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under 21 U.S.C. 802(41). Such rule-making may be commenced simultaneously with the issuance of the temporary order issued under paragraph (a) of this section.

[88 FR 50041, Aug. 1, 2023]

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

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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]

Drug Enforcement Administration, Justice

§ 1309.21

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 (either 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.

(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.

[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	

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[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

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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 the 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 manufactures or distributes a scheduled listed chemical product or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.

(c) The requirement of registration is waived for any person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter, 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 only distributes a prescription drug product containing a List I chemical that is regulated pursuant to paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter.

(e) 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.

(f) 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 intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).

(g) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited solely to the distribution of Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one fluid ounce (30 ml) or less.

(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), or (f) 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 the activities, as required by § 1309.21.

(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), or (f) of this section pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and §§ 1309.51 through 1309.55. 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 section 304 of the Act (21 U.S.C. 824) is warranted.

(k) Any person exempted from the registration requirement under this section must comply with the security requirements set forth in §§ 1309.71

through 1309.73 and the recordkeeping and reporting requirements set forth under Parts 1310, 1313, 1314, and 1315 of this chapter.

[75 FR 4981, Feb. 1, 2010, as amended at 77 FR 4236, Jan. 25, 2012]

§ 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 export a pseudoephedrine or phenylpropanolamine drug product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before October 3, 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.

(c) Each person required by sections 302 or 1007 of the Act (21 U.S.C. 822 or 957) to obtain a registration to manufacture or import prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before March 3, 2010. The exemption will remain in effect for each person who has

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made such application until the Administration has approved or denied the application. This exemption applies only to registration; all other chemical control requirements set forth in this part and parts 1310, 1313, and 1315 of this chapter remain in full force and effect.

[67 FR 14860, Mar. 28, 2002, as amended at 75 FR 4982, Feb. 1, 2010]

§ 1309.26 Exemption of law enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Administration, any customs officer, any officer or employee of the U.S. Food and Drug Administration, and any Federal or Insular officer who is lawfully engaged in the enforcement of any federal law relating to listed chemicals, controlled substances, drugs, or customs, and is duly authorized to possess and distribute List I chemicals in the course of his/her official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to listed chemicals and controlled substances and is duly authorized to possess and distribute List I chemicals in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of official duties, possess any List I chemical and distribute any such chemical to any other official who is also exempted by this section and acting in the course of official duties.

[60 FR 32454, June 22, 1995, as amended at 81 FR 97021, Dec. 30, 2016]

APPLICATION FOR REGISTRATION

§ 1309.31 Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is approved and

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a Certificate of Registration is issued by the Administrator to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his registration.

(c) At the time a person is first registered, that person shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above persons to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the person is assigned to a group which has an expiration date less than eleven months from the date of which the person is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire on the expiration date following the date on which the person is registered.

§ 1309.32 Application forms; contents; signature.

(a) Any person who is required to be registered pursuant to § 1309.21 and is not so registered, shall apply on DEA Form 510 using the secure application portal at www.DEADiversion.usdoj.gov.

(b) Any person who is registered pursuant to § 1309.21, shall apply for reregistration on DEA Form 510a using the secure application portal at www.DEADiversion.usdoj.gov.

(c) DEA Forms 510 and 510a may be obtained online at www.DEADiversion.usdoj.gov. DEA will send renewal notifications via email to registrants approximately calendar 60 days prior to their registration expiration date. Registrants are responsible for keeping their email address current in the secure application portal on DEA's website throughout the duration of their registration. Only applications submitted online through the secure application portal on DEA's website will be accepted for processing.

(d) Each application for registration must include the Administration Chemical Code Number, as set forth in § 1310.02 of this chapter, for each List I

chemical to be manufactured, distributed, imported, or exported.

(e) Registration shall not entitle a person to engage in any activity with any List I chemical not specified in his or her application.

(f) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(g) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the application or other document a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign the application or other document. The power of attorney shall be valid until revoked by the applicant.

[60 FR 32454, June 22, 1995, as amended at 75 FR 10680, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016; 87 FR 21023, Apr. 11, 2022]

§ 1309.33 Filing of application; joint filings.

All applications for registration shall be submitted online at www.DEAdiversion.usdoj.gov for filing. The appropriate registration fee and any required attachments must accompany the application.

[87 FR 21023, Apr. 11, 2022]

§ 1309.34 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If the application is found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not be accepted for filing.

(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 1309.35 and has no bearing on

whether the application will be granted.

[60 FR 32454, June 22, 1995, as amended at 87 FR 21023, Apr. 11, 2022]

§ 1309.35 Additional information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

§ 1309.36 Amendments to and withdrawals of applications.

(a) An application may be amended or withdrawn without permission of the Administration at any time before the date on which the applicant receives an order to show cause pursuant to § 1309.46. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, including a request that the applicant submit the required fee, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

ACTION ON APPLICATIONS FOR REGISTRATION: REVOCATION OR SUSPENSION OF REGISTRATION

§ 1309.41 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review the application for registration and other information gathered by the

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Administrator regarding an applicant in order to determine whether the applicable standards of Section 303 of the Act (21 U.S.C. 823) have been met by the applicant.

§ 1309.42 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 511) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section 303 of the Act (21 U.S.C. 823). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to Section 1309.46 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1309.51.

(b) The Certificate of Registration (DEA Form 511) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the amount of fee paid, and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to List I chemicals or controlled substances.

§ 1309.43 Suspension or revocation of registration.

(a) The Administrator may suspend any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time he determines.

(b) The Administrator may revoke any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(c) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to Section 1309.46 and, if requested by the registrant, shall hold a hearing pursuant to Section 1309.51. Notwithstanding the requirements of this Section, however, the Administrator may suspend any registration pending a final order pursuant to § 1309.44.

(d) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all List I chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, to the nearest office of the Administration or to authorized agents of the Administration; or

(2) Place all such List I chemicals in his or her possession under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

(e) In the event that revocation or suspension is limited to a particular chemical or chemicals, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of the Administrator revoking or suspending registration with respect to a particular chemical or chemicals, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular chemical or chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, which are affected by the revocation or suspension; or

(2) Place all of such chemicals under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

[60 FR 32454, June 22, 1995, as amended at 62 FR 5916, Feb. 10, 1997]

§ 1309.44 Suspension of registration pending final order.

(a) The Administrator may suspend any registration simultaneously with

or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he shall serve with the order to show cause pursuant to § 1309.46 an order of immediate suspension that shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of immediate suspension, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular chemical or chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, which are affected by the revocation or suspension; or

(2) Place all of such chemicals under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to Section 1309.46, which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

[60 FR 32454, June 22, 1995, as amended at 62 FR 5916, Feb. 10, 1997]

§ 1309.45 Extension of registration pending final order.

In the event that an applicant for reregistration (who is doing business under a registration previously granted

and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

§ 1309.46 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 of the Act (21 U.S.C. 823) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the application for registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 of the Act (21 U.S.C. 824), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

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(d)(1) *When to File: Hearing Request.* A party that wishes to request a hearing in response to an order to show cause must file with the Office of the Administrative Law Judges and serve on DEA such request no later than 30 days following the date of receipt of the order to show cause. Service of the request on DEA shall be accomplished by sending it to the address, or email address, provided in the order to show cause.

(2) *When to File: Answer.* A party requesting a hearing shall also file with the Office of the Administrative Law Judges and serve on DEA an answer to the order to show cause no later than 30 days following the date of receipt of the order to show cause. A party shall also serve its answer on DEA at the address, or email address, provided in the order to show cause. The presiding officer may, upon a showing of good cause by the party, consider an answer that has been filed out of time.

(3) *Contents of Answer; Effect of Failure to Deny.* For each factual allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have, and is unable to obtain, sufficient information to admit or deny the allegation. When a party intends in good faith to deny only a part of an allegation, the party shall specify so much of it as is true and shall deny only the remainder. A statement of a lack of information shall have the effect of a denial. Any factual allegation not denied shall be deemed admitted.

(4) *Amendments.* Prior to the issuance of the prehearing ruling, a party may as a matter of right amend its answer one time. Subsequent to the issuance of the prehearing ruling, a party may amend its answer only with leave of the presiding officer. Leave shall be freely granted when justice so requires.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

[60 FR 32454, June 22, 1995, as amended at 81 FR 97021, Dec. 30, 2016; 87 FR 68044, Nov. 14, 2022]

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HEARINGS

§ 1309.51 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application therefore, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 303 and 304 of the Act (21 U.S.C. 823–824), by §§1309.52 through 1309.55, and by the procedures for administrative hearings under the Act set forth in §§1316.41 through 1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

[60 FR 32454, June 22, 1995, as amended at 81 FR 97021, Dec. 30, 2016]

§ 1309.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 1309.53 Request for hearing or appearance; waiver; default.

(a) Any person entitled to a hearing pursuant to §§1309.42 and 1309.43 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b)(1) Any person entitled to a hearing pursuant to §1309.42 or 1309.43 who fails to file a timely request for a hearing, shall be deemed to have waived their right to a hearing and to be in default, unless the registrant/applicant establishes good cause for failing to file a timely hearing request. Any person who has failed to timely request a hearing under paragraph (a) may seek to be excused from the default by filing

a motion with the Office of Administrative Law Judges establishing good cause to excuse the default no later than 45 days after the date of receipt of the order to show cause. Thereafter, any person who has failed to timely request a hearing under paragraph (a) and seeks to be excused from the default, shall file such motion with the Office of the Administrator, which shall have exclusive authority to rule on the motion.

(2) Any person who has requested a hearing pursuant to this section but who fails to timely file an answer and who fails to demonstrate good cause for failing to timely file an answer, shall be deemed to have waived their right to a hearing and to be in default. Upon motion of DEA, the presiding officer shall then enter an order terminating the proceeding.

(3) In the event DEA fails to prosecute or a person who has requested a hearing fails to plead (including by failing to file an answer) or otherwise defend, said party shall be deemed to be in default and the opposing party may move to terminate the proceeding. Upon such motion, the presiding officer shall then enter an order terminating the proceeding, absent a showing of good cause by the party deemed to be in default. Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.

(c) If any person entitled to participate in a hearing pursuant to this section fails to file a notice of appearance either as part of a hearing request or separately, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived their opportunity to participate in the hearing, unless such person shows good cause for such failure.

(d) A default, unless excused, shall be deemed to constitute a waiver of the applicant's/registrant's right to a hearing and an admission of the factual allegations of the order to show cause.

(e)(1) In the event that a registrant/applicant is deemed to be in default pursuant to paragraph (b)(1) of this section and has not established good cause to be excused from the default, or the

presiding officer has issued an order terminating the proceeding pursuant to paragraphs (b)(2) or (b)(3) of this section, DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to §1316.67 of this chapter.

(2) In the event that DEA is deemed to be in default and the presiding officer has issued an order terminating the proceeding pursuant to paragraph (b)(3) of this section, the presiding officer shall transmit the record to the Administrator for his consideration no later than five business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, DEA may seek relief only by filing a motion with the Office of the Administrator establishing good cause to excuse its default.

(3) A party held to be in default may move to set aside a default final order issued by the Administrator by filing a motion no later than 30 days from the date of issuance by the Administrator of a default final order. Any such motion shall be granted only upon a showing of good cause to excuse the default.

[60 FR 32454, June 22, 1995. Redesignated at 62 FR 13968, Mar. 24, 1997; 87 FR 68045, Nov. 14, 2022]

§ 1309.54 Burden of proof.

(a) At any hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 of the Act (21 U.S.C. 823) are not satisfied.

(b) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

[60 FR 32454, June 22, 1995. Redesignated at 62 FR 13968, Mar. 24, 1997]

§ 1309.55 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the FEDERAL REGISTER (unless

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expedited pursuant to Section 1309.44(c)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[60 FR 32454, June 22, 1995. Redesignated at 62 FR 13968, Mar. 24, 1997]

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

§ 1309.61 Modification in registration.

Any registrant may apply to modify his or her registration to authorize the handling of additional List I chemicals or to change his or her name or address, by submitting a letter of request 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. The letter shall contain the registrant's name, address, and registration number as printed on the certificate of registration, and the List I chemicals to be added to his registration or the new name or address and shall be signed in accordance with § 1309.32(g). No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 511) to the registrant, who shall maintain it with the old certificate of registration until expiration.

[75 FR 10680, Mar. 9, 2010]

§ 1309.62 Termination of registration.

(a) The registration of any person shall terminate, without any further action by the Administration, if and when such person dies, ceases legal existence, discontinues business or professional practice, or surrenders a registration. Any registrant who ceases legal existence or discontinues business or professional practice shall promptly notify the Special Agent in Charge of the Administration in the area in which the person is located of such fact and seek authority and instructions to dispose of any List I

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chemicals obtained under the authority of that registration. Any registrant who ceases legal existence or discontinues business or professional practice or wishes to surrender a registration shall notify the Special Agent in Charge of the Administration in the area in which the person is located of such fact and seek authority and instructions to dispose of any List I chemicals obtained under the authority of that registration.

(b) The Special Agent in Charge shall authorize and instruct the person to dispose of the List I chemical in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substances;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

[60 FR 32454, June 22, 1995, as amended at 62 FR 5916, Feb. 10, 1997; 76 FR 61564, Oct. 5, 2011; 77 FR 4236, Jan. 27, 2012]

§ 1309.63 Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.

SECURITY REQUIREMENTS

§ 1309.71 General security requirements.

(a) All applicants and registrants must provide effective controls and procedures to guard against theft and diversion of List I chemicals. Chemicals must be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.

(b) In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:

(1) The type, form, and quantity of List I chemicals handled;

(2) The location of the premises and the relationship such location bears on the security needs;

(3) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(4) The availability of electronic detection and alarm systems;

(5) The extent of unsupervised public access to the facility;

(6) The adequacy of supervision over employees having access to List I chemicals;

(7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored; and

(8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.

(c) Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the Special Agent in Charge in the region in which the security controls and procedures will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

[60 FR 32454, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997; 67 FR 14861, Mar. 28, 2002; 71 FR 56023, Sept. 26, 2006; 75 FR 10680, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]

§ 1309.72 Felony conviction; employer responsibilities.

(a) The registrant shall exercise caution in the consideration of employment of persons who will have access to listed chemicals, who have been convicted of a felony offense relating to controlled substances or listed chemicals, or who have, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause. (For purposes of this subsection, the term "for cause" means

a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances or listed chemicals.) The registrant should be aware of the circumstances regarding the action against the potential employee and the rehabilitative efforts following the action. The registrant shall assess the risks involved in employing such persons, including the potential for action against the registrant pursuant to §1309.43. If such person is found to have diverted listed chemicals, and, in the event of employment, shall institute procedures to limit the potential for diversion of List I chemicals.

(b) It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

§ 1309.73 Employee responsibility to report diversion.

Reports of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall

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inform all employees concerning this policy.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

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- 1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

AUTHORITY: 21 U.S.C. 802, 827(h), 830, 871(b) 890.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1310.01 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]

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA

Chemical Code Number set forth opposite it.

(a) List I chemicals

- (1) Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN) 8512
- (2) Anthranilic acid, its esters, and its salts 8530
- (3) Benzyl cyanide 8735
- (4) Ephedrine, its salts, optical isomers, and salts of optical isomers 8113
- (5) Ergonovine and its salts 8675
- (6) Ergotamine and its salts 8676
- (7) N-Acetylanthranilic acid, its esters, and its salts 8522
- (8) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers 8317
- (9) Phenylacetic acid, its esters, and its salts 8791
- (10) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers 1225
- (11) Piperidine and its salts 2704
- (12) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers 8112
- (13) 3,4-Methylenedioxyphenyl-2-propanone 8502
- (14) Methylamine and its salts ... 8520
- (15) Ethylamine and its salts 8678
- (16) Propionic anhydride 8328
- (17) Isosafrole 8704
- (18) Safrole 8323
- (19) Piperonal 8750
- (20) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine) 8115
- (21) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers 8119
- (22) Hydriodic Acid 6695
- (23) Benzaldehyde 8256
- (24) Nitroethane 6724
- (25) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone) 2011
- (26) Red phosphorus 6795
- (27) White phosphorus (Other names: Yellow Phosphorus) 6796