(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.

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§ 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