https://www.deadiversion.usdoj.gov/21cfr/cfr/1312/1312 25.htm

Extracted by GlobalMSDS Ltd 8 January 2019

PART 1312 — IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

EXPORTATION OF CONTROLLED SUBSTANCES

§1312.25 Amendment, cancellation, expiration of export permit.

- (a) Exporters may only request that an export permit or application for an export 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 exporters must submit all requests for an amendment at least one full business day in advance of the date of release from the port of export. Exporters must specifically request that an amendment be made; supplementary information submitted by an exporter 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 release of a shipment of controlled substances. If the exporter'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 exporter will distribute the amended permit in accordance with §1312.24. 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 release of a shipment in accordance with the terms of the permit.
- (1) An exporter may request that an export 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 exporter may request that an export permit or application for a permit be amended to change the proposed port of export, the anticipated date of release by a customs officer, or the method of transport.
- (3) An exporter may request that an export permit or application for a permit be amended to change the justification provided as to why an export shipment is needed to meet the legitimate scientific or medical needs of the country of import.
- (4) An exporter may request that an export permit or application for a permit be amended to change any registrant notes.
- (5) Prior to departure of the shipment from the exporter's registered location, an exporter may request that an export permit or application for a permit be amended to increase the total base weight of a controlled substance. However, the total base weight or the strength of the product (if listed) of a controlled substance may not exceed that permitted for import as indicated on the import permit from the foreign competent national authority. Exporters are not required to amend an export permit for the sole purpose of decreasing the total base weight of a controlled substance authorized to be exported. However, the balance of any unexported authorized quantity of controlled substances on an export permit is void upon release 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. Exporters 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 from the port of export.
- (6) An exporter may request that an export permit be amended to remove a controlled substance from the permit. However, an exporter may not amend an export permit to add or replace a controlled substance to the item(s) to be exported. Exporters who desire to export a different controlled substance than that contained on their issued export 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 §1312.22.
- (7) An exporter may not amend the exporter's name (as it appears on their DEA certificate of registration), the name of the foreign importer(s), or the foreign permit information as provided in the DEA Form 161, 161R, or 161R-EEA. Exporters 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 §1312.22.
- (b) An export permit will be void and of no effect after the date specified therein, which date must conform to the expiration date specified in the supporting import certificate or other

https://www.deadiversion.usdoj.gov/21cfr/cfr/1312/1312 25.htm

Extracted by GlobalMSDS Ltd

8 January 2019

documentary evidence upon which the export permit is founded, but in no event will the date be more than 180 calendar days after the date the permit is issued.

(c) An export permit may be canceled after being issued, at the request of the exporter 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 an export permit at any time for proper cause.

[81 FR 97032, Dec. 30, 2016]