

§ 1309.21

party endorsed checks will not be accepted. These application fees are not refundable.

[60 FR 32454, June 22, 1995; 60 FR 35264, July 6, 1995]

REQUIREMENTS FOR REGISTRATION

§ 1309.21 Persons required to register.

(a) Every person who distributes, imports, or exports any List I chemical, other than those List I chemicals contained in a product exempted under §1300.02(b)(28)(i)(D) of this chapter (irrespective of the threshold provisions under §1300.02(b)(28)(i)(D)(2) of this chapter), or who proposes to engage in the distribution, importation, or exportation of any List I chemical, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§1309.24 through 1309.26 of this part. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such 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.)

(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under §1300.02(b)(28)(i)(D) of this chapter, or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§1309.24 through 1309.26 of this part.

[67 FR 14860, Mar. 28, 2002]

§ 1309.22 Separate registration for independent activities.

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

- (1) Retail distributing of List I chemicals;
- (2) Non-Retail distributing of List I chemicals;
- (3) Importing List I chemicals; and
- (4) Exporting List I chemicals.

(b) Every person who engages in more than one group of independent activi-

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ties shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§1309.24 through 1309.26, except that 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.

[60 FR 32454, June 22, 1995, as amended at 61 FR 32926, June 26, 1996; 67 FR 14860, Mar. 28, 2002]

§ 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 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.

§ 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 such agent or employee is acting in the usual course of his or her business or employment.

(b) The requirement of registration is waived for any person who distributes a product containing a List I chemical that is regulated pursuant to §1300.02(b)(28)(i)(D), if that person is registered with the Administration to manufacture, distribute or dispense a controlled substance.

(c) The requirement of registration is waived for any person who imports or exports a product containing a List I

chemical that is regulated pursuant to §1300.02(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance.

(d) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to §1300.02(b)(28)(i)(D) of this chapter.

(e) The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are limited to the distribution of below-threshold quantities of a pseudoephedrine, phenylpropanolamine, or combination ephedrine product that is regulated pursuant to §1300.02(b)(28)(i)(D) of this chapter, in a single transaction to an individual for legitimate medical use, irrespective of whether the form of packaging of the product meets the definition of ordinary over-the-counter pseudoephedrine or phenylpropanolamine product under §1300.02(b)(31) of this chapter. The threshold for a distribution of a product in a single transaction to an individual for legitimate medical use is 24 grams of pseudoephedrine, phenylpropanolamine, or ephedrine base.

(f) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste disposal.

(g) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and isotainers (with capacities greater than or equal to 2500 gallons in a single container).

(h) The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

(i) If any person exempted under paragraph (b), (c), (d), (e), (f) or (g) of this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for such activities, as required by §1309.21 of this part.

(j) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a waiver granted under paragraph (b), (c), (d), (e), (f) or (g) of this section pursuant to the procedures set forth in §§1309.43 through 1309.46 and 1309.51 through 1309.55 of this part. In considering the revocation or suspension of a person's waiver granted pursuant to paragraph (b) or (c) of this section, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to 21 U.S.C. 824 is warranted.

(k) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in §§1309.71-1309.73 of this part and the record-keeping and reporting requirements set forth under parts 1310 and 1313 of this chapter.

[67 FR 14860, Mar. 28, 2002]

§ 1309.25 Temporary exemption from registration for chemical registration applicants.

(a) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in this part 1309 and parts 1310, and 1313 of this chapter remain in full force and effect.

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or