

## Drug Enforcement Administration, Justice

## § 1309.21

### MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

- 1309.61 Modification in registration.  
1309.62 Termination of registration.  
1309.63 Transfer of registration.

### SECURITY REQUIREMENTS

- 1309.71 General security requirements.  
1309.72 Felony conviction; employer responsibilities.  
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AUTHORITY: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

SOURCE: 60 FR 32454, June 22, 1995, unless otherwise noted.

### GENERAL INFORMATION

#### § 1309.01 Scope of part 1309.

Procedures governing the registration of manufacturers, distributors, importers and exporters of List I chemicals pursuant to Sections 102, 302, 303, 1007 and 1008 of the Act (21 U.S.C. 802, 822, 823, 957 and 958) are set forth generally by those sections and specifically by the sections of this part.

#### § 1309.02 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 13968, Mar. 24, 1997]

#### § 1309.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

[75 FR 10680, Mar. 9, 2010]

### FEES FOR REGISTRATION AND REREGISTRATION

#### § 1309.11 Fee Amounts.

(a) For each application for registration or reregistration to manufacture for distribution the applicant shall pay an annual fee of \$3,699.

(b) For each application for registration or reregistration to distribute (ei-

ther retail distribution or non-retail distribution), import, or export a list I chemical, the applicant shall pay an annual fee of \$1,850.

[85 FR 44734, July 24, 2020]

#### § 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture, distribute, import, or export the applicant shall pay the fee when the application for registration or reregistration is submitted for filing online using the secure application portal at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov).

(b) Payment shall be made online by Automated Clearing House funds transfer, by credit card, or by any other means made available at the time of submission using the secure application portal at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov).

[87 FR 21022, Apr. 11, 2022]

### REQUIREMENTS FOR REGISTRATION

#### § 1309.21 Persons required to register.

(a) Unless exempted by law or under §§1309.24 through 1309.26 or §§1310.12 through 1310.13 of this chapter, the following persons must annually obtain a registration specific to the List I chemicals to be handled:

(1) Every person who manufactures or imports or proposes to manufacture or import a List I chemical or a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) Every person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under paragraph (1)(iv) of the definition of regulated transaction in §1300.02 of this chapter.

(b) Only persons actually engaged in the activities are required to obtain a registration; related or affiliated persons who are not engaged in the activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(c) The registration requirements are summarized in the following table:

## SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS

Business activity	Chemicals	DEA forms	Application fee	Registration period (years)	Coincident activities allowed
(1) Manufacturing	List I, ..... Drug products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New-510 ..... Renewal-510a ....	3,699	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
(2) Distributing .....	List I, ..... Scheduled listed chemical products.	New-510 ..... Renewal-510a ....	1,850	1	
(3) Importing .....	List I, ..... Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New-510 ..... Renewal-510a ....	1,850	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
(4) Exporting .....	List I, ..... Scheduled listed chemical products.	New-510 ..... Renewal-510a ....	1,850	1	

[75 FR 4980, Feb. 1, 2010, as amended at 77 FR 4236, Jan. 27, 2012; 77 FR 15250, Mar. 15, 2012; 85 FR 44734, July 24, 2020]

**§ 1309.22 Separate registration for independent activities.**

(a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing of List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) Distributing of List I chemicals and scheduled listed chemical products.

(3) Importing List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(4) Exporting List I chemicals and scheduled listed chemical products.

(b) Except as provided in paragraphs (c) and (d) of this section, every person who engages in more than one group of independent activities must obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24 through 1309.26.

(c) A person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

(d) A person registered to manufacture any List I chemical shall be authorized to distribute that List I chemical after manufacture, but no other

chemical that the person is not registered to manufacture.

[75 FR 4981, Feb. 1, 2010]

**§ 1309.23 Separate registration for separate locations.**

(a) A separate registration is required for each principal place of business at one general physical location where List I chemicals are manufactured, distributed, imported, or exported by a person.

(b) The following locations shall be deemed to be places not subject to the registration requirement:

(1) A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered; and

(2) An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

[60 FR 32454, June 22, 1995, as amended at 75 FR 4981, Feb. 1, 2010]

**§ 1309.24 Waiver of registration requirement for certain activities.**

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if