

## § 1300.02

## 21 CFR Ch. II (4–1–23 Edition)

Samoa, and the Northern Mariana Islands.

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### § 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:

*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).

*Administration* means the Drug Enforcement Administration.

*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).

*At retail*, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

*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—

- (1) Negotiating contracts;
- (2) Serving as an agent or intermediary; or
- (3) 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.

*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).

*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.

*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.

*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.

*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.

*Competent national authority*, for purposes of importation and exportation of controlled substances and listed chemicals, means an entity lawfully entitled to authorize the import and export of controlled substances, and to regulate or enforce national controls over listed chemicals, and included as such in the directory of “Competent National Authorities Under the International Drug Control Treaties” published by the United Nations Office on Drugs and Crime.

*Customs officer* means either an Officer of the Customs as defined in 19 U.S.C. 1401(i) (that is, of the U.S. Customs and Border Protection), or any individual duly authorized to accept entries of merchandise, to collect duties, and to enforce the customs laws of any commonwealth, territory, or possession of the United States.

*Customs territory of the United States* means the several States, the District of Columbia, and Puerto Rico.

*Drug product* means an active ingredient in dosage form that has been approved or otherwise may be lawfully

marketed under the Federal Food, Drug, and Cosmetic Act for distribution in the United States.

*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.

*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.

*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.

*Export* means, with respect to any article, any taking out or removal of such article from the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs laws, export control laws enforced by other agencies, or related laws of the United States).

*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).

*Import* means, with respect to any article, any bringing in or introduction of such article into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

*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.

*Listed chemical* means any List I chemical or List II chemical.

*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.

*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.

*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).

*Name* means the official name, common or usual name, chemical name, or brand name of a substance.

*Person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

*Port of entry*, unless distinguished as being a foreign port of entry, means any place at which a customs officer is duly authorized to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs laws of the United States (whether or not such place is a port of entry as defined in title 19 of the United States Code or its associated implementing regulations). Examples of ports of entry include, but are not limited to, places designated as ports of entry or customs stations in title 19 of the *Code of Federal Regulations* or by the governing customs authority of that area. When shipments are transported under U.S. Customs and Border Protection immediate transportation procedures, the port of entry shall be the port of final destination.

*Port of export* means, unless distinguished as being a foreign port of export, any place under the control of a customs officer where goods are loaded on an aircraft, vessel or other conveyance for export outside of the United States. For goods loaded aboard an aircraft or vessel in the United States that stops at several ports before departing the United States, the port of export is the first port where the goods were loaded. For goods off-loaded from the original conveyance to another conveyance (even if the aircraft or vessel belongs to the same carrier) at any port subsequent to the port where the first on-loading occurred in the United States, the port where the goods were loaded onto the last conveyance before departing the United States is the port of export. For reporting purposes, in the case of an otherwise lawful export occurring by mail, the port of export is the place of mailing.

*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.

*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).

*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).

*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.

*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.

*Regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or ex-

ports 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.

*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.

*Regulated transaction* means:

(1) 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:

(i) 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;

(ii) 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;

(iii) 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;

(iv) 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 (1)(v) of this definition, unless—

(A) 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

(B) 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;

(v) 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

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

(2) 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.

*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 ephedrine, pseudoephedrine, or phenylpropanolamine 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.

*Return information* means supplemental information required to be reported to the Administration following an import or export transaction containing the particulars of the trans-

action and any other information as the Administration may specify.

*Scheduled listed chemical product* means:

(1) A product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

(2) Scheduled listed chemical product does not include any product that 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 (1) of this definition may not be considered to be a controlled substance.

*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.

*United States*, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States, which, in addition to the customs territory of the United States, include but are not limited to the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

*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.

[75 FR 16304, Mar. 31, 2010, as amended at 77 FR 4233, Jan. 27, 2012; 81 FR 97019, Dec. 30, 2016; 85 FR 68461, Oct. 29, 2020]

#### **§ 1300.03 Definitions relating to electronic orders for controlled substances and electronic prescriptions for controlled substances.**

For the purposes of this chapter, the following terms shall have the meanings specified:

*Application service provider* means an entity that sells electronic prescription or pharmacy applications as a