(3) An importer may request that an import permit or application for a permit be amended to change the justification provided as to why an import shipment is needed to meet the legitimate scientific or medical needs of the United States.

(4) An importer may request that an import permit or application for a permit be amended to change any registrant notes.

(5) Prior to departure of the shipment from its original foreign location, an importer may request that an import permit or application for a permit be amended to increase the total base weight of a controlled substance. At the U.S. port of entry, an importer may request that an import permit be amended in accordance with §1312.15(a). Importers are not required to amend an import permit for the sole purpose of decreasing the total base weight of a controlled substance authorized to be imported. However, the balance of any unimported authorized quantity of controlled substances on an import permit is void upon entry of a shipment on the issued permit or upon expiration of the unused permit in accordance with paragraph (b) of this section, whichever is sooner. Other than for an amendment to an import permit under §1312.15(a), importers must submit a request for an amendment to increase the total base weight of a controlled substance at least three business days in advance of the date of release by a customs officer.

(6) An importer may request that an import permit be amended to remove a controlled substance from the permit. However, an importer may not amend an import permit to add or replace a controlled substance/Administration controlled substance code number to the item(s) to be imported. Importers who desire to import a different controlled substance than that contained on their issued import permit or permit application must submit a request for the permit or permit application to be canceled and request a new permit in accordance with §1312.12.

(7) An importer may not amend the importer's name (as it appears on their DEA certificate of registration) or the name of the foreign exporter as provided in the DEA Form 357. Importers who need to make any changes to any of these fields must submit a request for the permit or permit application to be canceled and request a new permit in accordance with §1312.12.

(b) An import permit will be void and of no effect after the expiration date specified therein, and in no event will the date be more than 180 calendar days after the date the permit is issued. Amended import permits will retain the original expiration date.

(c) An import permit may be canceled after being issued, at the request of the importer submitted to the Administration through the DEA Diversion Control Division secure network application, provided that no shipment has been made thereunder.

Nothing in this part will affect the right, hereby reserved by the Administration, to cancel a permit at any time for proper cause.

[81 FR 97027, Dec. 30, 2016]

§1312.17 Special report from importers.

Whenever requested by the Administrator, importers shall render to him not later than 30 days after receipt of the request therefor a statement under oath of the stocks of controlled substances on hand as of the date specified by the Administrator in his request, and, if desired by the Administrator, an estimate of the probable requirements for legitimate uses of the importer for any subsequent period that may be designated by the Administrator. In lieu of any special statement that may be considered necessary, the Administrator may accept the figures given upon the reports subsequent by said importer under part 1304 of this chapter.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13969, Mar. 24, 1997]

§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 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]

§ 1312.19 Distribution of import declaration.

The importer must furnish an official record of the declaration (available through the DEA Diversion Control Division secure network application after the Administration issues a transaction identification number) to the foreign shipper. The foreign shipper must submit an official record of the declaration to the competent national authority of the exporting country, if required as a prerequisite to export authorization. The importer, or their agent, must submit an official record of the declaration and/or required data concerning the import transaction to a customs officer at the port of entry in compliance with all import control requirements of agencies with import control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. The importer must ensure that an official record of the declaration accompanies the shipment to its final destination, which must only be the registered location of the importer (*i.e.*, drop shipments are prohibited). The importer must maintain an official record of the declaration in accordance with part 1304 of this chapter.

[81 FR 97029, Dec. 30, 2016]