AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

SOURCE: 36 FR 7778, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1301.01 Scope of this part 1301.

Procedures governing the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances pursuant to sections 301–304 and 1007–1008 of the Act (21 U.S.C. 821–824 and 957–958) are set forth generally by those sections and specifically by the sections of this part.

[62 FR 13945, Mar. 24, 1997]

§ 1301.02 Definitions.

Any term used 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 13945, Mar. 24, 1997]

§ 1301.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

[75 FR 10676, Mar. 9, 2010]

REGISTRATION

§ 1301.11 Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

(b) As provided in sections 303(f) and 401(h) of the Act (21 U.S.C. 823(f) and 841(h)), it is unlawful for any person who falls within the definition of ''online pharmacy'' (as set forth in section 102(52) of the Act (21 U.S.C. 802(52)) and §1300.04(h) of this chapter) to deliver, distribute, or dispense a controlled substance by means of the Internet if such person is not validly registered with a modification of such registration authorizing such activity (unless such person is exempt from such modified registration requirement under the Act or this chapter). The Act further provides that the Administrator may only issue such modification of registration to a person who is registered as a pharmacy under section 303(f) of the Act (21 U.S.C. 823(f)). Accordingly, any pharmacy registered pursuant to §1301.13 of this part that falls within the definition of an online pharmacy and proposes to dispense controlled substances by means of the Internet must obtain a modification of its registration authorizing such activity following the submission of an application in accordance with §1301.19 of this part. This requirement does not apply to a registered pharmacy that does not fall within the definition of an online pharmacy set forth in §1300.04(h). Under the Act, persons other than registered pharmacies are not eligible to obtain such a modification of registration but remain liable under section 401(h) of the Act (21 U.S.C. 841(h)) if they deliver, distribute, or dispense a controlled substance while acting as an online pharmacy without being validly registered with a modification authorizing such activity.

[74 FR 15621, Apr. 6, 2009]

§1301.12 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) or subsection 1007(b)(1)(B) of the Act (21 U.S.C. 822(c)(2) or 957(b)(1)(B));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location in the same State in which he or she practices) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

(4) A freight forwarding facility, as defined in §1300.01 of this part, provided that the distributing registrant operating the facility has submitted written notice of intent to operate the facility by registered mail, return receipt requested (or other suitable means of documented delivery) and such notice has been approved. The notice shall be submitted to the Special Agent in Charge of the Administration's offices in both the area in which the facility is located and each area in which the distributing registrant maintains a registered location that will transfer controlled substances through the facility. The notice shall detail the registered locations that will utilize the facility, the location of the facility, the hours of operation, the individual(s) responsible for the controlled substances, the security and recordkeeping procedures that will be employed, and whether controlled substances returns will be processed through the facility. The notice must also detail what state licensing requirements apply to the facility and the registrant's actions to comply with