

PART 1312 — IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

IMPORTATION OF CONTROLLED SUBSTANCES

§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

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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]