

of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(29) The term *retail distributor* means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine, or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. For the purposes of this paragraph, sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual for legitimate medical use. Also for the purposes of this paragraph, a grocery store is an entity within Standard Industrial Classification (SIC) code 5411, a general merchandise store is an entity within SIC codes 5300 through 5399 and 5499, and a drug store is an entity within SIC code 5912.

(30) The term *tableting machine* means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

[62 FR 13941, Mar. 24, 1997; 62 FR 15392, Apr. 1, 1997]

## PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

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 Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 23, 1973, and amended at 51 FR 5319, Feb. 13, 1986]

### REGISTRATION

#### § 1301.11 Persons required to register.

(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 §§ 1301.22-1301.26. 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) [Reserved]

[62 FR 13945, Mar. 24, 1997]

#### § 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) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of