process electronic prescriptions that require the additional information.

### § 1311.302 Additional application provider requirements.

(a) If an application provider identifies or is made aware of any issue with its application that make the application non-compliant with the requirements of this part, the application provider must notify practitioners or pharmacies that use the application as soon as feasible, but no later than five business days after discovery, that the application should not be used to issue or process electronic controlled substance prescriptions.

(b) When providing practitioners or pharmacies with updates to any issue that makes the application non-compliant with the requirements of this part, the application provider must indicate that the updates must be installed before the practitioner or pharmacy may use the application to issue or process electronic controlled substance prescriptions.

### § 1311.305 Recordkeeping.

(a) If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.

(b) Records required by this subpart must be maintained electronically for two years from the date of their creation or receipt. This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.

(c) Records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

(d) Records required by this part must be made available to the Administration upon request.

(e) If an application service provider ceases to provide an electronic prescription application or an electronic pharmacy application or if a registrant ceases to use an application service provider, the application service provider must transfer any records subject to this part to the registrant in a format that the registrant's applications are capable of retrieving, displaying, and printing in a readable format.

(f) If a registrant changes application providers, the registrant must ensure that any records subject to this part are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(g) If a registrant transfers its electronic prescription files to another registrant, both registrants must ensure that the records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(h) Digitally signed prescription records must be transferred or migrated with the digital signature.

## PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

Sec.

AUTHORITY: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

SOURCE: 36 FR 7815, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

### § 1312.01 Scope of part 1312.

Procedures governing the importation, exportation, transshipment and intransit shipment of controlled substances pursuant to section 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are governed generally by those sections and specifically by the sections of this part.

### § 1312.02 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 part 1300 of this chapter.

[62 FR 13969, Mar. 24, 1997]

### § 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. |

[81 FR 97025, Dec. 30, 2016]

## IMPORTATION OF CONTROLLED SUBSTANCES

### § 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.

[81 FR 97026, Dec. 30, 2016]

### § 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), email address(es), etc.), and business of the consignor, if known at the time the application is submitted, but if unknown at that time, the fact should be indicated and the name and address afterwards furnished to the Administration as soon as ascertained by the importer;

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

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

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

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

(6) The name of the importing carrier or vessel (if known), or if unknown it should be stated whether the shipment will be made by express, freight, or otherwise, imports of controlled substances in Schedules I or II and narcotic drugs in Schedules III, IV, or V by mail being prohibited);

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

[81 FR 97026, Dec. 30, 2016]

### § 1312.13 Issuance of import permit.

(a) The Administrator may authorize importation of any controlled substance listed in Schedule I or II or any narcotic drug listed in Schedule III, IV, or V if he finds:

(1) That the substance is crude opium, poppy straw, concentrate of poppy straw, or coca leaves, in such quantity as the Administrator finds necessary to provide for medical, scientific, or other legitimate purposes;

(2) That the substance is necessary to provide for medical and scientific needs or other legitimate needs of the United States during an emergency where domestic supplies of such substance or drug are found to be inadequate, or in any case in which the Administrator finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Controlled Substances Act (21 U.S.C. 823); or

(3) That the domestic supply of any controlled substance is inadequate for scientific studies, and that the importation of that substance for scientific purposes is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

(4) That the importation of the controlled substance is for ballistics or other analytical or scientific purposes, and that the importation of that substance is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

(b) The Administrator may require that such non-narcotic controlled substances in Schedule III as he shall designate by regulation in §1312.30 of this part be imported only pursuant to the issuance of an import permit. The Administrator may authorize the importation of such substances if he finds that the substance is being imported for medical, scientific or other legitimate uses.

(c) If a non-narcotic substance listed in Schedule IV or V is also listed in Schedule I or II of the Convention on Psychotropic Substances, 1971, it shall be imported only pursuant to the issuance of an import permit. The Administrator may authorize the importation of such substances if it is found that the substance is being imported for medical, scientific or other legitimate uses.

(d) The Administrator may require an applicant to submit such documents or written statements of fact relevant

to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(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.

(f) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the Administrator shall permit, pursuant to section 1002(a)(1) or 1002(a)(2)(A) of the Act (21 U.S.C. 952(a)(1) or (a)(2)(A)), the importation of approved narcotic raw material (opium, poppy straw and concentrate of poppy straw) having as its source:

(1) Turkey,
(2) India,
(3) Spain,
(4) France,
(5) Poland,
(6) Hungary, and
(7) Australia.

(g) At least eighty (80) percent of the narcotic raw material imported into the United States shall have as its original source Turkey and India. Except under conditions of insufficient supplies of narcotic raw materials, not more than twenty (20) percent of the narcotic raw material imported into the United States annually shall have as its source Spain, France, Poland, Hungary and Australia.

[36 FR 23624, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 41776, Aug. 18, 1981; 52 FR 17289, May 7, 1987; 73 FR 6851, Feb. 6, 2008; 81 FR 97027, Dec. 30, 2016]

### § 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 county). 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).

[81 FR 97027, Dec. 30, 2016]

### § 1312.15 Shipments in greater or less amount than authorized.

(a) If the shipment made under an import permit is greater than the maximum amount authorized to be imported under the permit, as determined at the weighing by the District Director of the U.S. Customs and Border Protection or customs service of an Insular Area, such difference shall be seized subject to forfeiture, pending an explanation; except that shipments of substances exceeding the maximum authorized amount by less than 1 percent may be released to the importer upon the filing by him of an amended import permit in accordance with §1312.16(a). If the substance is included in Schedule I, it will be summarily forfeited to the Government.

(b) If the shipment made under the permit is less than the maximum amount authorized to be imported under the permit as determined at the weighing by the District Director of the U.S. Customs and Border Protection or customs service of an Insular Area, such difference, when ascertained by the Administration, shall be recredited to the tentative allotment against which the quantity covered by the permit was charged, and the balance of any such tentative allotment with any such recredits will remain available to the importer to whom made (unless previously revoked in whole or in part), for importations pursuant to any permit or permits as are requested and issued during the remainder of the calendar year to which the allotment is applicable. No permit shall be issued for importation of a quantity of controlled substances as a charge against the tentative allotment for a given calendar year, after the close of such calendar year, unless the Administrator decides to make an exception for good cause shown.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 81 FR 97027, Dec. 30, 2016]

### § 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.

[81 FR 97027, Dec. 30, 2016]

### §1312.17 Special report from importers.

Whenever requested by the Administrator, importers shall render to him not later than 30 days after receipt of the request therefor a statement under oath of the stocks of controlled substances on hand as of the date specified by the Administrator in his request, and, if desired by the Administrator, an estimate of the probable requirements for legitimate uses of the importer for any subsequent period that may be designated by the Administrator. In lieu of any special statement that may be considered necessary, the Administrator may accept the figures given upon the reports subsequent by said importer under part 1304 of this chapter.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13969, Mar. 24, 1997]

### §1312.18 Import declaration.

(a) Any non-narcotic controlled substance listed in Schedule III, IV, or V, not subject to the requirement of an import permit pursuant to §1312.13 (b) or (c) of this chapter, may be imported if that substance is needed for medical, scientific or other legitimate uses in the United States, and will be imported

pursuant to a controlled substances 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:

(1) The name, address, and registration number of the importer; and the name and address and registration number of the import broker, if any; and

(2) A complete description of the controlled substances to be imported, including drug name, dosage form, National Drug Code (NDC) number, the Administration Controlled Substances Code Number as set forth in part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the net quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof; and

(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

(4) The name and address of the consignor in the foreign country of exportation, and any registration or license numbers if the consignor is required to have such numbers either by the country of exportation or under U.S. law.

(d) Notwithstanding the time limitations included in paragraph (b) of this section, an applicant may obtain a special waiver of these time limitations in emergency or unusual instances, provided that a specific confirmation is received from the Administrator or his delegate advising the registrant to proceed pursuant to the special waiver.

(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.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 52 FR 17290, May 7, 1987; 62 FR 13969, Mar. 24, 1997; 75 FR 10682, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012; 81 FR 97028, Dec. 30, 2016]

### § 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.

[81 FR 97029, Dec. 30, 2016]

EXPORTATION OF CONTROLLED SUBSTANCES

### § 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.

[81 FR 97029, Dec. 30, 2016]

### § 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), email address (es), etc.);

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

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

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

otherwise), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued; 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), email address(es), etc.) and business of the consignee; and the name/business name, address/business address, contact information (*e.g.*, telephone number(s), email address(es), etc.) and business of the exporter. Upon receipt and review, the Administration will assign each completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

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

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

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

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

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

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

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

[81 FR 97029, Dec. 30, 2016]

### § 1312.23 Issuance of export permit.

(a) The Administrator may authorize exportation of any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III or IV if he finds that such exportation is permitted by subsections 1003(a), (b), (c), (d), or (f) of the Act (21 U.S.C. 953(a), (b), (c), (d), or (f).

(b) The Administrator may require that such non-narcotic controlled substances in Schedule III as shall be designated by regulation in §1312.30 of this part be exported only pursuant to the issuance of an export permit. The Administrator may authorize the exportation of such substances if he finds that such exportation is permitted by section 1003(e) of the Act (21 U.S.C. 953(e)).

(c) If a non-narcotic substance listed in Schedule IV or V is also listed in Schedule I or II of the Convention on Psychotropic Substances, it shall be exported only pursuant to the issuance of an export permit. The Administrator may authorize the exportation of such substances if he finds that such exportation is permitted by section 1003(e) of the Act (21 U.S.C. 953(e)).

(d) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(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.

(f) No export permit shall be issued for the exportation, or reexportation, of any controlled substance to any country when the Administration has information to show that the estimates or assessments submitted with respect to that country for the current period, under the Single Convention on Narcotic Drugs, 1961, or the Convention on Psychotropic Substances, 1971, have been, or, considering the quantity proposed to be imported, will be exceeded. If it shall appear through subsequent advice received from the International Narcotics Control Board of the United Nations that the estimates or assessments of the country of destination have been adjusted to permit further importation of the controlled substance, an export permit may then be issued if otherwise permissible.

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 72 FR 72929, Dec. 26, 2007; 81 FR 97032, Dec. 30, 2016]

### § 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.

[81 FR 97032, Dec. 30, 2016]

### § 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.

[81 FR 97032, Dec. 30, 2016]

### §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.

[81 FR 97033, Dec. 30, 2016]

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

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

(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), email address(es), etc.) of the consignee in the country of destination, and any registration or license number if the consignee is required to have such numbers either by the country of destination or under United States law. In addition, documentation must be provided to show that:

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

(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), email address(es) and business of the consignee in the first country).

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

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

(c) Notwithstanding the time limitations included in paragraph (a) of this

section, a registrant may obtain a special waiver of these time limitations in emergency or unusual instances; provided that a specific confirmation is received from the Administrator or his delegate advising the registrant to proceed pursuant to the special waiver.

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

(e) An exporter may amend an export declaration in the same circumstances in which an exporter may request amendment to an export permit, as set forth in §1312.25(a)(1) through (7). Amendments to declarations must be submitted through the DEA 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.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 52 FR 17290, May 7, 1987; 62 FR 13969, Mar. 24, 1997; 75 FR 10683, Mar. 9, 2010; 81 FR 97033, Dec. 30, 2016]

### §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.

[81 FR 97035, Dec. 30, 2016]

### § 1312.29 Domestic release prohibited.

An exporter or a forwarding agent acting for an exporter must either deliver the controlled substances to the port or border, or deliver the controlled substances to a bonded carrier approved by the consignor for delivery to the port or border, and may not, under any other circumstances, release a shipment of controlled substances to anyone, including the foreign consignee or his agent, within the United States.

### § 1312.30 Schedule III, IV, and V nonnarcotic controlled substances requiring an import and export permit.

The following Schedule III, IV, and V non-narcotic controlled substances have been specifically designated by the Administrator of the Drug Enforcement Administration as requiring import and export permits pursuant to sections 201(d)(1), 1002(b)(2), and 1003(e)(3) of the Act (21 U.S.C. 811(d)(1), 952(b)(2), and 953(e)(3)):

(a) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product.

(b) [Reserved]

[52 FR 17291, May 7, 1987, as amended at 64 FR 35930, July 2, 1999; 83 FR 48953, Sept. 28, 2018; 85 FR 51645, Aug. 21, 2020]

## TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

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

(a) A controlled substance listed in schedule I may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that:

(1) The controlled substance is necessary for scientific, medical, or other legitimate purposes in the country of destination, and

(2) A transshipment permit has been issued by the Administrator.

(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:

(1) The date of execution;

(2) The identification and description of the controlled substance;

(3) The net quantity thereof;

(4) The number and size of the controlled substance containers;

(5) The name, address, and business of the foreign exporter;

(6) The foreign port of exportation;

(7) The approximate date of exportation;

(8) The identification of the exporting carrier;

(9) The name, address and business of the importer, transferor, or transshipper;

(10) The registration number, if any, of the importer, transferor or transshipper;

(11) The U.S. port of entry;

(12) The approximate date of entry;

(13) The name, address and business of the consignee at the foreign port of entry;

(14) The shipping route from the U.S. port of exportation to the foreign port of entry;

(15) The approximate date of receipt by the consignee at the foreign port of entry; and

(16) The signature of the importer, transferor or transshipper, or his agent accompanied by the agent's title.

(c) An application shall be accompanied by an export license, permit, or a certified copy of the export license, permit, or other authorization, issued by a competent authority of the country of origin (or other documentary evidence deemed adequate by the Administrator).

(d) An application shall be accompanied by an import license or permit or a certified copy of such license or permit issued by a competent authority of the country of destination (or other documentary evidence deemed adequate by the Administrator), indicating that the controlled substance:

(1) Is to be applied exclusively to scientific, medical or other legitimate uses within the country of destination;

(2) Will not be exported from such country;

(3) Is needed therein because there is an actual shortage thereof and a demand therefor for scientific, medical or other legitimate uses within such country; and

(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.

(e) Verification by an American consular officer of the signatures on a foreign import license or permit shall be required, if such license or permit does not bear the seal of the authority signing them.

(f) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(g) The Administrator shall, within 21 days from the date of receipt of the application, either grant or deny the application. The applicant shall be accorded an opportunity to amend the application, with the Administrator either granting or denying the amended application within 7 days of its receipt. If the Administrator does not grant or deny the application within 21 days of its receipt, or in the case of an amended application, within 7 days of its receipt, the application shall be deemed approved and the applicant may proceed.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and further amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10683, Mar. 9, 2010; 81 FR 97035, Dec. 30, 2016]

### § 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.

[81 FR 97036, Dec. 30, 2016]

HEARINGS

### § 1312.41 Hearings generally.

(a) In any case where the Administrator shall hold a hearing regarding the denial of an application for an import, export or transshipment permit, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 1002 and 1003 of the Act (21 U.S.C. 952 and 953), by §§1312.42–1312.47, and by the procedures for administrative hearings under the Act set forth in §§1316.41–1316.67 of this chapter.

(b) [Reserved]

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1312.42 Purpose of hearing.

(a) If requested by a person applying for an import, export, or transshipment permit, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance or denial of such permit to such person.

(b) Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1312.43 Waiver or modification of rules.

The Administrator of the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

[36 FR 23625, Dec. 11, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1312.44 Request for hearing or appearance; waiver.

(a) Any applicant entitled to a hearing pursuant to §1312.42 and who desires a hearing on the denial of his application for an import, export, or transshipment permit shall, within 30 days after the date of receipt of the denial of his application, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any applicant entitled to a hearing pursuant to §1312.42 may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(c) If any applicant entitled to a hearing pursuant to §1312.42 fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing unless he shows good cause for such failure.

(d) If the applicant waives or is deemed to have waived this opportunity for the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to §1312.47 without a hearing.

[37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1312.45 Burden of proof.

At any hearing on the denial of an application for an import, export, or transshipment permit, the Administrator shall have the burden of proving that the requirements for such permit pursuant to sections 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are not satisfied.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1312.46 Time and place of hearing.

(a) If any applicant for an import, export, or transshipment permit requests a hearing on the issuance or denial of

his application, the Administrator shall hold such hearing. Notice of the hearing shall be given to the applicant of the time and place at least 30 days prior to the hearing, unless the applicant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1312.47 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the issuance or denial of the application for and import, export, or transshipment permit. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon the applicant.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

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

Sec.



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

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

### § 1313.01 Scope.

Procedures governing the importation, exportation, transshipment and in-transit shipment of listed chemicals pursuant to section 1018 of the Act (21 U.S.C. 971) are governed generally by that section and specifically by the sections of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995]

### § 1313.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13969, Mar. 24, 1997]