PART 1312 — IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

EXPORTATION OF CONTROLLED SUBSTANCES

§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.

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