

§ 1312.30

21 CFR Ch. II (4–1–21 Edition)

§ 1312.30 Schedule III, IV, and V non-narcotic controlled substances requiring an import and export permit.

The following Schedule III, IV, and V non-narcotic controlled substances have been specifically designated by the Administrator of the Drug Enforcement Administration as requiring import and export permits pursuant to sections 201(d)(1), 1002(b)(2), and 1003(e)(3) of the Act (21 U.S.C. 811(d)(1), 952(b)(2), and 953(e)(3)):

(a) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product.

(b) [Reserved]

[52 FR 17291, May 7, 1987, as amended at 64 FR 35930, July 2, 1999; 83 FR 48953, Sept. 28, 2018; 85 FR 51645, Aug. 21, 2020]

TRANSSHIPMENT AND IN-TRANSIT
SHIPMENT OF CONTROLLED SUBSTANCES

§ 1312.31 Schedule I: Application for prior written approval.

(a) A controlled substance listed in schedule I may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that:

(1) The controlled substance is necessary for scientific, medical, or other legitimate purposes in the country of destination, and

(2) A transshipment permit has been issued by the Administrator.

(b) An application for a transshipment permit must be submitted to the Regulatory Section, Diversion Control Division, Drug Enforcement Administration, at least 30 calendar days, or in the case of an emergency as soon as is practicable, prior to the expected date of arrival at the first port in the United States. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. A separate permit is required for each shipment of controlled substance to be imported, transferred, or transshipped. Each application must contain the following:

- (1) The date of execution;
- (2) The identification and description of the controlled substance;
- (3) The net quantity thereof;

(4) The number and size of the controlled substance containers;

(5) The name, address, and business of the foreign exporter;

(6) The foreign port of exportation;

(7) The approximate date of exportation;

(8) The identification of the exporting carrier;

(9) The name, address and business of the importer, transferor, or transshipper;

(10) The registration number, if any, of the importer, transferor or transshipper;

(11) The U.S. port of entry;

(12) The approximate date of entry;

(13) The name, address and business of the consignee at the foreign port of entry;

(14) The shipping route from the U.S. port of exportation to the foreign port of entry;

(15) The approximate date of receipt by the consignee at the foreign port of entry; and

(16) The signature of the importer, transferor or transshipper, or his agent accompanied by the agent's title.

(c) An application shall be accompanied by an export license, permit, or a certified copy of the export license, permit, or other authorization, issued by a competent authority of the country of origin (or other documentary evidence deemed adequate by the Administrator).

(d) An application shall be accompanied by an import license or permit or a certified copy of such license or permit issued by a competent authority of the country of destination (or other documentary evidence deemed adequate by the Administrator), indicating that the controlled substance:

(1) Is to be applied exclusively to scientific, medical or other legitimate uses within the country of destination;

(2) Will not be exported from such country;

(3) Is needed therein because there is an actual shortage thereof and a demand therefor for scientific, medical or other legitimate uses within such country; and

(4) If the import license or permit, or the certified copy of such, is not written in English or bilingual with another language and English, the application must include a certified translation of the permit or license. For purposes of this requirement, certified translation means that the translator has signed the translation legally attesting the accuracy of the translation.

(e) Verification by an American consular officer of the signatures on a foreign import license or permit shall be required, if such license or permit does not bear the seal of the authority signing them.

(f) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(g) The Administrator shall, within 21 days from the date of receipt of the application, either grant or deny the application. The applicant shall be accorded an opportunity to amend the application, with the Administrator either granting or denying the amended application within 7 days of its receipt. If the Administrator does not grant or deny the application within 21 days of its receipt, or in the case of an amended application, within 7 days of its receipt, the application shall be deemed approved and the applicant may proceed.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and further amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10683, Mar. 9, 2010; 81 FR 97035, Dec. 30, 2016]

§ 1312.32 Schedules II, III, IV: Advance notice.

(a) A controlled substance listed in Schedules II, III, or IV may be imported into the United States for transshipment, or may be transferred or

transshipped within the United States for immediate exportation, provided that written notice is submitted to the Regulatory Section, Diversion Control Division, Drug Enforcement Administration, at least 15 calendar days prior to the expected date of date of arrival at the first port in the United States. See the Table of DEA mailing Addresses in §1321.01 of this chapter for the current mailing addresses.

(b) A separate advance notice is required for each shipment of controlled substance to be imported, transferred, or transshipped. Each advance notice must contain those items required by §1312.31(b) and (c). If the export license, permit, or other authorization, issued by a competent national authority of the country of origin, is not written in English or bilingual with another language and English, the notice must be accompanied by a certified translation of the export license, permit, or other authorization. For purposes of this requirement, certified translation means that the translator has signed the translation legally attesting the accuracy of the translation.

[81 FR 97036, Dec. 30, 2016]

HEARINGS

§ 1312.41 Hearings generally.

(a) In any case where the Administrator shall hold a hearing regarding the denial of an application for an import, export or transshipment permit, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 1002 and 1003 of the Act (21 U.S.C. 952 and 953), by §§1312.42–1312.47, and by the procedures for administrative hearings under the Act set forth in §§1316.41–1316.67 of this chapter.

(b) [Reserved]

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1312.42 Purpose of hearing.

(a) If requested by a person applying for an import, export, or transshipment permit, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues