



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 (ITDS); 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: Final rule.

SUMMARY: The Drug Enforcement Administration is updating 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 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 (ITDS). This rule additionally contains amendments that 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 rule also includes additional substantive and technical and stylistic amendments.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. However, compliance with the revisions to DEA regulations made by this rule is not required until [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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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 (21 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).¹ 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 chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader² for an international transaction³ involving a listed

¹ 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).

² 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).

³ An “international transaction” is a transaction that involves “the shipment of a listed chemical across an

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),⁴ 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

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).

⁴ 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).

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.⁵ 28 CFR 0.100 et seq.

Within the DEA, the Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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. *Purpose of Regulatory Action*

⁵ Due to an internal reorganization, on September 19, 2016, the DEA Office of Diversion Control became the Diversion Control Division. Throughout the document any references referring to the Office of Diversion Control have been updated to reflect this change.

1. Executive Order 13659

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 the International Trade Data System (ITDS) and supporting systems of data and other relevant documents (exclusive of applications for permits, licenses, or certifications) required for imported and exported goods. Participating agencies are "[a]ll federal agencies that require documentation for clearing or licensing the importation and exportation of cargo." Section 3 of Executive Order 13659 describes the ITDS as "an electronic information exchange capability, or "single window," through which businesses will transmit data required by participating agencies for the importation or exportation of cargo." Within the ITDS, businesses are able to transmit their import and export data using through an Electronic Data Interchange (EDI), an electronic communication framework providing standards for exchanging data via any electronic means. CBP has identified the Automated Commercial Environment (ACE), and any successor system to ACE, to serve as an authorized EDI for purposes of import and export data required by CBP and participating agencies.

In light of Executive Order 13659, the DEA is updating its regulations regarding the import and export of tableting and encapsulating machines, controlled substances, and listed chemicals. The amendments codify existing practices, incorporate existing procedures and technological advancements, and implement the President's Executive Order on streamlining the export/import process.

Previous DEA regulations specifically required applications for permits, declarations, and other required notices and reports to be filed in paper form, or by electronic means in some circumstances. To comply with Executive Order 13659, the DEA is amending its regulations to integrate DEA procedures related to the importation and exportation of tableting and encapsulating machines, controlled substances, and listed chemicals with the ITDS.

The ITDS excludes applications for permits, licenses, or certifications. In light of this, DEA registrants and regulated persons will continue to use the DEA application and filing process for permit applications that must be completed in advance of importation or exportation; however, the processes will be electronic rather than paper. As a result, DEA registrants or regulated persons applying for permits (DEA Forms 161, 161R, 161R-EEA, and 357) or filing notifications or reports with the DEA will apply or file directly with DEA electronically through the Diversion Control Division secure network application.

The DEA import/export declarations (DEA Forms 236, 486 and 486A), will also be replaced with an electronic process. Upon receipt of a complete declaration through the Diversion Control Division secure network application, DEA will provide the importer or exporter with the notice of receipt that must then be filed with CBP as part of the CBP import or export filing through ACE, or any successor system. DEA will also transmit the declaration information electronically to CBP 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 is

requiring such domestic regulated transaction reports to be submitted through the DEA Diversion Control Division secure network application, in addition to import and export regulated transactions. Mandatory reporting requirements for domestic regulated transactions are included as part of this rule 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.

Additionally, this final rule contains amendments that implement section 4, Re-exportation Among Members of the European Economic Area, of the Improving Regulatory Transparency for New Medical Therapies Act, Pub. L. 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.

This rule 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.

2. Pilot Program

The DEA published a general notice in the *Federal Register* announcing, in coordination with U.S. Customs and Border Protection (CBP), a pilot test of the ITDS involving the electronic submission of data related to the importation and exportation of controlled substances and listed chemicals.⁶ The pilot program is testing the electronic

⁶ *Electronic Filing of Certain Import/Export Data Relating to Controlled Substances and Listed Chemicals: Announcement of the Partner Government Agency Message Set/Document Image System Test and Request for Participants*, July 15, 2016. 81 FR 46058-89. To be eligible to apply for and participate in

transmission through CBP's ACE system, of data, forms and documents required by the DEA using the Partner Government Agency (PGA) Message Set and the Document Image System (DIS). The data, forms, and documents will be transmitted for review by the DEA. The PGA Message Set and DIS would enable importers, exporters, and brokers to electronically transmit data required by the DEA directly through ACE; this electronic process will replace certain paper-based processes that are used outside of the pilot program.

The test commenced on August 1, 2016, and will continue until publication of a notice in the *Federal Register*. Any party seeking to participate in the test was instructed to contact their CBP client representative.

The DEA anticipated that this pilot program would help prepare for a successful transition from the paper-based process to the electronic entry and transmission of data to ACE. As of October 25, 2016 there were 35 companies, representing 95 registration numbers, participating in the pilot program.

DEA and CBP have determined that the pilot program has successfully tested the functionality for electronic submission of data related to the importation and exportation of controlled substances and listed chemicals. As a result, the pilot program will be concluded as of the effective date of this final rule. At that time, all importers, exporters, and brokers will be able to use ACE to electronically file required data and

the pilot, an applicant had to be a self-filing importer or broker, with the ability to file ACE Entry and Entry Summaries certified for cargo release using a software program that has completed ACE certification testing for the PGA Message Set and DIS, and, if an exporter, must have the ability to file electronically in the Automated Export System (AES) or in ACE AES Direct.

documentation associated with the importation and exportation of controlled substances and listed chemicals.

3. Notice of Proposed Rulemaking

The DEA published a notice of proposed rulemaking (NPRM) in the *Federal Register* incorporating all the above changes on September 15, 2016.⁷ The NPRM provided an opportunity for persons to submit written comments on the proposal on or before October 17, 2016. The DEA specifically solicited comments on the economic impact of the rule, and requested that commenters describe the specific nature of any impact on small entities and provide empirical data to illustrate the extent of such impact.

C. Summary of the Major Provisions of the Regulatory Action

The DEA is finalizing the rule as proposed except where otherwise stated in the paragraphs below.

Below are summaries of provisions contained in the final rule.

1. Mandatory Electronic Applications and Filings

The DEA is amending its regulations to authorize electronic submission of data, and 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

⁷ *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*, September 15, 2016. 81 FR 63575. The DEA's Economic Impact Analysis (EIA), was made available in its entirety under "Supporting Documents" in the public docket of this action at <http://www.regulations.gov>, under FDMS Docket ID: DEA-2016-0017 (Docket No. DEA-403).

supports downstream information processing and dissemination. The Open Data Policy states that information should be collected electronically by default.

Executive Order 13659 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 through using an EDI, an electronic communication framework providing standards for exchanging data via any electronic means. Data is transmitted through the EDI links to ACE, which serves as the single window for CBP.

Mandatory electronic applications and filings allow for the DEA to create an efficient, streamlined reporting structure of regulated activities.

2. Import and Export Permits for Controlled Substances

The DEA is amending its regulations regarding expiration dates associated with imports and exports of controlled substances. The DEA is changing 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 standardizes expiration procedures as not all months have the same number of days.

The DEA is revising §§ 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 will submit a request to amend or cancel an application for an import or export permit,

amend an issued import or export permit, or request cancelation of an issued import or export permit to the Administration through the DEA Diversion Control Division secure network application.

Consistent with current practice, importers and exporters will 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; 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.

Consistent with current practice, importers and exporters will 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 will not be allowed to exceed the total base weight of controlled substance(s) listed on the corresponding foreign permit. Neither will 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. Under § 1312.15(a), importers will 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 may not amend permits to add or replace a controlled substance/Administration controlled substance code number to the item(s) to be imported or exported. Importers and exporters who desire to import or export a different controlled substance than that contained on their issued permit or permit application must submit a request for the permit or permit application to be canceled and request 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 Diversion Control Division 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 not 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 will 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 are not amendable.

However, also consistent with current practice, as stated above, the DEA will 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 Diversion Control Division secure network application.

Importers and exporters will be required to make an official request through the DEA Diversion Control Division secure network application for an amendment.

Supplementary information submitted by an importer or exporter through the DEA Diversion Control Division secure network application will not automatically trigger the amendment process. An amendment will have no effect on the date of expiration of the permit; an amended import or export permit will have the same expiration date as the originally issued permit. Importers and exporters will be able to request that an issued import or export permit be canceled provided that no shipment has yet been made.

Under revised § 1312.16(a)(5), registrants and regulated persons will 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 will 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.

DEA registrants have been able to submit DEA forms electronically for several years, and are familiar with the DEA Diversion Control Division secure network application

system. If a DEA registrant needs to change information on an application for a permit that is not amendable, they must submit a new application for a permit. The registrant will follow the same process used with the original submission and submit the forms electronically. The DEA will review the submission, process the document and issue a Transaction Identification Number (TIN). The estimated time to complete the online document is minimal. Requiring the new submission will ensure the integrity of the information in the DEA system as well as what is transmitted to CBP.

To make an allowable amendment, a DEA registrant will access the DEA secure network application and provide the Transaction Identification Number which was assigned with the original submission. The system will provide access to the registrant's application for a permit, and the registrant can then make the appropriate changes. The DEA will review the changes and process the document. To ensure that there is no delay in CBP releasing a product from being imported or exported, the DEA provides the amended documents or new submissions to CBP in its daily feed.

As a result of the ITDS/ACE system relying on the Harmonized Tariff System (HTS) used by CBP to properly release products for import or export, the DEA had to identify the proper HTS codes for the substances under its control. The HTS codes are utilized in ACE and directly correlate to Administration Controlled Substance Code Number. As a result, the DEA will not allow a registrant to amend an application by adding a controlled substance that has a different Administration Controlled Substance Code Number. This will ensure a more streamlined process and will allow CBP to efficiently release product in a timely manner.

Countries that are parties to international drug control treaties have an established competent national authority (CNA) (identified in the United Nations Office on Drugs and Crime publication “Competent National Authorities Under the International Drug Control Treaties”) that oversees the handling of controlled substances and listed chemicals to include the approval of imports and exports. All CNAs make certain reports to the International Narcotics Control Board (INCB) on the distribution of the substances being imported and exported. The DEA communicates directly with CNAs or through the INCB if issues arise regarding official authorization documents submitted to the DEA by DEA registrants.

For the reasons discussed above, the DEA is also requiring electronic reporting of return information for controlled substances imported or exported under permit procedures.

3. Import and Export Declarations for Controlled Substances

The DEA is also amending §§ 1312.18 and 1312.27 to specify an expiration date for import and export declarations for controlled substances.

Such declarations did not 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 previous regulation. 21 CFR 1312.16 and 1312.25. Similar to permits, declarations filed with the DEA are sometimes 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, declarations expire 180 calendar days after the date the declaration is deemed filed with the Administration.

The DEA is incorporating 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 is also incorporated into a new § 1312.03 which references a list of applicable forms for part 1312, and will state the declaration forms are electronic. This information is listed multiple in the applicable regulations.

Consistent with current requirements, controlled substance declarations will 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). The DEA is retaining this 15-day-advance filing 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. Under revised §§ 1312.18(b) and 1312.27(a), controlled substance declarations are not deemed filed until the Administration issues a transaction identification number. However, the DEA is allowing registrants and regulated persons 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. Finally, DEA regulations requiring declarations to be completed in triplicate would be eliminated.

The DEA is amending 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 is changing §§ 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 and regulated persons

will submit a request to amend or cancel a filed declaration to the Administration through the DEA Diversion Control Division secure network application.

Consistent with current practice, importers and exporters will 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.

Importers and exporters will 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, 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. 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 procedures will 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.

Importers and exporters will continue to be able to amend a filed import or export declaration to remove a controlled substance. However, importers and exporters will 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 need to make changes to any of these fields will 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.

The DEA is not 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.

Importers and exporters will 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.

The DEA will 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; such amendments would be required to be made through the DEA Diversion Control Division secure network application.

Importers and exporters will be required to make an official request through the DEA Diversion Control Division secure network application for an amendment.

Supplementary information submitted by an importer or exporter through the DEA Diversion Control Division secure network application will not automatically trigger the amendment process. An amendment will have no effect on the date of expiration of the declaration; an amended import or export declaration will have the same expiration date as the originally filed declaration.

Importers and exporters will be able to request that filed import or export declarations be canceled provided that no shipment has yet been made.

Registrants will be required to submit all requests for an amendment that will 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 CBP. 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 will be required to be submitted to the DEA at least one business day before the anticipated date of release by a customs CBP 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.

DEA registrants have been able to submit DEA forms electronically for several years, and are familiar with the DEA Diversion Control Division secure network application system. If a DEA registrant needs to change information on a declaration that is not amendable, they must submit a new declaration. 21 CFR 1312.12, 1312.18, 1312.22, and 1312.27. The registrant will follow the same process used with the original submission and submit the forms electronically. The DEA will review the submission, process the

document and issue a Transaction Identification Number (TIN). The estimated time to complete the online document is minimal. Requiring the new submission will ensure the integrity of the information in the DEA system as well as what is transmitted to CBP.

To make an allowable amendment, a DEA registrant will access the DEA Secure Network Application and provide the Transaction Identification Number which was assigned with the original submission. The system will provide access to the registrant's declaration, and the registrant can then make the appropriate changes. The DEA will review the changes and process the document. To ensure that there is no delay in CBP releasing a product from being imported or exported, the DEA provides the amended documents or new submissions to CBP in its daily feed.

As a result of the ITDS/ACE system relying on the Harmonized Tariff System (HTS) used by CBP to properly release products for import or export, the DEA had to identify the proper HTS codes for the substances under its control. The HTS codes are utilized in ACE and directly correlate to Administration Controlled Substance Code Number. As a result, the DEA will not allow a registrant to amend a declaration by adding a controlled substance that has a different Administration Controlled Substance Code Number. This will ensure a more streamlined process and will allow CBP to efficiently release product in a timely manner.

As stated previously all countries that are parties to international drug control treaties have an established CNA that oversees the handling of controlled substances and listed chemicals to include the approval of imports and exports. All CNAs make certain reports to the INCB on the distribution of the substances being imported and exported. The DEA

communicates directly with CNAs or through the INCB if issues arise regarding official authorization documents submitted to the DEA by DEA registrants.

For the reasons stated above, the DEA is also requiring mandatory electronic filing of return information for controlled substances imported or exported under declaration procedures.

4. Imports, Exports, and International Transactions for Listed Chemicals

The DEA is amending part 1313 to provide that each regulated person who seeks to import or export a listed chemical that meets or exceeds a threshold quantity, must notify/provide a declaration to the DEA (by filing a DEA Form 486/486A through the DEA Diversion Control Division secure network application) of the intended import or export not later than 15 calendar days before the date of release by a customs officer at the port of entry. Regarding imports and exports for those entities with regular customer and regular importer status, the notification must be filed at least three business days before the date of release by a customs officer at the port of entry. All declarations must be signed and dated by the importer or exporter and must contain the address of the final destination for the shipment.

The DEA is specifying that all 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.

In § 1313.32 the DEA is incorporating the mandatory electronic filing of notifications of international transactions involving listed chemicals which meet or exceed the threshold amount identified in § 1310.04. The broker or trader must notify the DEA (by

filing a DEA Form 486 through the DEA Diversion Control Division secure network application) of the intended international transaction not later than 15 calendar days before the transaction is to take place. The DEA is amending § 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.

5. Reexportation of Controlled Substances Among Members of the European Economic Area

This final rule implements section 4, Re-exportation Among Members of the European Economic Area, of the Improving Regulatory Transparency for New Medical Therapies Act, Pub. L. 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, and provided that the conditions specified in the 2015 Act are met.

In order to effectuate the changes contained in the 2015 Act, the final rule implements the following changes:

- Allowing unlimited reexports among EEA countries.
- Eliminating the 180 day time period to complete reexport (reexport from first country to the second country (ies)).
- No longer requiring bulk substances to undergo further manufacturing processes within the first EEA country if the substance is to be reexported within the EEA.
- No longer requiring that the exporter must provide product and consignee information beyond the first country in advance of (prior to) export from the United States.
- Establishing a new Form 161R–EEA for the reporting of reexports among members of the EEA. (The form is accessed, completed, and submitted through the DEA Diversion Control Division secure network application.)

All other requirements that existed prior to the enactment of the 2015 Act (and which were not modified by Congress in 2015 Act) remain. Additionally, 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). Finally, 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, for the purpose

of consistency, the DEA is making corresponding changes to its reexport of controlled substances under declaration procedures found in § 1312.27.

6. Domestic Transaction and Import and Export Reports for Tableting and Encapsulating Machines

The DEA is mandating electronic reporting requirements in § 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 is implementing usage of a new form, DEA Form 452, Reports for Regulated Machines, which covers imports, exports, and domestic regulated transactions of tableting and encapsulating machines. The new form will be accessed, completed, and submitted by regulated persons entirely through the DEA Diversion Control Division secure network application. Upon receipt and review, the Administration will assign each completed report a transaction identification number. The DEA Form 452 will not be deemed filed until the Administration issues a transaction identification number. This 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 DEA Form 452 is used for both domestic transactions and import/export transactions of tableting and encapsulating machines, and the reporting requirements implemented by this final rule differ.

Domestic Transactions: Previously in 21 CFR 1310.05(a)(4) and (b), regulated persons who engaged 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. The new § 1310.05(b)(2) in the final rule, makes the oral reporting mandatory and mandates the electronic filing of the written report. Additionally, the new § 1310.05(b)(2) requires 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) is required to be filed within 15 calendar days after the order has been shipped by the seller.

Import/Export Transactions: The DEA is requiring that the DEA Form 452 be submitted to the DEA through the DEA Diversion Control Division secure network application 15 calendar days before the anticipated date of arrival at the port of entry or port of export. Under this final rule, an importer or exporter 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 may proceed with the import or export of the machine(s) as soon as the transaction identification number has been issued. These changes are in § 1310.05(c). Additionally, the DEA revised § 1310.06(e)(1)(v) so that reports of importation of tableting or encapsulating machines include the reason for the importation, i.e., medical, commercial, scientific, or other legitimate use of the machine.

The DEA also added paragraph (c)(2) to § 1310.05 to require import shipments of tableting machines or encapsulating machines that have been denied release by customs to be reported to the Administration, through the DEA Diversion Control Division secure network application, within 5 business days of denial. If an importer subsequently

receives notice from a customs officer that their shipment will be released into the United States, the importer is 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.

The DEA is requiring electronic filing of return information, specifying the particulars of the transaction, for tableting and encapsulating machines imported or exported 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. Return information requirements are incorporated into a new paragraph (h) in § 1310.06 and requires the filing of the report with the Administration (on DEA Form 452) utilizing the DEA Diversion Control Division secure network application.

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

The DEA is incorporating 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 requirements of these monthly mail-order reports, the DEA is implementing usage of a new form, DEA Form 453. The new form will be accessed,

completed, and submitted by regulated persons entirely through the DEA Diversion Control Division secure network application. 21 CFR 1310.03(c) is 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. This 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 previous § 1310.06(i), redesignated in this final rule as § 1310.06(k), is revised to reflect that the monthly mail-order information is required to be submitted to the DEA on Form 453. 21 CFR 1310.03(c) is 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. This 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 technically amending § 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.

8. Transshipments of Controlled Substances

Applications for transshipment permits are still 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 Diversion Control Division Web site informing persons seeking to transship schedule I controlled substances on 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 Diversion Control Division 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 is explicitly stating 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.

9. Transshipment of Listed Chemicals

Advance notification is still 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 that meets or exceeds the threshold reporting requirements into the United States for transshipment. Advance notification is also still 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 Diversion Control Division Web site. While a broker or trader for an international transaction might be able to electronically submit the required information from a domestic IP address, for consistency and fairness across all transshipment activities, the DEA is allowing 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.

D. List of Changes in the Final Rule

This section discusses the minor changes implemented by this final rule that were not discussed in the NPRM. The minor changes include, among others, correcting minor typographical errors and updating citation listings and internal organizational changes within the DEA.

The effective date of this final rule remains 30 days from the date of publication. However, the compliance date was extended to 180 days after the publication of the final rule for all transactions, not only for tableting and encapsulating machines.

The DEA has eliminated the definitions of shipment and split shipment that were proposed in the NPRM. Because of the elimination of these definitions, the DEA has amended §§ 1312.13(e) and 1312.23(e) in a manner that is different than proposed. The language added to this section emphasizes that a shipment of controlled substances is 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 as opposed to multiple conveyances. In addition, the language will coincide with current policy by prohibiting a load of goods from being divided into multiple parts to be placed onto more than one conveyance, even if the goods are on the same loading document. A single permit could not be used for this situation above.

In §§ 1310.05, 1312.12, 1312.18, 1312.22, 1312.27, 1313.17, and 1313.27, the 24-hour reporting requirement to the DEA for the denial of imported/exported controlled substances, listed chemicals, tableting or encapsulating machines, has been changed to five business days.

In revised §§ 1312.22(d)(1), 1312.31(d)(4), and 1312.32(b), the phrase “and the attestation has been notarized” has been deleted.

II. Discussion of Comments

The DEA received 12 comments on the NPRM. Eleven commenters generally supported this rule while also raising issues of concern and one commenter expressed opposition to the NPRM. Three comments were not posted due to the entire comment containing confidential business information; one comment was not posted because it was unrelated to the NPRM; thus, only eight comments were posted. All of the relevant comments are summarized below, along with the DEA’s responses.

A. Electronic Applications and Filings, Generally (5 issues)

[1] **Comment:** Two commenters asked for clarification regarding the signature requirement applicable to declarations and applications submitted via the DEA Diversion Control Division secure network application.

Response: The user will login to the DEA Diversion Control Division secure network application using the user name and password. Upon completion of any of the forms associated with this rule, the user must submit the form by acknowledging the information on the form is complete and accurate. The acknowledgement serves as a signature. The DEA believes the use of electronic forms will eliminate the need for manual signatures and result in an overall reduction in burden. In addition, this rule does not alter the signature requirements for other documents; the definitions of “digital signature” and “electronic signature” (as defined in § 1300.03), and the requirements for signatures associated with electronic orders and electronic prescriptions (as found in part 1311) remain unchanged.

[2] **Comment:** Three commenters suggested that the DEA should provide for the continued availability and use of paper forms and hard copy reporting for imports and exports. Two commenters stated that other DEA systems such as CSOS and ARCOS have similar provisions, and in the event that the DEA’s electronic system was unavailable for any reason, an alternate method of applying for and approving imports and exports is needed as a contingency. However, the commenter stated that the DEA needs to have a stable electronic declaration system with no programming issues, because if a glitch in the system occurs, this could result in delayed shipments and significant cost for industry. The commenter stated that it was essential for importers and exporters to

continue to have the paper option for more time to correct any information derived from other databases that may be inaccurate. The commenters also requested that CBP provide additional guidance on how and by whom the electronic [CBP] certifications should be submitted, in order to ensure that companies are able to meet all of the DEA legal requirements.

Response: Upon review of results from the ITDS Pilot Program, the DEA is extending the compliance date of the final rule to 180 days after publication for all provisions contained in the rule.⁸ The ITDS Pilot Program (discussed above and in the General Notice at 81 FR 46058, July 15, 2016) has been underway since August 2016. Although no system failures or processing errors occurred during the ITDS Pilot Program, the DEA believes that more electronic transactions will provide a better test of the secure network application. The DEA anticipates that, during the extended compliance period, registrants and regulated persons will utilize both the secure network application and the current paper-based system. This will allow DEA to continue to test the integrity of the secure network application and enable DEA to correct any systemic issues while also ensuring an alternate method to conduct business is available so that trade is not impeded.

In response to the request that CBP provide additional guidance on how the electronic certifications should be submitted and by whom, the DEA recommends reviewing the ITDS implementation guidelines on CBP's website, <https://www.cbp.gov/document/guidance/dea-implementation-guide-ace>.

⁸ The final rule will be effective 30 days after publication in the Federal Register so registrants and regulated persons may opt to either submit forms and report information electronically via the secure network application in anticipation of the mandatory compliance date, or registrants and regulated persons may continue with paper submissions until the mandatory compliance date. This will not affect DEA's ability to continue to submit data to the ITDS/ACE.

[3] **Comment:** Three commenters stated that currently, the only way to submit a Declaration/Application for import/export from an analytical laboratory registrant is by sending a hard copy to the DEA, and that the DEA Diversion Control Division secure network application does not support imports/exports from analytical laboratory registrants. The commenter noted that, since an analytical laboratory is not required to register drug codes on the registration, the drop down list on the secure network application would need to be extensive or a free text box would need to be added. In addition, because there are many drug impurity reference standards that are imported/exported, the commenter suggested that the continued use of a paper-based system for imports/exports from analytical laboratory registrants is necessary until a free text box is added to the secure network application.

Response: As discussed, the DEA is extending the compliance date of the final rule to 180 days after publication for all provisions contained in the rule. The ITDS Pilot Program (as discussed and in the General Notice at 81 FR 46058, July 15, 2016) has been underway since August 2016. Although no system failures or processing errors occurred during the ITDS Pilot Program, the DEA believes an extended compliance date will enable more electronic transactions to test the integrity of the secure network application and ensure DEA can address any systemic issues before mandatory compliance. However, with the implementation of ITDS, the DEA Diversion Control Division secure network application will enable analytical laboratory registrants to provide all of the required information electronically. Any registrant, including analytical laboratories, unable to complete the necessary import/export forms for any reason may contact Diversion Control Division's Regulatory Section at 202-307-7194 or

CSIMEX@usdoj.gov. Unforeseen issues that prevent any registrant from completing the necessary import/export forms will be resolved on a case-by-case basis.

[4] **Comment:** Two commenters expressed concern that requiring registrants to report the date that the product was released by a customs official as well as the amount released by a customs official is repetitive since the Automated Commercial Environment (ACE) systems will include this information. The commenters requested that the DEA remove this requirement from the proposed rule. In support of their request, the commenters stated that it would be difficult for the registrant to obtain this information since these activities are handled by their brokers, and the registrant does not have access to the ACE system. The commenters went on to say that traditionally, the registrant reports when the substances leave their facility as this is the only date the registrant has direct knowledge of.

Response: The DEA appreciates the commenter's concerns. The DEA believes the release date is available. Some importers/exporters may need to obtain this information from their brokers. To remove the ambiguity created from the "date of import," the DEA chose the date of release by a customs officer. In addition, the DEA is requiring the date the shipment arrives (for imports) or leaves (for exports) the registered location or place of business. These two dates provide the proper accountability of the amounts of controlled substances or listed chemicals.

[5] **Comment:** One commenter expressed concern about the protection of data submitted electronically. The commenter supported the use of electronic submissions to streamline customs procedures, and requested additional information regarding how electronically submitted confidential business information would be protected, especially

in light of the significant security and competitive business interests at stake regarding the data contained in such transmissions. The commenter stated that it was essential that CBP take adequate measures to secure and protect this data from public access and release, and suggested that CBP implement training and certification procedures for employees with access to such information.

Response: The DEA cannot respond to questions regarding CBPs information system security practices. All questions regarding CBPs information system security practices should be directed to CBP.

B. Import and Export Permits for Controlled Substances (5 issues)

[1] **Comment:** One commenter requested that the DEA eliminate the proposed requirement that a translation be notarized when a translation of a foreign government-issued import license or Permit is necessary, because the wording in the current DEA regulations is sufficient. The commenter stated that the requirement that any such translation be notarized is not necessary, because it would place an additional burden on exporters without a commensurate benefit.

Response: The DEA proposed that translations be notarized in order to ensure that translations are complete and accurate. However, the DEA has reviewed this comment and after further consideration has removed the requirement for a notarized translation in §§ 1312.22, 1312.31, and 1312.32. The DEA is retaining the requirement that the translator certify the translation. For the purposes of this requirement, certified translation means that the translator has signed the translation legally attesting to the accuracy of the translation. The regulatory text in §§ 1312.22(d)(1), 1312.31(d)(4), and 1312.32(b) have been modified to reflect this change.

[2] **Comment:** One commenter asked for clarification about what is meant by “serial number” and how this information would be used to identify the foreign consignee. The commenter also wanted to know what to do if no such designation is present on the current packaging. Finally, the commenter wanted to know what the definition of “narcotic” was in this context.

Response: The DEA proposed to modify § 1312.26 because it required exporters to keep Copy 3 of the export permit along with “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.” As discussed in the NPRM, with the implementation of ITDS, Copy 3 is obsolete and with this final rule, exporters will be required to keep an “official record of the export permit,” rather than Copy 3, with any such serial numbers. As the NPRM did not propose or discuss any other modifications to § 1312.26, the comment will be considered as a basis for potential modifications in the future.

[3] **Comment:** Two commenters sought further modification of the pre-NPRM and pre-final rule regulation at § 1312.22(d)(7) (implemented as § 1312.22(h)(6) by this final rule) which requires that a controlled substance “will be exported from the first country to the second country (or second countries) no later than 180 days after the controlled substance was exported from the United States.” As these commenters noted, this 180-day requirement was established by the DEA in the 2007 regulation implementing the Controlled Substance Export Reform Act of 2005 (CSERA), but was not imposed by the CSERA itself. Noting that the 2015 Act contains a provision (21 U.S.C. 953(g)(1)) that eliminates the 180-day requirement for reexports within the EEA, some commenters requested that the DEA remove this requirement for all markets (not just the EEA

countries) as they view it as an unnecessary hindrance. One commenter requested that the DEA increase the 180-day requirement to 365 days for reexports outside of the EEA.

Response: This category of comments is outside the scope of the NPRM. As indicated above, the 180-day requirement was implemented in a rulemaking that concluded in 2007 (72 FR 72921, December 26, 2007), and this requirement was *not* issued for public comment in the NPRM. For the reasons stated above and in the NPRM, consistent with the 2015 Act, the DEA eliminated the 180-day requirement for reexports within the EEA. However, the 2015 Act left intact the reexport requirements for reexports outside of the EEA and, accordingly, the NPRM did not reopen for public comment the regulatory requirements for reexports outside the EEA. Rather, with regard to reexports, the NPRM only sought comments on the new regulations that were necessitated by the 2015 Act.⁹ While the 180-day requirement for reexports outside the EEA is therefore outside the scope of the NPRM, DEA continues to believe that the justification for the requirement set forth in the 2006 proposed rule (71 FR 61436, October 18, 2006) and 2007 final rule remains valid.

[4] **Comment:** One commenter asked for clarification in reference to adding a reexport market to the list of countries on the Export Declaration after the initial U.S. Export.

Response: All countries that are parties to any of the Conventions referred to in 21 U.S.C. 953(f)(1) will be included in the list of countries when completing forms 161R and 161R-EEA. Countries that are not parties to any of the Conventions will not be

⁹ For formatting purposes, the NPRM renumbered certain regulations relating to reexports outside the EEA, and thus the text of such regulations was included in the proposed rule section of the NPRM. However, the substance of such regulations was not altered from that promulgated in the 2007 final rule.

included as, consistent with the statute, reexport permits would not be granted for shipments to those countries.

[5] **Comment:** One commenter commented on the DEA's proposed definition of shipment. This commenter stated that the definition of shipment conflicts with how it is used in the DEA's regulations. First, the commenter reasoned that because the definition of shipment is placed in §§ 1300.01 and 1300.02 then this definition will apply to all parts of the DEA's regulations. Second, this commenter noted that the definition of shipment applies only to goods that are imported or exported. By defining shipment in this manner, the commenter reasoned that the term shipment can no longer be used in reference to domestic transactions involving controlled substances and listed chemicals. In addition, the commenter stated that shipment as defined conflicts with the definition of international transaction as set forth in 21 U.S.C. 802(42). International transaction is defined in part as, "a transaction involving the shipment of listed chemicals across an international border (other than a United States Border)***." As such, this commenter noted that the CSA contemplates shipments that are not imports into the United States or exporters from the United States.

Response: The DEA appreciates this comment. Based on this comment the DEA has decided to modify the regulation text in a way that is different than what was proposed. To remove the possibility of having the definition of shipment apply to all of DEA's regulations, the DEA is removing the definition of shipment from the definition sections of §§ 1300.01 and 1300.02. In addition, the DEA is removing the definition of split shipment from the same sections. The DEA has modified the text of §§ 1312.13(e) and 1312.23(e) relating to the issuance of import and export permits. The language

added in these sections allows for the same intended effect as the proposed language while eliminating the possibility of having the definition of shipment apply to all DEA regulations. Therefore, the introduction of this language will emphasize that a shipment of controlled substances is 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). In addition, the language will coincide with current policy by prohibiting a load of goods from being divided into multiple parts to be placed onto more than one conveyance, even if the goods are on the same loading document. A single permit could not be used for this situation above.

C. Import and Export Declarations for Controlled Substances (1 issue)

[1] **Comment:** One commenter requested that the DEA clarify whether an import or export declaration is effective immediately upon assignment of a Transaction Identification Number by the DEA so that the importer or exporter does not need to wait the full 15 days. The commenter also asked for additional clarification to make clear that if the DEA has not issued a Transaction Identification Number within 15 days of submission of the declaration, the import or export can be shipped, as is currently allowed. The commenter stated that if this was not the case then importers or exporters could have to wait much longer than 15 days for DEA to issue the Transaction Identification Number, which would be a significant change from current practice.

Response: Controlled substances may be imported or exported as soon as a Transaction Identification Number (TIN) is issued. The DEA works expeditiously to

confirm the accuracy of the declarations and will issue a TIN as soon as possible. When the TIN is issued for a controlled substances declaration in less than 15 days the importers and exporters may immediately request release by a customs official and do not need to wait for the expiration of the 15 days. Any delay in issuing a TIN is generally due to incomplete or inaccurate information on the declaration form and the submitters delay in providing complete and correct information. The declaration is deemed submitted when a TIN is issued; therefore, in the rare instances where 15 days have elapsed without the issuance of a TIN, the importer or exporter must wait for the TIN and may not request release by a customs official. As a practical matter, in the new ITDS/ACE system the customs official will not release a shipment without DEA's transmission of the TIN (among other data) to CBP.

D. Import and Export Declarations and Notices for Listed Chemicals (13 issues)

[1] **Comment:** One commenter was concerned with the proposal to require electronic filing of the DEA Form 486 via the Diversion Control Division secure network application. The commenter was concerned whether steps have or will be taken to reduce confusion or delays in releasing an import or export declaration that may be associated with multiple electronic DEA Form 486s but only a single invoice. In addition, the commenter wanted clarification on whether the DEA had consulted with foreign competent national authorities regarding the impact of requiring the processing of multiple electronic DEA Form 486s relating to the same order, in light of the fact that foreign competent authority applications are not limited to a specific number of lines for a particular order or license application.

Response: The DEA appreciates the commenter's concerns. The concerns raised by the commenter are beyond the scope of this rulemaking and will not be addressed.

However the DEA does not take issue with the use of multiple Form 486s.

[2] **Comment:** One commenter requested clarification on the differing requirements for an import or export transaction to proceed upon receipt of the TIN. The commenter wanted to know if the DEA intended for exporters to request release from customs immediately after issuance of the TIN as explicitly stated for importers.

Response: The DEA intends to treat importers and exporters the same in regards to the import or export transaction proceeding upon receipt of the TIN. However, allowing listed chemicals to ship before the 15-day notification requirement would be in conflict with 21 U.S.C. 971(a). Referring to import declarations, §1313.12(b) states that listed chemicals that meet or exceed threshold quantities identified in § 1310.04(f), or which do have an established threshold, may not be imported until a transaction identification number (TIN) has been issued, and the Administrator shall be notified of the importation of the listed chemical not later than 15 days before it takes place. Referring to export declarations, §1313.21(b) states that exporters may not request that the listed chemical be released until a transaction identification number (TIN) has been issued. The Administrator shall be notified of the importation of the listed chemical not later than 15 days before it takes place. Therefore prior to export or import a TIN has to be issued and importers and exporters have to wait the 15-day period.

[3] **Comment:** Four commenters recommended that the DEA establish a regulatory timeframe by which the agency will issue transaction identification numbers to allow for business certainty. One commenter recommended an initial deadline of three business

days for the DEA to review a transaction and issue the transaction identification number. The commenters expressed a concern about business decisions and timing. They stated that the lack of a definite deadline to issue the transaction identification number will cause delayed or canceled shipments and lost revenues.

Response: The DEA understands the commenters' sensitivity to time and potential for competitive advantage/disadvantage based on timely shipment of products. However, the DEA declines to set a specific timeframe for the issuance of a TIN. The DEA works expeditiously to confirm the accuracy of the declarations and will issue a TIN as soon as possible. Any delay in issuing a TIN is generally due to incomplete or inaccurate information on the declaration form and the submitters' delay in providing complete and correct information.

[4] **Comment:** Two commenters requested that the DEA clarify the discrepancy between whether the timeframe is three calendar days or three business days advance notification before the date of release by customs officers at the port of entry. One commenter suggested that since the time period is so small, the DEA should use its proposed text to require three business days to allow sufficient time for businesses to react to the unexpected delays or unexpected promptness of shipments. The commenter recommends that the DEA add appropriate language within the text of the rule clarifying its statement in the preamble that registrants can proceed with the import or export transaction as soon as the transaction identification number has been issued regardless of whether the three days have passed.

Response: The DEA appreciates the opportunity to correct any errors. After reviewing the language in the preamble the DEA, in two instances, erroneously stated 3

“calendar” days, rather than “business” days. The DEA has corrected the language in the preamble. The term three “business” days is also discussed repeatedly in the preamble and clearly stated in the regulatory text. However, importers and exporters may proceed with the transaction as soon as the TIN is issued regardless of whether the three days have elapsed. The regulatory text has been updated to clarify this requirement.

[5] **Comment:** One commenter requested that the DEA issue waivers/exemptions with respect to the proposed revisions in §§ 1313.12, 1313.14, and 1313.17. These proposed revisions would require that all imported shipments first go to the registered location before being subsequently shipped to the final destination (referred to within the industry as “drop shipment”). The commenter cited potential shipping risks and the substantial economic hardships small U.S. businesses would face in the competitive world market as a result of the proposed revisions. The commenter also expressed concern about the fact that the proposed revision to §1313.14, did not specify whether it applied to List I or List II chemicals or both.

Response: The DEA appreciates the commenter’s concerns. The proposed revision to §1313.14 still applies to List I chemicals. “Drop shipments” have always been permitted for List II chemicals, and this rulemaking will not change that. However with respect to List I chemicals, page 63598 of the published NPRM stated,

“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, are explicitly prohibited under the proposed revisions to § 1313.14.

[6] **Comment:** Five commenters suggested that the DEA allow listed chemicals to be relieved of the 15-day waiting period as allowed for controlled substances. The commenters stated that the DEA did not explain the reasoning behind this decision, and that it was inconsistent with other DEA regulations that treat controlled substances with stronger regulation than listed chemicals. The commenters recommended that the DEA modify the proposed rule to state that listed chemicals can also proceed with the import or export transaction as soon as the transaction identification number has been issued, regardless of whether the 15 calendar days have elapsed since its issuance

Response: After careful consideration, the DEA has decided not to allow the shipment to proceed when the TIN is issued. As stated above prior to export or import a TIN has to be issued and importers and exporters have to wait the 15-day period.

[7] **Comment:** One commenter stated that the proposed amendments to §§ 1313.12(d) and 1313.21(d) to require an import or export declaration on DEA Form 486 or 486A at least three business day before the date of release by a customs officer exceeds the statutory authority granted to DEA under 21 U.S.C. 971(b). The commenter stated that the previous versions of §§1313.12(d) and 1313.21(d) are consistent with the statutory limit on the timing of the waiver for transactions involving regular importers and regular customers.

Response: The DEA appreciates this comment. However, the DEA continues to believe that this modification is within its statutory authority pursuant to 21 U.S.C. 971. As stated in the NPRM it is necessary for DEA to provide customs officers with the

necessary information first so that the customs officers can then clear a shipment of relevant listed chemicals. Because of this, the DEA determined that three business days is needed to review all pertinent information relating to the shipment and transmit the data accurately to the ITDS. As a result, the waiver of the entire 15 day period can no longer be applied in these specific instances.

As stated in the NPRM accompanying this final rule, 21 U.S.C. 971(b) provides the DEA with authority to waive the 15 day requirement, by regulation, for imports of listed chemicals by regular importers and exports of listed chemicals between regulated persons and regular customers. The DEA is exercising this authority in the final rule. The DEA does acknowledge that 21 U.S.C. 971(b)(1) requires regulated persons subject to waivers to notify the DEA of the transaction “at the time of any importation or exportation.” To maintain the effect of this provision the DEA is allowing registrants to proceed with the import and export transaction as soon as the transaction identification number is issued, regardless of whether the three-calendar day period has concluded. In addition, the DEA considers the notification provided to the DEA by the customs officers at the time of release to meet the requirements of 21 U.S.C. 971(b)(1). With these two allowances the DEA believes that it is meeting the statutory requirements and is setting forth reasonable requirements.

[8] **Comment:** One commenter stated that the wording used in revised §§1313.12(d) and 1313.21(d) is ambiguous. The commenter noted that the “name and description” of a listed chemical may not appear on the product label, and that DEA labeling requirements apply to controlled substances and not listed chemicals. The commenter suggested that the phrase “name and description of each listed chemical” would be better phrased as

“trade name of the listed chemical or mixture containing one or more listed chemical.”

The commenter argues that this wording would be consistent with § 1310.13, which requires an applicant for exemption from registration to provide the DEA with the trade name(s) of its chemical mixture(s).

Response: Under the DEA labeling requirements, the “name and description” of a listed chemical does not necessarily mean the trade name. The DEA is looking to determine what the listed chemical is. Therefore the trade name is not the only description that can be used.

[9] **Comment:** One commenter suggested an amendment to the DEA Form Data. The commenter stated that the current wording could require that any waiting period in the consignee country be completed before beginning any waiting period in the United States. The commenter stated that variations in national requirements may result in situations where the consignee is not required to have a permit; this would accommodate situations in which the competent national authority of a consignee may require documentation of a bona fide intent to import prior to issuing a permit; finally this would expedite shipments by allowing concurrent waiting periods in both countries.

Response: The registrant would still be required to abide by the laws of the country of import.

[10] **Comment:** Two commenters expressed concern over the proposed amendment to the language in §§ 1313.17 and 1313.27 to require an importer or exporter to notify the DEA within 24 hours of the denial of the release of an import or export of listed chemicals. The commenters asked that the DEA remove the 24-hour period, because the need for the shortened time frame was not apparent, and cited instances where it might

been unworkable because the consignor and customs agents are working different schedules, the denial occurs late Friday or over the weekend, or the business office is closed for 24 or more hours during which customs may have denied the release.

Response: Thank you for your comment. Two commenters expressed similar concerns, and the DEA has decided to change the 24-hour reporting requirement to a 5-business-day reporting requirement. The DEA believes that this will give registrants enough time to notify the DEA and work with Customs to secure a release. See regulation text changes in §§1310.05, 1312.12, 1312.18, 1312.22, 1312.27, 1313.17, and 1313.27.

[11] **Comment:** In proposed 21 CFR 1310.05(b)(1), the DEA added several factors that regulated persons may consider when determining whether a loss or disappearance of a listed chemical was unusual or excessive. One commenter stated that they are not certain the added language provides clarity to persons that handle listed chemicals or the DEA field staff. Specifically, the commenter suggested that the determination of whether a loss or disappearance of a listed chemical is unusual or excessive is fact specific and could vary even within a specific entity. Against this backdrop the commenter suggested that the DEA remove these factors from 21 CFR 1310.05(b)(1). The commenter also suggested that the inclusion of these factors, while being similar to those factors in 21 CFR 1301.74(c), might cause DEA field staff to consider these factors mandatory.

In the alternative to removing the factors from the regulatory text, this same commenter submitted two suggestions. The commenter suggested that listed chemical handlers should consider these factors only if the factors help the handler determine whether a loss is unusual or excessive. In addition, the commenter suggested that the

factors should only be applied as to the specific facts surrounding the loss or disappearance.

Lastly, this commenter requested that the DEA discuss its reasoning for using slightly different factors than the agency uses in 21 CFR 1301.74(c) and to discuss the impact to regulated persons based on this change, including the interpretation.

Response: The DEA appreciates this comment. As noted in the text of 21 CFR 1310.05(b)(1) the consideration of these factors is not mandatory. The DEA states that regulated persons should consider, among others, the factors enumerated. The DEA recognizes that each business entity is unique and has different business practices. As a result, by enumerating these factors the DEA is providing factors that may assist the regulated person. The DEA recognizes and recommends that each regulated person will tailor their system to detect unusual or excessive loss or disappearance of listed chemicals to meet their specific business model. As a result, if the regulated person's business practice allows for the consideration of these factors then the DEA would expect the regulated person to consider the factors in determining if the loss or disappearance of a listed chemical is excessive or unusual. The language used by the DEA in § 1310.05(b)(1) allows for this flexibility. Furthermore, the DEA does not believe that the inclusion of these factors will cause DEA field staff to consider these factors mandatory. It should be noted that the factors used in § 1301.74(c) are not mandatory. Based on the above reasoning the DEA does not think it is prudent to amend the language in §1310.05(b)(1).

[12] **Comment:** One commenter stated that the DEA's Combat Methamphetamine Epidemic Act (CMEA) provided that listed chemicals could only be imported if a valid

customer order was in place. The commenter stated that although they had been abiding by the new language, it was challenging and presented an economic disadvantage due to the business nature of the chemicals they were handling.

Response: This comment is outside the scope of this rulemaking, and the DEA has no authority to modify the requirements of the CMEA.

[13] **Comment:** One commenter asked for electronic IDs for two locations - one for the List I Chemical Registered address and one for the List II Place of Business. The commenter stated that they had been told that all electronic entries are to be under the List I registered address electronic ID. The commenter objected to this, stating that the regulations and accepted addresses are different for List I and List II chemicals. For this reason, the commenter stated that there should be two electronic IDs to differentiate List I chemicals from List II chemicals, and that this should be addressed in the regulations since the DEA was requiring electronic filing of the DEA 486 Forms.

Response: The DEA allows more than one system account, one for List I registered location and one for List II place of business. To resolve any issues regarding system account setup or any other questions regarding listed chemicals declarations, please contact the Regulatory Section at 202-307-7194 or Chemical.IMEX@usdoj.gov.

*E. Reexportation of Controlled Substances Among Members of the
European Economic Area (3 issues)*

[1] **Comment:** Several commenters expressed the view that DEA should strike the proposed regulatory text (§ 1312.22(g)(2)) that requires persons who reexport within the EEA to report to DEA, within 30 days after each reexportion, information concerning the consignee, country, and product that was reexported. According to these commenters,

this requirement is difficult, if not impossible, for them to comply with because, according to the commenters, they are unable to track the controlled substances once they are transferred to another owner. As to this point, one of the commenters attached a letter from four members of Congress, written seven months after the bill was enacted, stating that holding the manufacturer responsible for complying with this reporting requirement after a product has "left the manufacturer's ownership" would be contrary to the intent of the 2015 Act. In addition, commenters assert that the requirement is unnecessary from a diversion control standpoint and that it could cause them to lose sales to foreign competitors who are not subject to this requirement. As to the letter point, some of the commenters assert that the purpose of the reexport provisions of the 2015 Act is to encourage U.S. commerce abroad and to prevent U.S. drug firms from moving U.S. manufacturing jobs overseas. Some of the commenters also contended that their request to strike this requirement is supported by the provision of the 2015 Act (21 U.S.C. 953(g)) that prohibits DEA from issuing any regulation "which impedes re-exportation of any controlled substance among [EEA] countries."

Response: While DEA has considered carefully the concerns of the commenters regarding their compliance with the 30-day reporting requirement, the law precludes the interpretation offered by these commenters that would eliminate this requirement once the controlled substances are no longer owned by the exporter. As stated in 21 U.S.C. 953(f)(6)(B), "In the case of re-exportation among members of the of the European Economic Area, *within 30 days after each re-exportation*, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such re-exportation has occurred and information

concerning the consignee, country, and product.” (Emphasis added.) The language of this statute is clear and there is no mention of ownership being a condition precedent to reporting pursuant to 21 U.S.C. 953(f)(6)(B).

As the United States Supreme Court has repeatedly held, "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843 (1984). Because 21 U.S.C. 953(f)(6)(B) unambiguously requires reporting "within 30 days after each re-exportation" within the EEA, and because the statute makes no exception to this requirement based on lack of ownership, DEA is obligated to incorporate this requirement in its regulations.

With regard to the letter from four members of Congress attached by one of the commenters, because this letter was written after the law was enacted, it cannot be considered legislative history. But even if it were part of the legislative history, *Chevron* indicates that the agency cannot rely on it if is inconsistent with the plain language of the statute.

The provision of 21 U.S.C. 953(g) prohibiting DEA from promulgating any regulation that "impedes" reexportation within the EEA does not alter this conclusion. Congress could not have meant by this provision that DEA cannot enforce a requirement that Congress itself explicitly enacted. Rather, the logical interpretation of this clause is that DEA cannot impose any *additional* requirements (beyond those imposed by Congress) that would impede reexports within the EEA. As explained in the NPRM, DEA has adhered to this requirement by, for example, omitting from the EEA reexport

regulations the requirement in the 2007 regulations that bulk substances undergo further manufacturing processes in the first country before reexporting to the second country.

[2] **Comment:** Two commenters requested that the shipping date should still be acceptable for reexports reported to the DEA, because customs clearance dates are not readily accessible by exporters in the first countries. One commenter expressed concern that requiring first country customs clearance dates would be burdensome and lead to reporting delays. Another commenter stated that for reexports within the EEA, subsequent reexports beyond the second country should not be reportable to the DEA, because this information serves no purpose for the DEA and would be unduly burdensome for U.S. exporters to collect and report.

Response: As stated earlier, the requirement to report the date of release by a customs official remains as proposed. Some importers/exporters may need to obtain this information from their brokers. To remove the ambiguity created from the “date of import” and “date of export,” the DEA chose the date of release by a customs officer. In addition, the DEA is requiring the date the shipment arrives (for imports) or leaves (for exports) the registered location or place of business. These two dates provide the proper accountability of the amounts of controlled substances or listed chemicals.

[3] **Comment:** One commenter requested that the European Economic Area (EEA) should apply to member countries as of November 25, 2015. For example, this commenter noted that when the 2015 Act was passed on November 25, 2015, the United Kingdom was still a member of the European Union. The commenter suggested that it is unclear whether or not the United Kingdom’s EEA membership will be affected after it separates from the European Union. To provide stability in implementing the 2015 Act’s

provisions, the commenter requested that the DEA consider, for purposes of the 2015 Act, that the EEA countries include those that were members on November 25, 2015.

Response: The 2015 Act is devoid of any language stating that the EEA includes those members as of November 25, 2015. Accordingly, the DEA interprets that for the EEA provisions to apply, the country must be a member at the time the export leaves the United States.

F. Miscellaneous Comments (2 issues)

Two comments were received that were not within the scope of this rulemaking, and will not be addressed. Both addressed drug scheduling actions that were outside the subject area of this final rule.

III. Section by Section Summary of the Final Rule

A. 21 CFR part 1300

For purposes of clarity and transparency, the DEA is updating 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. Additionally, the DEA is making a technical change to more concisely incorporate U.S. obligations under international treaties of drug control, as statutorily codified in the CSA.

B. 21 CFR part 1301

The DEA is amending §§ 1301.24, 1301.26, 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.

The DEA is also 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.

This topic has 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/DRL, 8701 Morrissette Drive, Springfield, VA 22152” to “Drug Enforcement Administration, Attn: Federal Register Representative/DRW, 8701 Morrissette 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.

C. 21 CFR part 1302

Corresponding to the removal of “jurisdiction of the United States” and the revised definitions of “export” and “import,” the DEA is making 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.

D. 21 CFR part 1303

Corresponding to recent internal DEA reorganization, the mailing addresses for §§ 1303.12(b) and (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.

E. 21 CFR part 1304

The DEA is making 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.)

The DEA is also making a technical amendment to amend § 1304.21(d) to separately state reporting requirements concerning imports and exports of controlled substances.

The record date for receipt, distribution, other transfer, or destruction will not change. The regulation will be amended to state that the record date for imports or exports of controlled substances is the anticipated date of release by a customs officer for permits and declarations and the date on which the controlled substance was released by a customs officer at the port of entry or port of export.

F. 21 CFR part 1308

The DEA is making two technical updates to part 1308. First, the DEA is amending § 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 is amending § 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, Pub. L. 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 is also realigning the paragraphs of § 1308.49 to properly separate the discussion of the circumstances in which a temporary scheduling order will be vacated.

G. 21 CFR part 1309

The DEA is amending § 1309.32(d) to add “manufactured” to the list of business activities each application 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 correcting and updating 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 correcting and updating 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 correcting two minor typographic issues in § 1309.71: capitalizing the first word of paragraph (b)(5) and adding an “and” at the end of paragraph (b)(7).

H. *21 CFR part 1310*

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

The DEA is incorporating 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 is implementing usage of a new form, DEA Form 453. The new form is accessed, completed, and submitted by regulated persons entirely through the DEA Diversion Control Division secure network application. 21 CFR 1310.03(c) is 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. This 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) is revised to reflect that the monthly mail-order information required to be submitted would now be submitted on the DEA Form 453 and is designated as § 1310.06(k). 21 CFR 1310.03(c) is 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. This 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 making a technical amendment 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 substantive requirements.

ii. Listed Chemicals and Tableting and Encapsulating
Machines

The DEA is amending § 1310.05 to require reports of unusual or excessive loss or disappearance of a listed chemical to be filed through the DEA Diversion Control Division secure network application. When determining whether a loss is unusual or excessive, the guidelines that the regulated person should consider are: (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 is clarifying 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 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 is also removing the phrase “whenever possible” from the oral reporting requirements of the current § 1310.05(b). The DEA believes that the phrase is redundant given 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 is restructuring § 1310.05(a) and (b) to reflect the revised reporting structure. Paragraph (a) is addressing those reports made solely to the local DEA office in accordance with the current and revised § 1310.05(a)(1) and (2). Paragraph (b) is addressing those reports made orally to the local DEA office with written reports being submitted through the DEA Diversion Control Division secure network application. The reporting requirements now located in § 1310.05(b) will 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 is clarifying § 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 are 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 is revised to reflect the various changes in §§ 1310.03—1310.05. Cross-citations have been amended to reflect where regulations have been moved and new forms instituted. In § 1310.06(a)(3) regulated persons are required 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 previous § 1310.06(c), which incorrectly referenced § 1310.05(a)(4) instead of § 1310.05(a)(3). 21 CFR 1310.06(c) previously stated 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 previous § 1310.05(a)(3) (now § 1310.05(b)(1)). The DEA also is making technical amendments in § 1310.06, including replacing the term “shall” in paragraphs (a) and (b).

The DEA is standardizing 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. In the revised § 1310.05(b)(2), the DEA is making the oral reporting mandatory and mandating the electronic filing of the written report. The DEA also is providing specific guidelines on when those reports must be given. The revised § 1310.05(b)(2) requires 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) is 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 reporting timeframe 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 is exercising 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, covers 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 previous § 1310.05(a)(4). The requirements for the content of domestic reports were moved from § 1310.06(d) to a new § 1310.06(f), while the requirements for reports of importations and exportations are all contained within § 1310.06(e). The DEA also is amending 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. In § 1310.06(e)(1)(vi) and (f)(3), the DEA is requiring 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 amending § 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 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 is required to be submitted electronically through the DEA Diversion Control Division 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 § 1310.06(h), importers are 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 are 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 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” or “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.

Regulatory changes in the final rule 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. In response to commenters who stated that the 24 hour notification requirement related to import or export denials was unreasonable, the DEA has modified this requirement from 24 hours to 5 business days. The DEA believes that 5 business days strikes a balance between investigative needs without unduly burdening the regulated community. 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.

I. *21 CFR part 1312*

The DEA is making a technical amendment 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 is amending § 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 is also amending § 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 or regulated person. Drop shipments, i.e., deliveries made by an importer directly to a customer

without passing through the registered location of the importer, are explicitly prohibited under the 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 made 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 amending its regulations regarding expiration dates associated with imports and exports of controlled substances. The DEA is changing 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 is also amending §§ 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 requiring that declarations expire 180 calendar days after the date the declaration is deemed filed with the Administration.

The DEA is modifying the condition previously found in § 1312.22(a) that requires an application 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 is 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 account for any changes in international treaties, conventions, or protocols which might be made in the future.

This final rule 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 amending §§ 1312.12, 1312.18, 1312.22, and 1312.27 to require registrants or regulated persons, 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 requiring 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 requiring 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 of release by customs. Both dates are needed to adequately monitor the closed system of distribution for import and export transactions.

The DEA is revising §§ 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. 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 is amending § 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 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 Diversion Control Division 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 Diversion Control Division 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 is amending §§ 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. For the purposes of this requirement, certified translation will mean that the translator has signed the translation legally attesting to the accuracy of the translation. 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.

In response to commenters who stated that the 24 hour notification requirement related to import or export denials was unreasonable, the DEA has modified this requirement from 24 hours to 5 business days. The DEA believes that 5 business days strikes a balance between investigative needs without unduly burdening the regulated community.

As mentioned above, in response to comments the DEA amended §§ 1312.13(e) and 1312.23(e) in a manner that is different than proposed. The language added to this section will emphasize that a shipment of controlled substances is 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 as opposed to multiple conveyances. In addition, the language will coincide with current policy by prohibiting a load of goods from being divided into multiple parts to be placed onto more than one conveyance, even if the goods are on the same loading document. A single permit could not be used for this situation above.

J. 21 CFR part 1313

The DEA is adding a new § 1313.03 that will consolidate the DEA Form information applicable to part 1313 in a corresponding change for the new § 1312.03. The new § 1313.03 will 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 is amending § 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 revision will impose the same requirement for import/export declarations as for listed chemicals.

Declarations (DEA Forms 486/486A) will not be deemed filed until the transaction identification number has been issued by the DEA. Upon receipt and review, the DEA will assign each declaration a transaction identification number (a unique identifier).

Once the declaration is accepted and assigned a transaction identification number, registrants will 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 change is consistent with current practices. Currently, the DEA assigns a Web Tracking Number to each declaration when it is submitted and accepted. The 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 wishes to clarify that import or export transactions may not proceed as soon as the transaction identification number has been issued, because the 15-calendar-day requirement since the filing of DEA Form 486/486A has not changed. Import or export transactions for which the 15-calendar-day notification has been waived, may proceed as soon as the transaction identification number has been issued, regardless of whether the 3 business days have elapsed since filing of DEA Form 486/486A.

The DEA is making 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 requiring that return

information must be reported within 30 calendar days after release by a customs officer at the port of entry, export, or reexport. All return information for applications or other initial filings that are required to be made electronically through the DEA Diversion Control Division secure network application would likewise be required to be filed electronically through the same system. As with controlled substance return information, the DEA is requiring 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 revising 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, are explicitly prohibited under the revisions to § 1313.14. Similarly, consistent with 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 amending § 1313.22(a) to add a cross-reference to § 1310.04(g) relating to listed chemicals that may be exported. This change will harmonize § 1313.22(a) with § 1313.21(a).

In response to commenters who stated that the 24 hour notification requirement related to import or export denials was unreasonable, the DEA has modified this requirement from 24 hours to 5 business days. The DEA believes that 5 business days strikes a balance between meeting investigative needs and not unduly burdening the regulated community.

K. 21 CFR part 1314

Corresponding to recent internal DEA reorganization, in § 1314.110, in paragraphs (a)(1) and (2), the phrase “Import/Export Unit,” will be removed and in its place “Regulatory Section, Diversion Control Division,” will be added.

L. 21 CFR part 1315

Corresponding to recent internal DEA reorganization, the mailing addresses for §§ 1303.12(b) and (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.

M. 21 CFR part 1316

The DEA is amending § 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 will 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 amending § 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.

The DEA is amending § 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 is also amending § 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 is making 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/DRL, 8701 Morrisette Drive, Springfield, VA 22152” to “Drug Enforcement Administration, Attn: Federal Register Representative/DRW, 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.

N. *21 CFR part 1321*

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

Pursuant to this final action all import and export applications and filings would be submitted through the DEA Diversion Control Division secure network application. The DEA will 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 will note with an asterisk that those filings must now be made electronically. The CFR sections listed under the DEA Import/Export Unit will 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 Diversion Control Division to the DEA Drug & Chemical Evaluation Section (DRE), 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) and (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.

IV. Regulatory Analyses

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

This final rule was developed in accordance with the principles of Executive Orders 12866 and 13563. The DEA has determined that this final 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 final rule can be found in the rulemaking docket at <http://www.regulations.gov>, under FDMS Docket ID: DEA-2016-0017 (Docket No. DEA-403).

Executive Order 12988, Civil Justice Reform

The 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, Federalism

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, Consultation and Coordination with Indian Tribal Governments

This final 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 solicited written comments regarding the DEA's economic threshold analysis of the impact of these proposed changes. The DEA requested that commenters provide detailed descriptions in their comment of any expected economic impacts, especially to small entities. Commenters were asked to provide empirical data to illustrate the nature and scope of such impact. No comments were received; thus, the analysis that accompanied the NPRM remains unchanged below.

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. This final 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 final 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 EPH, PSE, PPA, or 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 final 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 mandating 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 mandating 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 are 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,¹⁰ 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 Diversion Control Division 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

¹⁰ 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*.").

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 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 specifying 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 final rule. This rule will 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 final 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 final rule and has submitted this collection request to the Office of Management and Budget (OMB) for review and approval. This final rule updates the DEA regulations for import and export of controlled substances, listed chemicals, and tableting and encapsulating machines. The rule 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 Final Rule

The DEA is revising 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 revising 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 revising 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 revising 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 EPH, PSE, PPA, or GHB (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 EPH, PSE,

PPA, or GHB (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 mandating 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 amending § 1312.22 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, in § 1312.22 the DEA is requiring 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 Diversion Control Division secure network

application (available on the DEA Diversion Control Division Web site) that such export has occurred and the specifics of the transaction.

As part of the implementation of ITDS, the DEA is establishing a new DEA Form 161R–EEA, discussed in greater detail below, to be used by registrants or regulated persons 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 amending § 1312.22 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 requires 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 Diversion Control Division secure network application (available on the DEA Diversion Control Division Web site) that such export has occurred and the specifics of the transaction. Also consistent with current requirements, the amended text requires 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, are required to be accessed, completed, and submitted to the DEA through the DEA Diversion Control Division secure network application.

This final rule contains amendments that implement section 4, Re-exportation Among Members of the European Economic Area, of the Improving Regulatory Transparency for New Medical Therapies Act, Pub. L. 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 establishing 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 or regulated persons who export controlled substances for reexport among members of the European Economic Area. Specifically, in § 1312.22, the DEA is requiring 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 Diversion Control Division 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 previous § 1312.22(d)(7) (now § 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 Diversion Control Division 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 reexportations, the final rule does not create a new information collection burden for reexportations.

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 mandating 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 amending to § 1312.18(e) 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 Diversion Control Division Web site certifying that such import occurred and the details of the transaction.

The DEA is amending to § 1312.27(d) in the final 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 Diversion Control Division secure network application (available on the DEA Diversion Control Division 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 Diversion Control Division secure network application (available on the DEA Diversion Control Division 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 mandating 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 adding § 1312.12(d) 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, in § 1312.12(d), the DEA is requiring 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 Diversion Control Division secure network application (available on the DEA Diversion Control Division 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 establishing 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 previous § 1310.05(a)(4) for domestic regulated transactions in a tableting or encapsulating machine as well as the report required in the previous § 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 Diversion Control Division secure network application.

Moreover, under both the previous 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. The DEA now clarifies 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 Diversion Control Division 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 mandating 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 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 Diversion Control Division secure network application (available on the DEA Diversion Control Division 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.

As part of the implementation of the ITDS, the DEA is establishing 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 previous § 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 Diversion Control Division 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 Diversion Control Division 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 establishing 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 previous §§ 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 Diversion Control Division 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 units; 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 is amending 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.

Rule Text

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 amends 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. Revise definitions of “Export” and “Import”;

b. Add definitions of “Competent national authority”, “Customs officer”, “Port of entry”, “Port of export”, “Return information”, and “United States”, in alphabetical order;
and

c. Remove the definition of “Jurisdiction of the United States”.

The revisions and additions read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

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(i) (that is, of the U.S. Customs and Border Protection), 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's 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.

* * * * *

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. Add definitions of “Competent national authority”, “Customs officer”, “Export”, “Import”, “Port of entry”, “Port of export”, “Return information”, and “United States”, in alphabetical order; and

b. Remove definitions of “Chemical import” and “Jurisdiction of the United States”.

The additions read as follows:

§ 1300.02 Definitions relating to listed chemicals.

* * * * *

(b) * * *

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(i) (that is, of the U.S. Customs and Border Protection), 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.

* * * * *

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. In § 1301.12, revise paragraph (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. In § 1301.24, revise paragraph (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. In § 1301.26, revise paragraph (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. In § 1301.34, revise paragraph (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. In § 1301.74, revise paragraph (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.

(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. These sealing and labeling requirements are in addition to any sealing requirements required under applicable customs laws.

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. In § 1303.12:

a. In paragraph (b), remove “Drug and Chemical Evaluation Section, Drug Enforcement Administration” and add in its place “UN Reporting and Quota Section, Diversion Control Division”; and

b. In paragraph (d), remove “Drug & Chemical Evaluation Section, Drug Enforcement Administration” and add in its place “UN Reporting and Quota Section, Diversion Control Division”.

§ 1303.22 [AMENDED]

14. In § 1303.22 introductory text, remove “Drug & Chemical Evaluation Section, Drug Enforcement Administration” and add in its place “UN Reporting and Quota Section, Diversion Control Division”.

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. In § 1304.21, revise paragraph (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 anticipated date of release by a customs official for permit applications and declarations and the date on which the controlled substances are released by a customs officer at the port of entry or port of export for return information.

* * * * *

§ 1304.31 [AMENDED]

18. In § 1304.31(a), remove “Drug and Chemical Evaluation Section, Drug Enforcement Administration” and add in its place “UN Reporting and Quota Section, Diversion Control Division”.

§ 1304.32 [AMENDED]

19. In § 1304.32(a), remove “Drug and Chemical Evaluation Section, Drug Enforcement Administration” and add in its place “UN Reporting and Quota Section, Diversion Control Division”.

20. In § 1304.33, revise paragraphs (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, Diversion Control Division, 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) *Exceptions.* (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, Diversion Control Division, 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 this part.

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, Diversion Control Division, 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, Diversion Control Division, 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, Diversion Control Division, 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, Diversion Control Division, 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, Diversion Control Division, 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. In § 1309.26, revise paragraph (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. In § 1309.32, revise paragraph (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. In § 1309.71, revise paragraphs (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. In § 1310.03:

- a. In paragraph (b), remove “Section 1310.05” and add in its place “§ 1310.05”; and
- b. Revise paragraph (c).

The revision reads as follows:

§ 1310.03 Persons required to keep records and file reports.

* * * * *

(c)(1) Each regulated person who engages in a transaction with a nonregulated person which:

(i) Involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma hydroxybutyric acid (including drug products containing these chemicals or controlled substance); and

(ii) 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 Diversion Control Division secure network application.

(2) Each regulated person who engages in an export transaction which:

(i) Involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma hydroxybutyric acid (including drug products containing these chemicals or controlled substance); and

(ii) 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 Diversion Control Division secure network application.

38. In § 1310.05, revise paragraphs (a), (b), (c), (d) and (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 Diversion Control Division 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; and

(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 Diversion Control Division 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 Diversion Control Division 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 5 business days 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 Diversion Control Division

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 refiled 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, Diversion Control Division, 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(i)(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 (d) 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), e-mail 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 paragraph (a) of this section, 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), e-mail 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), e-mail address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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;

(iv) The name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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; and

(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), e-mail address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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), e-mail 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), e-mail 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), e-mail address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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; and

(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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division secure network application, following the return at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States 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), e-mail 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), e-mail address (es), etc.) and registration number.

(2) Purchaser's name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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 section 552(a) of title 5, by reason of section 552(b)(6) of title 5, 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, Diversion Control Division, 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 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; 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 Diversion Control Division 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), e-mail 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; and

(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 Diversion Control Division 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 5 business days 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 Diversion Control Division 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. In § 1312.13, revise paragraph (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. A single import permit shall authorize a quantity of goods to be imported/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 commercial loading document; a single permit shall not authorize a quantity of goods to be imported/exported if the goods are divided onto two or more conveyances. The permit must state that the Administration is satisfied that the consignment 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 Diversion Control Division 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. In § 1312.15:

a. In paragraph (a):

i. Remove the phrase “the U.S. Customs Service” and add in its place “U.S. Customs and Border Protection or customs service of an Insular Area”; and

ii. At the end of the first sentence, add the phrase “in accordance with § 1312.16(a)”;
and

b. In paragraph (b):

i. Remove the phrase “the U.S. Customs Service” and add in its place “U.S. Customs and Border Protection or customs service of an Insular Area”; and

ii. In the final sentence, remove “Director of the Administration” 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division

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 and paragraphs (b), (c) introductory text, and (c)(3); and
- b. 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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 paragraph (g) of this section.

(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 Diversion Control Division 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 5 business days 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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), e-mail 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), e-mail 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; and

(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), (g), and (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), (g), and (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. (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 Diversion Control Division 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) of this section, 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, 1961, 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 Diversion Control Division 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 Diversion Control

Division 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 paragraphs (f)(1) through (4) and (6) of this section 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) through (4) and (6) of this section and paragraph (g)(2) are met with respect to each subsequent country from which the controlled substance is exported pursuant to this paragraph (g); and

(B) The conditions applicable with respect to the second country under paragraphs (f)(1) through (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 (g).

(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 Diversion Control Division 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), e-mail address(es), etc.) and business of the consignee; and the name/business name, address/business address, contact information (e.g., telephone number(s), e-mail 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; and

(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 Diversion Control Division 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), (g), and (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 5 business days 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 Diversion Control Division 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. In § 1312.23, revise paragraph (e) 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. A single export permit shall authorize a quantity of goods to be 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 commercial loading document; a single permit shall not authorize a quantity of goods to be exported if the goods are divided onto two or more conveyances. Each export permit shall be predicated upon, *inter alia*, an import certificate or other documentary evidence issued by a foreign competent national authority.

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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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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), e-mail 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), e-mail 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.

(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.

(iv) The name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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

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

(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 Diversion Control Division 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), e-mail 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--(1) 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 Diversion Control Division 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.

(2) *Return information for reexports outside of the European Economic Area--(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 Diversion Control Division 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.

(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 Diversion Control Division 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.

(3) *Reexports among members of the European Economic Area--(i) 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)(2)(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 exporter must file a report with the Administration through the DEA Diversion Control Division 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), e-mail address(es), etc.) and business of the consignee; and the name/business name, address/business address, contact information (e.g., telephone number(s), e-mail 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 Diversion Control Division 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 Diversion Control Division 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 paragraph (f) of this section.

(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 5 business days 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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:

a. Revise paragraph (b) introductory text;

b. In paragraph (d)(2), remove the word “and” at the end of the paragraph;

c. In paragraph (d)(3), remove the period at the end of the paragraph and add “; and” in its place; and

d. Add paragraph (d)(4).

The revision and addition 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, Diversion Control Division, 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.

* * * * *

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, Diversion Control Division, 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.

**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 and 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) 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 Diversion Control Division 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 Diversion Control Division 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, Diversion Control Division, 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), e-mail address(es), etc.) of the chemical importer; the name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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), e-mail 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), e-mail 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. For List I chemicals, 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 Diversion Control Division 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.

65. 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, 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 § 1313.12(a) or (d). Amended declarations must be submitted to the Administration through the DEA Diversion Control Division 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 Diversion Control Division secure network application specifying the particulars of the transaction. This report must include the following information: the date on which the listed chemical was released by a customs officer at the port of entry; the date on which the listed chemical arrived at the importer's registered location or place of business; the actual quantity of the listed chemical released; the actual quantity of the listed chemical that arrived at the importer's location; the date of any subsequent transfer; a description of the subsequent transfer, including the actual quantity transferred, chemical, container, and name of transferees; the actual port of entry; and any other information 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 Diversion Control Division 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 5 business days 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 Diversion Control Division 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 and 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) 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 Diversion Control Division 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 Diversion Control Division 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, Diversion Control Division, 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), e-mail address(es), etc.) of the chemical exporter; the

name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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), e-mail 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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 5 business days 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 Diversion Control Division 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 § 1313.21(b).

74. In § 1313.31, revise paragraphs (b) introductory text and (b)(7), (8), (14), and (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, Diversion Control Division, 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), e-mail 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), e-mail 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 Diversion Control Division 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 Diversion Control Division 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. In § 1313.33, revise the paragraphs (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), e-mail address(es), etc.) of the chemical exporter; the name/business name, address/business address, and contact information (e.g., telephone number(s), e-mail 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), e-mail 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 Diversion Control Division 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 Diversion Control Division 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 Diversion Control Division 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, Diversion Control Division”.

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.

82. In part 1315, remove “Drug & Chemical Evaluation Section, Drug Enforcement Administration” and “Drug & Chemical Evaluation Section” and add in their place “UN

Reporting & Quota Section, Diversion Control Division, Drug Enforcement Administration”.

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subpart D—Administrative Hearings

83. 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.

84. In § 1316.47, revise paragraph (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 Sir:

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)

* * * * *

85. 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 Sir:

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

86. The authority citation for part 1321 continues to read:

Authority: 21 U.S.C. 871(b).

87. 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
DEA Administrator	
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
DEA Diversion Control Division	
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. ²	Drug Enforcement Administration, Attn: Diversion Control Division/DC, 8701 Morrisette Drive, Springfield, VA 22152
DEA Regulatory Section	
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. ¹ 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. ¹ 1310.05(c)(1)—Reports of imports and exports of a tableting machine or an encapsulating machine. ¹	Drug Enforcement Administration, Attn: Regulatory Section/DRG, 8701 Morrisette Drive, Springfield, VA 22152

<p>1310.05(c)(2)—Report of declared exports of machines refused, rejected, or returned. 1312.12(a)—Application for import permit (DEA Form 357).¹ 1312.18(b)—Import declaration (DEA Form 236) submission.¹ 1312.22(g)(8)—Request for return of unacceptable or undeliverable exported controlled substances.¹ 1312.27(a)—Controlled substances export declaration (DEA Form 236) filing.¹ 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).¹ 1313.12(e)—Quarterly reports of listed chemicals importation. 1313.21(b)—Authorization to export listed chemicals (DEA Form 486).¹ 1313.21(e)—Quarterly reports of listed chemicals exportation. 1313.22(c)—Notice of declared exports of listed chemicals refused, rejected or undeliverable.¹ 1313.31(b)—Advanced notice of importation for transshipment or transfer of listed chemicals. 1313.32(b)(1)—International transaction authorization (DEA Form 486).¹ 1314.110(a)(1)—Reports for mail-order sales. 1314.110(a)(2)—Request to submit mail-order sales reports.</p>	
DEA Drug & Chemical Evaluation Section	
<p>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.</p>	<p>Drug Enforcement Administration, Attn: Drug & Chemical Evaluation Section/DRE, 8701 Morrisette Drive, Springfield, VA 22152</p>
UN Reporting & Quota Section	
<p>1303.12(b)—Application for controlled substances procurement quota (DEA Form 250) filing and request 1303.12(d)—Controlled substances quota adjustment request. 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. 1315.22—Application for individual manufacturing quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 189) filing and</p>	<p>Drug Enforcement Administration, Attn: UN Reporting & Quota Section/DRQ, 8701 Morrisette Drive, Springfield, VA 22152</p>

<p>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, and 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.</p>	
Pharmaceutical Investigations Section	
<p>1304.04(d)—ARCOS separate central reporting identifier request. 1304.33(a)—Reports to ARCOS.</p>	<p>Drug Enforcement Administration, Attn: ARCOS Unit/DOPT, P.O. Box 2520, Springfield, VA 22152-2520 OR Drug Enforcement Administration, Attn: ARCOS Unit, 8701 Morrisette Drive, Springfield, VA 22152</p>
DEA Registration Section	
<p>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. 1301.52(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.</p>	<p>Drug Enforcement Administration, Attn: Registration Section/DRR P.O. Box 2639, Springfield, VA 22152-2639</p>
DEA Hearing Clerk	
<p>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.</p>	<p>Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, VA 22152</p>
DEA Federal Register Representative	
<p>1301.33(a)—Filing of written comments regarding application for bulk manufacture of Schedule I and II substances.² 1301.34(a)—Filing of written comments regarding application for importation of Schedule I and II substances.² 1303.11(c)—Filing of written comments regarding notice of an aggregate production quota.² 1303.13(c)—Filing of written comments regarding adjustments of aggregate production quotas.² 1303.13(c)—Filing of written comments regarding adjustments of aggregate production quotas.² 1308.43(g)—Filing of written comments regarding initiation of proceedings for rulemaking.²</p>	<p>http://www.regulations.gov/ Drug Enforcement Administration, Attn: Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, VA 22152</p>

¹ Applications/filings/reports are required to be filed electronically in accordance with this chapter.
² Applications/filings/reports may be filed electronically in accordance with this chapter.

Date: November 28, 2016.

Chuck Rosenberg,
Acting Administrator.

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