed chemicals must be retained for two years.

■ 78. Revise § 1313.35 to read as follows:

**§ 1313.35 Return declaration or amendment to Form 486 for international transactions.**

(a) Within 30 calendar days after an international transaction is completed, the broker or trader must file a report with the Administration through the DEA Office of Diversion Control secure network application about the particulars of the transaction. This report must include the following information: the date(s) on which the listed chemical was released by the foreign customs officer(s) at the port(s); the actual quantity of listed chemical that left the country of export; the actual quantity of the listed chemical released by a customs officer at the port of entry; chemical; container; name of transferees; and the transaction identification and any other information as the Administration may specify. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

(b) If an international transaction for which a DEA Form 486 has been filed fails to take place, the broker or trader must report to the Administration that the international transaction did not occur utilizing the DEA Office of Diversion Control secure network application as soon as the broker or trader becomes aware of the circumstances.

**PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS**

■ 79. The authority citation for part 1314 continues to read as follows:

**Authority:** 21 U.S.C. 802, 830, 842, 871(b), 875, 877, 886a.

**§ 1314.110 [Amended]**

■ 80. In § 1314.110, in paragraphs (a)(1) and (2), remove the phrase “Import/Export Unit,” and add in its place “Regulatory Section, Office of Diversion Control.”.

**PART 1315—IMPORTATION AND PRODUCTION QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE**

■ 81. The authority citation for part 1315 continues to read as follows:

**Authority:** 21 U.S.C. 802, 821, 826, 871(b), 952.

**§ 1315.22 [Amended]**

■ 82. In § 1315.22, remove “Drug & Chemical Evaluation Section, Drug Enforcement Administration” from the second sentence of the introductory text and add in its place “UN Reporting & Quota Section, Office of Diversion Control, Drug Enforcement Administration”.

**§ 1315.27 [Amended]**

■ 83. In § 1315.27, remove “Drug & Chemical Evaluation Section” and add in its place “UN Reporting & Quota Section, Office of Diversion Control, Drug Enforcement Administration”.

**§ 1315.32 [Amended]**

■ 84. In § 1315.32(e) and (g), remove “Drug & Chemical Evaluation Section, Drug Enforcement Administration” wherever it appears and add in its place “UN Reporting & Quota Section, Office of Diversion Control, Drug Enforcement Administration”.

**§ 1315.34 [Amended]**

■ 85. In § 1315.34(d), remove “Drug & Chemical Evaluation Section” from the second sentence and add in its place “UN Reporting & Quota Section, Office of Diversion Control, Drug Enforcement Administration”.

**§ 1315.36 [Amended]**

■ 86. In § 1315.36(b), remove “Drug & Chemical Evaluation Section, Drug

Enforcement Administration” from the second sentence and add in its place “UN Reporting & Quota Section, Office of Diversion Control, Drug Enforcement Administration”.

**PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES**

■ 87. The authority citation for part 1316, subpart D continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 875, 958(d), 965.

■ 88. Revise § 1316.47(a) to read as follows:

**§ 1316.47 Request for hearing.**

(a) Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing and/or an answer that complies with the following format (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address):

(Date) \_\_\_\_\_  
Drug Enforcement Administration, Attn: Hearing Clerk/OALJ  
(Mailing Address) \_\_\_\_\_  
Subject: Request for Hearing  
Dear Hearing Clerk:

The undersigned \_\_\_\_\_ (Name of the Person) hereby requests a hearing in the matter of: \_\_\_\_\_ (Identification of the proceeding).

(A) (State with particularity the interest of the person in the proceeding.)

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.)

(C) (State briefly the position of the person with regard to the particular objections or issues.)

All notices to be sent pursuant to the proceeding should be addressed to:

(Name) \_\_\_\_\_  
(Street Address) \_\_\_\_\_  
(City and State) \_\_\_\_\_  
Respectfully yours,  
(Signature of Person) \_\_\_\_\_

\* \* \* \* \*

■ 89. Revise § 1316.48 to read as follows:

**§ 1316.48 Notice of appearance.**

Any person entitled to a hearing and desiring to appear in any hearing, shall, if he or she has not filed a request for hearing, file within the time specified in the notice of proposed rulemaking, a written notice of appearance in the following format (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address):

(Date) \_\_\_\_\_  
Drug Enforcement Administration, Attn: Hearing Clerk/OALJ  
(Mailing Address) \_\_\_\_\_  
Subject: Notice of Appearance  
Dear Hearing Clerk:

Please take notice that \_\_\_\_\_ (Name of person) will appear in the matter of: \_\_\_\_\_ (Identification of the proceeding).

(A) (State with particularity the interest of the person in the proceeding.)

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.)

(C) (State briefly the position of the person with regard to the particular objections or issues.)

All notices to be sent pursuant to this appearance should be addressed to:

(Name) \_\_\_\_\_  
(Street Address) \_\_\_\_\_  
(City and State) \_\_\_\_\_  
Respectfully yours,  
(Signature of Person) \_\_\_\_\_

**PART 1321—DEA MAILING ADDRESSES**

■ 90. The authority citation for part 1321 continues to read:

**Authority:** 21 U.S.C. 871(b).

■ 91. Revise § 1321.01 to read as follows:

**§ 1321.01 DEA mailing addresses.**

The following table provides information regarding mailing addresses to be used when sending specified correspondence to the Drug Enforcement Administration.

TABLE OF DEA MAILING ADDRESSES

Code of Federal Regulations Section—Topic	DEA mailing address
<b>DEA Administrator</b>	
1308.43(b)—Petition to initiate proceedings for rulemaking. 1316.23(b)—Petition for grant of confidentiality for research subjects .... 1316.24(b)—Petition for exemption from prosecution for researchers. ...	Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, VA 22152.



## TABLE OF DEA MAILING ADDRESSES—Continued

Code of Federal Regulations Section—Topic	DEA mailing address
<b>DEA Office of Diversion Control</b>	
1307.03—Exception request filing. 1307.22—Delivery of surrendered and forfeited controlled substances. 1310.21(b)—Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances certification request.**	Drug Enforcement Administration, Attn: Office of Diversion Control/OD, 8701 Morrisette Drive, Springfield, VA 22152.
<b>DEA Regulatory Section</b>	
1301.71(d)—Security system compliance review for controlled substances. 1309.71(c)—Security system compliance review for List I chemicals ..... 1310.03(c)—Mail-Order reports involving transactions with nonregulated persons or exports.* 1310.05(b)(1)—Unusual or excessive loss or disappearance of listed chemicals 1310.05(b)(2)—Reports of domestic regulated transactions in a tableting machine or an encapsulating machine.* 1310.05(c)(1)—Reports of imports and exports of a tableting machine or an encapsulating machine.* 1310.05(c)(2)—Report of declared exports of machines refused, rejected, or returned. 1312.12(a)—Application for import permit (DEA Form 357).* 1312.18(b)—Import declaration (DEA Form 236) submission.* 1312.22(g)(8)—Request for return of unacceptable or undeliverable exported controlled substances.* 1312.27(a)—Controlled substances export declaration (DEA Form 236) filing.* 1312.31(b)—Controlled substances transshipment permit application. 1312.32(a)—Advanced notice of importation for transshipment or transfer of controlled substances. 1313.12(b)—Authorization to import listed chemicals (DEA Form 486/486A).* 1313.12(e)—Quarterly reports of listed chemicals importation. 1313.21(b)—Authorization to export listed chemicals (DEA Form 486).* 1313.21(e)—Quarterly reports of listed chemicals exportation. 1313.22(c)—Notice of declared exports of listed chemicals refused, rejected or undeliverable.* 1313.31(b)—Advanced notice of importation for transshipment or transfer of listed chemicals. 1313.32(b)(1)—International transaction authorization (DEA Form 486).* 1314.110(a)(1)—Reports for mail-order sales. 1314.110(a)(2)—Request to submit mail-order sales reports.	Drug Enforcement Administration, Attn: Regulatory Section/ODG, 8701 Morrisette Drive, Springfield, VA 22152.
<b>DEA Drug &amp; Chemical Evaluation Section</b>	
1308.21(a)—Exclusion of nonnarcotic substance. 1308.23(b)—Exemption for chemical preparations. 1308.24(d)—Exempt narcotic chemical preparations importer/exporter reporting. 1308.24(i)—Exempted chemical preparations listing. 1308.25(a)—Exclusion of veterinary anabolic steroid implant product application. 1308.26(a)—Excluded veterinary anabolic steroid implant products listing. 1308.31(a)—Exemption of a nonnarcotic prescription product application. 1308.32—Exempted prescription products listing. 1308.33(b)—Exemption of certain anabolic steroid products application. 1308.34—Exempted anabolic steroid products listing. 1310.13(b)—Exemption for chemical preparations. 1310.05(d)—Bulk manufacturer of listed chemicals reporting.	Drug Enforcement Administration, Attn: Drug & Chemical Evaluation Section/ODE, 8701 Morrisette Drive, Springfield, VA 22152.
<b>UN Reporting &amp; Quota Section</b>	
1303.12(b)—Application for controlled substances procurement quota (DEA Form 250) filing and request. 1303.12(d)—Controlled substances quota adjustment request.	Drug Enforcement Administration, Attn: UN Reporting & Quota Section/ODQ, 8701 Morrisette Drive, Springfield, VA 22152.

## TABLE OF DEA MAILING ADDRESSES—Continued

Code of Federal Regulations Section—Topic	DEA mailing address
1303.22—Application for individual manufacturing quota (DEA Form 189) filing and request for schedule I or II controlled substances. 1304.31(a)—Manufacturers importing narcotic raw material report submission. 1304.32(a)—Manufacturers importing coca leaves report submission. 315.22—Application for individual manufacturing quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 189) filing and request. 1315.32(e)—Application for procurement quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 250) filing and request. 1315.32(g)—Procurement quota adjustment request for ephedrine, pseudoephedrine, phenylpropanolamine. 1315.34(d)—Application for import quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 488) request and filing. 1315.36(b)—Request import quota increase for ephedrine, pseudoephedrine, or phenylpropanolamine	
<b>Pharmaceutical Investigations Section</b>	
1304.04(d)—ARCOS separate central reporting identifier request. 1304.33(a)—Reports to ARCOS.	Drug Enforcement Administration, Attn: ARCOS Unit/ODPT, P.O. Box 2520, Springfield, VA 22152–2520 OR Drug Enforcement Administration, Attn: ARCOS Unit, 8701 Morrisette Drive, Springfield, VA 22152.
<b>DEA Registration Section</b>	
1301.03—Procedures information request (controlled substances registration). 1301.13(e)(2)—Request DEA Forms 224, 225, and 363. 1301.14(a)—Controlled substances registration application submission. 1301.18(c)—Research project controlled substance increase request. 1301.51—Controlled substances registration modification request. 301.52(b)—Controlled substances registration transfer request. 1301.52(c)—Controlled substances registration discontinuance of business activities notification. 1309.03—List I chemicals registration procedures information request. 1309.32(c)—Request DEA Form 510. 1309.33(a)—List I chemicals registration application submission. 1309.61—List I chemicals registration modification request.	Drug Enforcement Administration, Attn: Registration Section/ODR P.O. Box 2639, Springfield, VA 22152–2639.
<b>DEA Hearing Clerk</b>	
1301.43—Request for hearing or appearance; waiver. 1303.34—Request for hearing or appearance; waiver. 1308.44—Request for hearing or appearance; waiver. 1316.45—Hearings documentation filing. 1316.46(a)—Inspection of record. 1316.47(a)—Request for hearing. 1316.48—Notice of appearance.	Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, VA 22152.
<b>DEA Federal Register Representative</b>	
1301.33(a)—Filing of written comments regarding application for bulk manufacture of Schedule I and II substances.** 1301.34(a)—Filing of written comments regarding application for importation of Schedule I and II substances.** 1303.11(c)—Filing of written comments regarding notice of an aggregate production quota.** 1303.13(c)—Filing of written comments regarding adjustments of aggregate production quotas.** 1303.13(c)—Filing of written comments regarding adjustments of aggregate production quotas.** 1308.43(g)—Filing of written comments regarding initiation of proceedings for rulemaking.**	<a href="http://www.regulations.gov/">http://www.regulations.gov/</a> . Drug Enforcement Administration, Attn: Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, VA 22152.

\* Applications/filings/reports are required to be filed electronically in accordance with this chapter.

\*\* Applications/filings/reports may be filed electronically in accordance with this chapter.

Dated: September 1, 2016.

**Chuck Rosenberg,**

*Acting Administrator.*

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