

## Drug Enforcement Administration, Justice

## § 1301.13

with a modification authorizing such activity.

[74 FR 15621, Apr. 6, 2009]

### § 1301.12 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) or subsection 1007(b)(1)(B) of the Act (21 U.S.C. 822(c)(2) or 957(b)(1)(B));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location in the same State or jurisdiction of the United States) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

(4) A freight forwarding facility, as defined in §1300.01 of this part, provided that the distributing registrant operating the facility has submitted written notice of intent to operate the facility by registered mail, return receipt requested (or other suitable means of documented delivery) and such notice has been approved. The notice shall be submitted to the Special Agent in Charge of the Administration's offices in both the area in which

the facility is located and each area in which the distributing registrant maintains a registered location that will transfer controlled substances through the facility. The notice shall detail the registered locations that will utilize the facility, the location of the facility, the hours of operation, the individual(s) responsible for the controlled substances, the security and record-keeping procedures that will be employed, and whether controlled substances returns will be processed through the facility. The notice must also detail what state licensing requirements apply to the facility and the registrant's actions to comply with any such requirements. The Special Agent in Charge of the DEA Office in the area where the freight forwarding facility will be operated will provide written notice of approval or disapproval to the person within thirty days after confirmed receipt of the notice. Registrants that are currently operating freight forwarding facilities under a memorandum of understanding with the Administration must provide notice as required by this section no later than September 18, 2000 and receive written approval from the Special Agent in Charge of the DEA Office in the area in which the freight forwarding facility is operated in order to continue operation of the facility.

[62 FR 13945, Mar. 24, 1997, as amended at 65 FR 44678, July 19, 2000; 65 FR 45829, July 25, 2000; 71 FR 69480, Dec. 1, 2006]

### § 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

(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 granted and 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/her registration, except that a bulk

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manufacturer of Schedule I or II controlled substances or an importer of Schedule I or II controlled substances may apply to be reregistered no more than 120 days before the expiration date of their registration.

(c) At the time a manufacturer, distributor, reverse distributor, researcher, analytical lab, importer, exporter or narcotic treatment program is first registered, that business activity 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 date of the month designated for that group. In assigning any of these business activities 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 business activity is assigned to a group which has an expiration date less than three months from the date of which the business activity 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 business activity is registered.

(d) At the time a retail pharmacy, hospital/clinic, practitioner or teaching institution is first registered, that business activity 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 business activities to a group, the Administration may select a group the expiration date of which is not less than 28 months nor more than 39 months from the date such business ac-

tivity was registered. After the initial registration period, the registration shall expire 36 months from the initial expiration date.

(e) Any person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substances activities, which are deemed to be independent of each other. Application for each registration shall be made on the indicated form, and shall be accompanied by the indicated fee. Fee payments shall be made in the form of a personal, certified, or cashier's check or money order made payable to the "Drug Enforcement Administration". The application fees are not refundable. Any person, when registered to engage in the activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he/she complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities. Any person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph under coincident activities. A single registration to engage in any group of independent activities listed below may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substances listed in Schedule I for which he/she has filed and had approved a research protocol.

(1)

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Business activity	Controlled substances	DEA application forms	Application fee (dollars)	Registration period (years)	Coincident activities allowed
(i) Manufacturing	Schedules I-V	New—225 Renewal—225a	2,293 2,293	1	Schedules I-V: May distribute that substance or class for which registration was issued; may not distribute or dispose any substance or class for which not registered. Schedules II-V: except a person registered to dispose of any controlled substance may conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfg. was issued.
(ii) Distributing	Schedules I-V	New—225 Renewal—225a	1,147 1,147	1	
(iii) Reverse distributing	Schedules I-V	New—225 Renewal—225a	1,147 1,147	1	
(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Online Pharmacy, Central fill pharmacy, Teaching Institution)	Schedules II-V	New—224 Renewal—224a Online Pharmacy—224c	551 551	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under State statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II-V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities. An online pharmacy may perform activities of retail pharmacy as well as online pharmacy activities.
(v) Research	Schedule I	New—225 Renewal—225a	184 184	1	A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in § 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.
(vi) Research	Schedules II-V	New—225 Renewal—225a	184 184	1	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempted from registration pursuant to § 1301.24; and conduct instructional activities with controlled substances.

Business activity	Controlled substances	DEA application forms	Application fee (dollars)	Registration period (years)	Coincident activities allowed
(vii) Narcotic Treatment Program (including compounding)	Narcotic Drugs in Schedules II–V	New—363 Renewal—363a	184 184	1	
(viii) Importing	Schedules I–V	New—225 Renewal—225a	1,147 1,147	1	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
(ix) Exporting	Schedules I–V	New—225 Renewal—225a	1,147 1,147	1	
(x) Chemical Analysis	Schedules I–V	New—225 Renewal—225a	184 184	1	May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to §1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws related to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

(2) DEA Forms 224, 225, and 363 may be obtained at any area office of the Administration or 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.

(3) Registrants will receive renewal notifications approximately 60 days prior to the registration expiration date. DEA Forms 224a, 225a, and 363a may be mailed, as applicable, to registrants; if any registered person does not receive such notification within 45 days before the registration expiration date, the registrant must promptly give notice of such fact and may request such forms by writing to the Registration Section, Drug Enforcement Administration.

(f) Each application for registration to handle any basic class of controlled substance listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter,

for each basic class to be covered by such registration.

(g) Each application for registration to import or export controlled substances shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each controlled substance whose importation or exportation is to be authorized by such registration. Registration as an importer or exporter shall not entitle a registrant to import or export any controlled substance not specified in such registration.

(h) Each application for registration to conduct research with any basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each such basic class to be manufactured or imported as a coincident activity of that registration. A statement listing the quantity of each such basic class of controlled substance to be imported or manufactured during the registration period for which application is being made shall be included

with each such application. For purposes of this paragraph only, manufacturing is defined as the production of a controlled substance by synthesis, extraction or by agricultural/horticultural means.

(i) 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.

(j) 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 Registration Unit of the Administration 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 applications. The power of attorney shall be valid until revoked by the applicant.

[62 FR 13946, Mar. 24, 1997, as amended at 68 FR 37409, June 24, 2003; 68 FR 41228, July 11, 2003; 68 FR 58598, Oct. 10, 2003; 71 FR 51112, Aug. 29, 2006; 74 FR 15622, Apr. 6, 2009; 75 FR 10676, Mar. 9, 2010]

**§ 1301.14 Filing of application; acceptance for filing; defective applications.**

(a) All applications for registration shall be submitted for filing to the Registration Unit, Drug Enforcement Administration. The appropriate registration fee and any required attachments must accompany the application. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.

(c) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing

to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(d) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to §1301.15 and has no bearing on whether the application will be granted.

[62 FR 13948, Mar. 24, 1997, as amended at 75 FR 10676, Mar. 9, 2010]

**§ 1301.15 Additional information.**

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she 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.

[62 FR 13948, Mar. 24, 1997]

**§ 1301.16 Amendments to and withdrawal of applications.**

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to §1301.37. 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.