

## § 1312.24

Nations that the estimates or assessments of the country of destination have been adjusted to permit further importation of the controlled substance, an export permit may then be issued if otherwise permissible.

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 72 FR 72929, Dec. 26, 2007; 81 FR 97032, Dec. 30, 2016]

### § 1312.24 Distribution of export permit.

The Administration shall transmit the export permit to the competent national authority of the importing country and shall make available to the exporter an official record of the export permit through secure electronic means. The exporter, or their agent, must submit an official record of the export permit and/or required data concerning the export transaction to a customs officer at the port of export in compliance with all export control requirements of agencies with export control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. The exporter must maintain an official record of the export permit (available from the secure network application on the DEA Diversion Control Division Web site after the Administration issues a transaction identification number) in accordance with part 1304 of this chapter as the record of authority for the exportation and shall transmit an official record of the export permit to the foreign importer. The exporter must ensure that an official record of the permit accompanies the shipment to its final destination. No shipment of controlled substances denied release for any reason shall be allowed to be released from the United States without subsequent authorization from the Administration.

[81 FR 97032, Dec. 30, 2016]

### § 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

## 21 CFR Ch. II (4-1-21 Edition)

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 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]

#### § 1312.26 Records required of exporter.

In addition to any other records required by this chapter, the exporter must keep a record of any serial numbers that might appear on packages of narcotic drugs in quantities of one ounce or more in such a manner as will identify the foreign consignee, along with an official record of the export permit, in accordance with part 1304 of this chapter.

[81 FR 97033, Dec. 30, 2016]

#### § 1312.27 Export/reexport declaration.

(a) Any person registered or authorized to export and seeking to export any non-narcotic controlled substance listed in Schedule III, IV, or V, which is not subject to the requirement of an export permit pursuant to § 1312.23(b) or (c), or any person registered or authorized to export and seeking to export any controlled substance in Schedule V, must file a controlled substances export declaration (DEA Form 236) with the Administration through the DEA Diversion Control Division secure network application not less than 15 calendar days prior to the anticipated date of release by a customs officer at the port of export, and distribute an official record of the declaration as hereinafter directed in § 1312.28. The declaration must be signed and dated by the exporter and must contain the address of the registered location from which the substances will be shipped for exportation. Upon receipt and review, the Administration will issue a