§ 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]