Drug Enforcement Administration, Justice

1312.30 Schedule III, IV, and V non-narcotic controlled substances requiring an import and export permit.

TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

1312.31 Schedule I: Application for prior written approval.

1312.32 Schedules II, III, IV: Advance notice.

HEARINGS

1312.41 Hearings generally.

1312.42 Purpose of hearing.

1312.43 Waiver or modification of rules.

1312.44 Request for hearing or appearance; waiver.

1312.45 Burden of proof.

1312.46 Time and place of hearing.

1312.47 Final order.

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.

 $[62\;\mathrm{FR}\;13969,\,\mathrm{Mar}.\;24,\,1997]$

§1312.03 Forms applicable to this part.

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

 $[81 \; \mathrm{FR} \; 97025, \, \mathrm{Dec.} \; 30, \, 2016]$

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.

§ 1312.12

(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;
- (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