

the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

[62 FR 13945, Mar. 24, 1997]

§ 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 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, 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 the above 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 teach-

ing 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 activity 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

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he/she has filed and had approved a re- (1)
search protocol.

Business activity	Controlled substances	DEA application forms	Applica- tion fee (dollars)	Reg- istra- tion period (years)	Coincident activities allowed
(i) Manufacturing	Schedules I through V	New—225 Renewal—225a	875 875	1	Schedules I through V: May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered. Schedules II through V: May conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a manufacturer was issued.
(ii) Distributing	Schedules I through V	New—225 Renewal—225a	438 438	1	
(iii) Dispensing or In- structing (Includes Practitioner Hos- pital/Clinic, Retail Pharmacy, Teach- ing Institution)	Schedules II through V	New—224 Renewal—224a	210 210	3	May conduct research and instruc- tional activities with those sub- stances for which registration was granted, except that a mid-level practitioner may conduct such re- search only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a nar- cotic controlled substance in Schedule II through V in a propor- tion not exceeding 20 percent of the complete solution, compound, or mixture.
(iv) Research	Schedule I	New—225 Renewal—225a	70 70	1	A researcher may manufacture or im- port 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 Section 1301.18 and to distribute such class to persons registered or au- thorized to conduct research with such class of substance or reg- istered or authorized to conduct chemical analysis with controlled substances.
(v) Research	Schedules II through V	New—225 Renewal—225a	70 70	1	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such sub- stances 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 per- sons registered or authorized to conduct chemical analysis, instruc- tional activities, or research with such substances, and to persons exempted from registration pursu- ant to Section 1301.24; and con- duct instructional activities with controlled substances.
(vi) Narcotic Treat- ment Program (in- cluding compounder)	Narcotic Drugs in Schedules II through V	New—363 Renewal—363a	70 70	1	

Business activity	Controlled substances	DEA application forms	Application fee (dollars)	Registration period (years)	Coincident activities allowed
(vii) Importing	Schedules I through V	New—225 Renewal—225a	438 438	1	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
(viii) Exporting	Schedules I through V	New—225 Renewal—225a	438 438	1	
(ix) Chemical Analysis	Schedules I through V	New—225 Renewal—225a	70 70	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 Section 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws relating 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 Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(3) DEA Forms 224a, 225a, and 363a will be mailed, as applicable, to each registered person approximately 60 days before the expiration date of his/her registration; if any registered person does not receive such forms within 45 days before the expiration date of his/her registration, he/she must promptly give notice of such fact and request such forms by writing to the Registration Unit of the Administration at the foregoing address.

(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 Administra-

tion 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.

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§ 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, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The appropriate registration fee and any required attachments must accompany the application.

(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 fil-

ing 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.

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§ 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.

(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, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

[62 FR 13949, Mar. 24, 1997]

§ 1301.17 Special procedures for certain applications.

(a) If, at the time of application for registration of a new pharmacy, the pharmacy has been issued a license from the appropriate State licensing