https://www.deadiversion.usdoj.gov/21cfr/cfr/1312/1312 16.htm

Extracted by GlobalMSDS Ltd 8 January 2019

PART 1312 — IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

IMPORTATION OF CONTROLLED SUBSTANCES

§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 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.

https://www.deadiversion.usdoj.gov/21cfr/cfr/1312/1312 16.htm

Extracted by GlobalMSDS Ltd

8 January 2019

- (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]