

Drug Enforcement Administration, Justice

§ 1307.12

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1307.01 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13966, Mar. 24, 1997]

§ 1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

[62 FR 13966, Mar. 24, 1997]

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.

[62 FR 13966, Mar. 24, 1997]

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 1307.11 Distribution by dispenser to another practitioner.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the

purpose of general dispensing by the practitioner to his or its patients: Provided, That:

(1) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(2) The distribution is recorded by the distributing practitioner in accordance with §1304.22(c) of this chapter and by the receiving practitioner in accordance with §1304.22(c) of this chapter;

(3) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter;

(4) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and §1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to this section and §1301.25 of this chapter will exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

[36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 31590, Aug. 5, 1985; 62 FR 13967, Mar. 24, 1997]

§ 1307.12 Distribution to supplier.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form, and quantity of the substance, the name, address, and registration number, if

§ 1307.13

any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Act (21 U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

(b) Distributions referred to in paragraph (a) may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

[65 FR 44679, July 19, 2000; 65 FR 45829, July 25, 2000]

§ 1307.13 Incidental manufacture of controlled substances.

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter (if such substance or class is listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to part 1301 of this chapter and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to part 1303 of this chapter, if such substances are disposed of in accordance with § 1307.21.

[36 FR 7801, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13967, Mar. 24, 1997]

21 CFR Ch. II (4-1-03 Edition)

DISPOSAL OF CONTROLLED SUBSTANCES

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant