

PART 1300—DEFINITIONS

Sec.

1300.01 Definitions relating to controlled substances.

1300.02 Definitions relating to listed chemicals.

AUTHORITY: 21 U.S.C. 802, 871(b), 951, 958(f)

SOURCE: 62 FR 13941, Mar. 24, 1997, unless otherwise noted.

§ 1300.01 Definitions relating to controlled substances.

(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 1301 through 1308 and part 1312 of this chapter, the following terms shall have the meanings 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).

(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 term *anabolic steroid* means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes:

- (i) 3 β ,17-dihydroxy-5 α -androstane
- (ii) 3 α ,17 β -dihydroxy-5 α -androstane
- (iii) 5 α -androstane-3,17-dione
- (iv) 1-androstenediol (3 β ,17 β -dihydroxy-5 α -androst-1-ene)
- (v) 1-androstenediol (3 α ,17 β -dihydroxy-5 α -androst-1-ene)
- (vi) 4-androstenediol (3 β ,17 β -dihydroxy-androst-4-ene)
- (vii) 5-androstenediol (3 β ,17 β -dihydroxy-androst-5-ene)
- (viii) 1-androstenedione ([5 α]-androst-1-en-3,17-dione)
- (ix) 4-androstenedione (androst-4-en-3,17-dione)

(x) 5-androstenedione (androst-5-en-3,17-dione)

(xi) bolasterone (7 α ,17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one)

(xii) boldenone (17 β -hydroxyandrost-1,4,-diene-3-one)

(xiii) calusterone (7 β ,17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one)

(xiv) clostebol (4-chloro-17 β -hydroxyandrost-4-en-3-one)

(xv) dehydrochloromethyltestosterone (4-chloro-17 β -hydroxy-17 α -methyl-androst-1,4-dien-3-one)

(xvi) Δ 1-dihydrotestosterone (a.k.a. '1-testosterone') (17 β -hydroxy-5 α -androst-1-en-3-one)

(xvii) 4-dihydrotestosterone (17 β -hydroxy-androstan-3-one)

(xviii) drostanolone (17 β -hydroxy-2 α -methyl-5 α -androstane-3-one)

(xix) ethylestrenol (17 α -ethyl-17 β -hydroxyestr-4-ene)

(xx) fluoxymesterone (9-fluoro-17 α -methyl-11 β ,17 β -dihydroxyandrost-4-en-3-one)

(xxi) formebolone (2-formyl-17 α -methyl-11 α ,17 β -dihydroxyandrost-1,4-dien-3-one)

(xxii) furazabol (17 α -methyl-17 β -hydroxyandrostano[2,3-c]-furazan)

(xxiii) 13 β -ethyl-17 β -hydroxygon-4-en-3-one

(xxiv) 4-hydroxytestosterone (4,17 β -dihydroxy-androst-4-en-3-one)

(xxv) 4-hydroxy-19-nortestosterone (4,17 β -dihydroxy-estr-4-en-3-one)

(xxvi) mestanolone (17 α -methyl-17 β -hydroxy-5 α -androstane-3-one)

(xxvii) mesterolone (1 α methyl-17 β -hydroxy-[5 α]-androstane-3-one)

(xxviii) methandienone (17 α -methyl-17 β -hydroxyandrost-1,4-dien-3-one)

(xxix) methandriol (17 α -methyl-3 β ,17 β -dihydroxyandrost-5-ene)

(xxx) methenolone (1-methyl-17 β -hydroxy-5 α -androst-1-en-3-one)

(xxxi) 17 α -methyl-3 β , 17 β -dihydroxy-5 α -androstane

(xxxii) 17 α -methyl-3 α ,17 β -dihydroxy-5 α -androstane

(xxxiii) 17 α -methyl-3 β ,17 β -dihydroxyandrost-4-ene

(xxxiv) 17 α -methyl-4-hydroxynandrolone (17 α -methyl-4-hydroxy-17 β -hydroxyestr-4-en-3-one)

(xxxv) methyldienolone (17 α -methyl-17 β -hydroxyestra-4,9(10)-dien-3-one)

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- (xxxvi) methyltrienolone (17 α -methyl-17 β -hydroxyestra-4,9-11-trien-3-one)
- (xxxvii) methyltestosterone (17 α -methyl-17 β -hydroxyandrost-4-en-3-one)
- (xxxviii) mibolerone (7 α ,17 α -dimethyl-17 β -hydroxyestr-4-en-3-one)
- (xxxix) 17 α -methyl- Δ 1-dihydrotestosterone (17 β -hydroxy-17 α -methyl-5 α -androst-1-en-3-one) (a.k.a. '17- α -methyl-1-testosterone')
- (xl) nandrolone (17 β -hydroxyestr-4-en-3-one)
- (xli) 19-nor-4-androstenediol (3 β , 17 β -dihydroxyestr-4-ene)
- (xlii) 19-nor-4-androstenediol (3 α , 17 β -dihydroxyestr-4-ene)
- (xliii) 19-nor-5-androstenediol (3 β , 17 β -dihydroxyestr-5-ene)
- (xliv) 19-nor-5-androstenediol (3 α , 17 β -dihydroxyestr-5-ene)
- (xlv) 19-nor-4-androstenedione (estr-4-en-3,17-dione)
- (xlvi) 19-nor-5-androstenedione (estr-5-en-3,17-dione)
- (xlvii) norbolethone (13 β , 17 α -diethyl-17 β -hydroxygon-4-en-3-one)
- (xlviii) norclostebol (4-chloro-17 β -hydroxyestr-4-en-3-one)
- (xlix) norethandrolone (17 α -ethyl-17 β -hydroxyestr-4-en-3-one)
- (l) normethandrolone (17 α -methyl-17 β -hydroxyestr-4-en-3-one)
- (li) oxandrolone (17 α -methyl-17 β -hydroxy-2-oxa-[5 α]-androst-3-one)
- (lii) oxymesterone (17 α -methyl-4,17 β -dihydroxyandrost-4-en-3-one)
- (liii) oxymetholone (17 α -methyl-2-hydroxymethylene-17 β -hydroxy-[5 α]-androst-3-one)
- (liv) stanozolol (17 α -methyl-17 β -hydroxy-[5 α]-androst-2-eno[3,2-c]-pyrazole)
- (lv) stenbolone (17 β -hydroxy-2-methyl-[5 α]-androst-1-en-3-one)
- (lvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)
- (lvii) testosterone (17 β -hydroxyandrost-4-en-3-one)
- (lviii) tetrahydrogestrinone (13 β , 17 α -diethyl-17 β -hydroxygon-4,9,11-trien-3-one)
- (lix) trenbolone (17 β -hydroxyestr-4,9,11-trien-3-one)
- (lx) Any salt, ester, or ether of a drug or substance described in this paragraph. Except such term does not include an anabolic steroid that is expressly intended for administration

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through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(5) The term *basic class* means, as to controlled substances listed in Schedules I and II:

(i) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in § 1308.11(b) of this chapter;

(ii) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.11(c) of this chapter;

(iii) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.11(d) of this chapter;

(iv) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(B) Apomorphine;

(C) Codeine;

(D) Etorphine hydrochloride;

(E) Ethylmorphine;

(F) Hydrocodone;

(G) Hydromorphone;

(H) Metopon;

(I) Morphine;

(J) Oxycodone;

(K) Oxymorphone;

(L) Thebaine;

(M) Mixed alkaloids of opium listed in Section 1308.12(b)(2) of this chapter;

(N) Cocaine; and

- (O) Ecgonine;
 - (v) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in §1308.12(c) of this chapter; and
 - (vi) Methamphetamine, its salts, isomers, and salts of its isomers;
 - (vii) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
 - (viii) Phenmetrazine and its salts;
 - (ix) Methylphenidate;
 - (x) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.12(e) of this chapter.
- (6) The term *commercial container* means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.
- (7) The term *compounder* means any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.
- (8) The term *controlled substance* has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.).
- (9) The term *customs territory* of the United States means the several States, the District of Columbia, and Puerto Rico.
- (10) The term *detoxification treatment* means the dispensing, for a period of time as specified below, of a narcotic drug or narcotic drugs in decreasing doses to an individual to alleviate ad-

verse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time. There are two types of detoxification treatment: Short-term detoxification treatment and long-term detoxification treatment.

(i) Short-term detoxification treatment is for a period not in excess of 30 days.

(ii) Long-term detoxification treatment is for a period more than 30 days but not in excess of 180 days.

(11) The term *dispenser* means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(12) The term *export* means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).

(13) The term *exporter* includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in any schedule.

(14) The term *hearing* means:

(i) In part 1301 of this chapter, 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).

(ii) In part 1303 of this chapter, any hearing held regarding the determination of aggregate production quota or the issuance, adjustment, suspension, or denial of a procurement quota or an individual manufacturing quota.

(iii) In part 1308 of this chapter, any hearing held for the issuance, amendment, or repeal of any rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

(15) The term *import* means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or

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not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(16) The term *importer* includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

(17) The term *individual practitioner* means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(18) The term *institutional practitioner* means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(19) The term *interested person* means any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

(20) The term *inventory* means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

(21) (i) *The term isomer* means the optical isomer, except as used in §1308.11(d) and §1308.12(b)(4) of this chapter. As used in §1308.11(d) of this chapter, the term "isomer" means any optical, positional, or geometric isomer. As used in §1308.12(b)(4) of this chapter, the term "isomer" means any optical or geometric isomer.

(ii) As used in §1308.11(d) of this chapter, the term "positional isomer" means any substance possessing the same molecular formula and core structure and having the same functional group(s) and/or substituent(s) as

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those found in the respective schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective schedule I hallucinogen. Rearrangements of alkyl moieties within or between functional group(s) or substituent(s), or divisions or combinations of alkyl moieties, that do not create new chemical functionalities or destroy existing chemical functionalities, are allowed i.e., result in compounds which are positional isomers. For purposes of this definition, the "core structure" is the parent molecule that is the common basis for the class; for example, tryptamine, phenethylamine, or ergoline. Examples of rearrangements resulting in creation and/or destruction of chemical functionalities (and therefore resulting in compounds which are not positional isomers) include, but are not limited to: ethoxy to *alpha*-hydroxyethyl, hydroxy and methyl to methoxy, or the repositioning of a phenolic or alcoholic hydroxy group to create a hydroxyamine. Examples of rearrangements resulting in compounds which would be positional isomers include: *tert*-butyl to *sec*-butyl, methoxy and ethyl to isopropoxy, N,N-diethyl to N-methyl-N-propyl, or *alpha*-methylamino to N-methylamino.

(22) 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.

(23) The term *label* means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

(24) The term *labeling* means all labels and other written, printed, or graphic matter:

(i) Upon any controlled substance or any of its commercial containers or wrappers, or

(ii) Accompanying such controlled substance.

(25) The term *Long Term Care Facility (LTCF)* means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

(26) The term *maintenance treatment* means the dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

(27) The term *manufacture* means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance. The term *manufacturer* means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

(28) The term *mid-level practitioner* means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice.

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

(30) The term *narcotic drug* means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(ii) Poppy straw and concentrate of poppy straw.

(iii) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.

(iv) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(v) Ecgonine, its derivatives, their salts, isomers and salts of isomers.

(vi) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (b)(31)(i) through (v) of this section.

(31) The term *narcotic treatment program* means a program engaged in maintenance and/or detoxification treatment with narcotic drugs.

(32) The term *net disposal* means, for a stated period, the quantity of a basic class of controlled substance distributed by the registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of controlled substance or a noncontrolled substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of controlled substance or a noncontrolled substance or in the manufacture of dosage forms of that basic class.

(33) The term *pharmacist* means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under

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the supervision of a pharmacist licensed by such State.

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

(35) The term *prescription* means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

(36) The term *proceeding* means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act (21 U.S.C. 811), commencing with the publication by the Administrator of the 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 *reverse distributor* means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—

(i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

(ii) Where necessary, processing such substances or arranging for processing such substances for disposal.

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

(43) 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.

(44) The term *central fill pharmacy* means a pharmacy which is permitted by the state in which it is located to prepare controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

(45) The term *automated dispensing system* means a mechanical system that performs operations or activities,

other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

[62 FR 13941, Mar. 24, 1997, as amended at 65 FR 44678, July 19, 2000; 68 FR 37409, June 24, 2003; 68 FR 41228, July 11, 2003; 70 FR 25465, May 13, 2005; 70 FR 74656, Dec. 16, 2005; 71 FR 60427, Oct. 13, 2006; 72 FR 67852, Dec. 3, 2007]

§ 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* means the regulated person has imported or exported a listed chemical at least once within the past six months, or twice within the past twelve months from or to a foreign manufacturer, distributor, or end user of the chemical that has an established business with a fixed street address. A person or business that functions as a broker or intermediary is not a customer for purposes of this definition.

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(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.

(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 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.

(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 part 1313 of this chapter.

(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, 1313, and 1315 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 other than a scheduled listed chemical product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to paragraph (b)(28)(i)(E) of this section, unless—

(1) 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 the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical;

(E) Any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under §1310.03(c) of this chapter; or

(F) Any transaction in a chemical mixture designated in §§1310.12 and 1310.13 of this chapter that the Administrator has exempted from regulation.

(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 or phenylpropranolamine 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. 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 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.

(32) The term *drug product* means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act for distribution in the United States.

(33) The term *valid prescription* means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

(34)(i) The term *scheduled listed chemical product* means a product that contains ephedrine, pseudoephedrine, or phenylpropranolamine and may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a non-prescription drug. Ephedrine, pseudoephedrine, and phenylpropranolamine include their salts, optical isomers, and salts of optical isomers.

(ii) Scheduled listed chemical product does not include any product that

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is a controlled substance under part 1308 of this chapter. In the absence of such scheduling by the Attorney General, a chemical specified in paragraph (b)(34)(i) of this section may not be considered to be a controlled substance.

(35) The term *regulated seller* means a retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor.

(36) The term *mobile retail vendor* means a person or entity that makes sales at retail from a stand that is intended to be temporary or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(37) The term *at retail*, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

[62 FR 13941, Mar. 24, 1997; 62 FR 15392, Apr. 1, 1997; 67 FR 14859, Mar. 28, 2002, as amended at 68 FR 23203, May 1, 2003; 68 FR 57803, Oct. 7, 2003; 71 FR 56023, Sept. 26, 2006; 72 FR 17406, Apr. 9, 2007; 72 FR 37448, July 10, 2007]

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

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