Supplier means any registered person entitled to fill order forms pursuant to §1305.06 of this chapter.

§ 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:


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 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).

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.

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.

**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).

**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.

**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.

**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.

**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 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.

**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
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chemical, or an international trans-
action involving shipment of a listed
chemical, or if the Administrator es-
tablishes a threshold amount for a spe-
cific listed chemical, a threshold
amount as determined by the Adminis-
trator, which includes a cumulative
threshold amount for multiple trans-
actions, 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 regu-
lated 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 con-
tract carrier, or to or by a warehouse-
man for storage in the lawful and usual
course of the business of the ware-
houseman, except that if the carriage
or storage is in connection with the
distribution, importation, or export-
ation 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 spe-
cific listed chemical or chemicals spec-
fied by regulation of the Adminis-
trator as excluded from this definition
as unnecessary for enforcement of the
Act;

(iv) Any transaction in a listed chem-
ical that is contained in a drug other
than a scheduled listed chemical prod-
uct that may be marketed or distrib-
uted lawfully in the United States
under the Federal Food, Drug, and Cos-
metic Act, subject to paragraph (1)(v)
of this definition, unless—

(A) The Administrator has deter-
mined pursuant to the criteria in
§1310.10 of this chapter that the drug or
group of drugs is being diverted to ob-
tain the listed chemical for use in the
illicit production of a controlled sub-
stance; and

(B) The quantity of the listed chem-
ical contained in the drug included in
the transaction or multiple trans-
actions 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 dis-
tributor 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 Admin-
istrator has exempted from regulation.

(2) A distribution, importation, or ex-
portation of a tableting machine or en-
capsulating machine except that such
term does not include a domestic law-
ful distribution in the usual course of
business between agents and employees
of a single regulated person; in this
context, agents or employees means in-
dividuals 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 pseudoe
phedrine or phenylpropanol-
amine are limited almost exclusively to
sales for personal use, both in number
of sales and volume of sales, either di-
rectly 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.

Scheduled listed chemical product
means:

(1) A product that contains ephed-
rine, pseudoephedrine, or phenyl-
propanolamine 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 opti-
cal 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
cheduling by the Attorney General, a
chemical specified in paragraph (1) of
this definition may not be considered
to be a controlled substance.

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§ 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 hosted service, where the entity controls access to the application and maintains the software and records on its servers.

Audit trail means a record showing who has accessed an information technology application and what operations the user performed during a given period.

Authentication means verifying the identity of the user as a prerequisite to allowing access to the information application.

Authentication protocol means a well specified message exchange process that verifies possession of a token to remotely authenticate a person to an application.

Biometric authentication means authentication based on measurement of the individual’s physical features or repeatable actions where those features or actions are both distinctive to the individual and measurable.

Biometric subsystem means the hardware and software used to capture, store, and compare biometric data. The biometric subsystem may be part of a larger application. The biometric sub-system is an automated system capable of:

1. Capturing a biometric sample from an end user.
2. Extracting and processing the biometric data from that sample.
3. Storing the extracted information in a database.
4. Comparing the biometric data with data contained in one or more reference databases.
5. Determining how well the stored data matches the newly captured data and indicating whether an identification or verification of identity has been achieved.

Cache means to download and store information on a local server or hard drive.

Certificate policy means a named set of rules that sets forth the applicability of the specific digital certificate to a particular community or class of application with common security requirements.

Certificate revocation list (CRL) means a list of revoked, but unexpired certificates issued by a certification authority.

Certification authority (CA) means an organization that is responsible for verifying the identity of applicants, authorizing and issuing a digital certificate, maintaining a directory of public keys, and maintaining a Certificate Revocation List.

Certified information systems auditor (CISA) means an individual who has been certified by the Information Systems Audit and Control Association as qualified to audit information systems and who performs compliance audits as a regular ongoing business activity.

Credential means an object or data structure that authoritatively binds an identity (and optionally, additional attributes) to a token possessed and controlled by a person.

Credential service provider (CSP) means a trusted entity that issues or registers tokens and issues electronic credentials to individuals. The CSP may be an independent third party or may issue credentials for its own use.

CSOS means controlled substance ordering system.

Digital certificate means a data record that, at a minimum—

1. Identifies the certification authority issuing it;
2. Names or otherwise identifies the certificate holder;
3. Identifies the certificate holder;
4. Contains information that is encrypted with a private key of the certificate authority;
5. Contains information that specifies the functions that the certificate authority can perform.

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.