proposed rule, amended rule, or repeal in the FEDERAL REGISTER.

(37) The term *purchaser* means any registered person entitled to obtain and execute order forms pursuant to §§ 1305.04 and 1305.06.

(38) The term *readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized record-keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

(39) The terms *register* and *registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

(40) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(41) The term *supplier* means any registered person entitled to fill order forms pursuant to § 1305.08 of this chapter.

(42) The term *freight forwarding facility* means a separate facility operated by a distributing registrant through which sealed, packaged controlled substances in unmarked shipping containers (i.e., the containers do not indicate that the contents include controlled substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer controlled substances from any location the distributing registrant operates that is registered with the Administration to manufacture, distribute, or import controlled substances, or, with respect to returns, registered to dispense controlled substances, provided that the notice required by § 1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved. For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor, and/or importer.

[62 FR 13941, Mar. 24, 1997, as amended at 65 FR 44678, July 19, 2000]

§ 1300.02 Definitions relating to listed chemicals.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

(b) As used in parts 1309, 1310, and 1313 of this chapter, the following terms shall have the meaning specified:

(1) The term *Act* means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951) as amended.

(2) The term *Administration* means the Drug Enforcement Administration.

(3) The term *Administrator* means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(4) The terms *broker* and *trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(i) Negotiating contracts;

(ii) Serving as an agent or intermediary; or

(iii) Fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

(5) The term *chemical* export means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the United States).

(6) The term *chemical exporter* is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

(7) The term *chemical import* means with respect to a listed chemical, any

bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the Customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(8) The term *chemical importer* is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

(9) The term *chemical mixture* means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

(10) The term *customs territory of the United States* means the several States, the District of Columbia, and Puerto Rico.

(11) The term *encapsulating machine* means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

(12) The term *established business relationship with a foreign customer* means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer for purposes of this definition. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of 15-day advance notice requirements of § 1313.24 of this chapter:

(i) The name and street address of the chemical exporter and of each regular customer;

(ii) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;

(iii) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(iv) The duration of the business relationship;

(v) The frequency and number of transactions occurring during the preceding 12-month period;

(vi) the amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and regular customer;

(vii) The method of delivery (direct shipment or through a broker or forwarding agent); and

(viii) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

(13) The term *established record as an importer* means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of § 1313.15 of this chapter:

(i) The name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(ii) The frequency and number of transactions occurring during the preceding 12 month period.

(14) The term *hearing* means any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

(15) The term *international transaction* means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(16) The term *jurisdiction of the United States* means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

(17) The term *listed chemical* means any List I chemical or List II chemical.

(18) The term *List I chemical* means a chemical specifically designated by the Administrator in §1310.02(a) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

(19) The term *List II chemical* means a chemical, other than a List I chemical, specifically designated by the Administrator in §1310.02(b) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

(20) The term *name* means the official name, common or usual name, chemical name, or brand name of a substance.

(21) The term *person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(22) The term *readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

(23) The terms *register* and *registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

(24) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(25) The term *regular customer* means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in §1300.02(b)(12).

(26) The term *regular importer* means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

(27) The term *regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

(28) The term *regulated transaction* means:

(i) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(A) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(B) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, and 1313 of this chapter;

(C) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(D) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(1)(i) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers, pseudoephedrine or its salts, optical isomers, or salts of optical isomers, or phenylpropanolamine or its salts, optical isomers, or salts of optical isomers unless otherwise exempted under §1310.11 of this chapter, except that any sale of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products by retail distributors shall not be a regulated transaction; or

(ii) The Administrator has determined pursuant to the criteria in §1310.10 of this chapter that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(2) The quantity of ephedrine, pseudoephedrine, phenylpropanolamine, or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine by retail distributors or by distributors required to submit reports by §1310.03(c) shall be 24 grams of pseudoephedrine or 24 grams of phenylpropanolamine in a single transaction. For combination ephedrine products the threshold for any sale by retail distributors or by distributors required to submit reports by §1310.03(c) shall be 24 grams of ephedrine in a single transaction.

(E) Any transaction in a chemical mixture listed in §1310.13 of this chapter.

(ii) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course 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.

(31) The term ordinary over-the-counter pseudoephedrine or phenylpropanolamine product means any product containing pseudoephedrine or phenylpropanolamine that is—

(i) Regulated pursuant to the Act; and

(ii)(A) Except for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and that is packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches, and

(B) For liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base.

(32) The term combination ephedrine product means a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers,

and therapeutically significant quantities of another active medicinal ingredient.

[62 FR 13941, Mar. 24, 1997; 62 FR 15392, Apr. 1, 1997; 67 FR 14859, Mar. 28, 2002]

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