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 the applicant shall pay an annual fee of $3,047.

(b) For each application for registration or reregistration to distribute, import, or export a List I chemical, the applicant shall pay an annual fee of $1,523.

[77 FR 15250, Mar. 15, 2012]

§ 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.

(b) Payments should be made in the form of a credit card; a personal, certified, or cashier's check; or a money order made payable to ''Drug Enforcement Administration.'' Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

[75 FR 4980, Feb. 1, 2010]

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
Manufacturing ...	List I	New–510	$3,047	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
	Drug products containing ephedrine, pseudoephedrine, phenylpropanolamine.	Renewal–510a.	3,047		
Distributing	List I	New–510	1,523	1	
	Scheduled listed chemical products.	Renewal–510a.	1,523		
Importing	List I	New–510	1,523	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
	Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	Renewal–510a.	1,523		
Exporting	List I	New–510	1,523	1	
	Scheduled listed chemical products.	Renewal–510a.	1,523		

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

§ 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