

§ 1312.16

previously revoked in whole or in part), for importations pursuant to any permit or permits as are requested and issued during the remainder of the calendar year to which the allotment is applicable. No permit shall be issued for importation of a quantity of controlled substances as a charge against the tentative allotment for a given calendar year, after the close of such calendar year, unless the Administrator decides to make an exception for good cause shown.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 81 FR 97027, Dec. 30, 2016]

§ 1312.16 Amendment, cancellation, expiration of import permit.

(a) Importers may only request that an import permit or application for an import permit be amended in accordance with paragraphs (a)(1) through (7) of this section. Requests for an amendment must be submitted through the DEA Diversion Control Division secure network application. Except as provided in paragraph (a)(5) of this section and § 1312.15(a), importers must submit all requests for an amendment at least one full business day in advance of the date of release by a customs officer. Importers must specifically request that an amendment be made; supplementary information submitted by an importer through the DEA Diversion Control Division secure network application will not automatically trigger the amendment process. While the request for an amendment is being reviewed by the Administration, the original permit will be temporarily stayed and may not be used to authorize entry of a shipment of controlled substances. If the importer's request for an amendment to an issued permit is granted by the Administration, the Administration will immediately cancel the original permit and re-issue the permit, as amended, with a revised permit number. The DEA and importer will distribute the amended permit in accordance with § 1312.14. If a request for an amendment is denied by the Administration, the temporary stay will be lifted; once lifted, the originally issued permit may immediately be used to authorize entry of a shipment

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in accordance with the terms of the permit, subject to the shipment being compliant with all other applicable laws.

(1) An importer may request that an import permit or application for a permit be amended to change the National Drug Control number, description of the packaging, or trade name of the product, so long as the description is for the same basic class of controlled substance as in the original permit.

(2) An importer may request that an import permit or application for a permit be amended to change the proposed port of entry, the date of release by a customs officer, or the method of transport.

(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