Title 21 —Food and Drugs
Chapter II —Drug Enforcement Administration, Department of Justice
Part 1301 —Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances
Registration

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.
Source: 36 FR 7778, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

§ 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, 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 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. Generally, the application fees are not refundable; however, they may be issued in limited circumstances at the discretion of the Administrator. These circumstances include: Applicant error, such as duplicate payments, payment for incorrect business activities, or

payments made by persons who are exempt under this section from application or renewal fees; DEA error; and death of a registrant within the first year of the three-year registration cycle. 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)

Summary of Registration Requirements and Limitations

Business activity	Controlled substances	DEA application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(i) Manufacturing	Schedules I-V	New—225 Renewal—225a	3,699	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: May conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfr. was issued.
(ii) Distributing	Schedules I-V	New—225 Renewal—225a	1,850	1	May acquire Schedules II-V controlled substances from collectors for the purposes of destruction.

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(iii) Reverse distributing	Schedules I-V	New—225 Renewal—225a	1,850	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	888	3	May conduct research and instructional activities with those controlled 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 manufacturer an aqueous or oleaginous solution 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	296	1	A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that

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					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	296	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

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					or research with such substances, and to persons exempted from registration pursuant to § 1301.24; and conduct instructional activities with controlled substances.
(vii) Narcotic Treatment Program (including compounder)	Narcotic Drugs in Schedules II-V	New-363 Renewal-363a	296	1	May operate one or more mobile narcotic treatment programs as defined under § 1300.01(b), provided approval has been obtained under § 1301.13(e)(4).
(viii) Importing	Schedules I-V	New—225 Renewal—225a	1,850	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	1,850	1	
(x) Chemical Analysis	Schedules I-V	New—225 Renewal—225a	296	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 §

Business activity	Controlled substances	DEA application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
					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 online at *www.DEAdiversion.usdoj.gov*. Only applications submitted online through the secure application portal on DEA's website will be accepted for processing.

(3) DEA will send renewal notifications via email to registrants approximately 60 calendar days prior to their registration expiration date. Registrants are responsible for maintaining a current email address in application portal on DEA's website. DEA Forms 224a, 225a, and 363a may be obtained online at *www.DEAdiversion.usdoj.gov*. Only renewal applications submitted online through the secure application portal on DEA's website will be accepted for processing.

(4) For any narcotic treatment program (NTP) intending to operate a mobile NTP, the registrant must notify the local DEA office, in writing, of its intent to do so, and the NTP must receive explicit written approval from the local DEA office prior to operating the mobile NTP. The mobile NTP may only operate in the same State in which the NTP is registered.

(i) Registrants are not required to obtain a separate registration for conveyances (mobile components) utilized by the registrant to transport controlled substances away from registered locations for dispensing at unregistered locations as part of a mobile NTP. Vehicles must possess valid county/city and State information (*e.g.,* a vehicle information number (license plate number) on file at the registered location of the NTP. Registrants are also required to provide proper city/county and State licensing and registration to DEA at the time of inspection, and prior to transporting controlled substances away from their registered location.

(ii) A mobile NTP is not permitted to reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location. NTPs with mobile components are not allowed to modify their registrations to authorize their mobile components to act as collectors under 21 CFR 1301.51 and 1317.40. Mobile components of NTPs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and will not transport patients.

(iii) A mobile NTP may operate at any remote location or locations within the same State as its registered location, including correctional facilities, so long as doing so is otherwise consistent with applicable Federal, State, tribal, and local laws and regulations, and so long as the local DEA office, when notified pursuant to this section, does not otherwise direct.

(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; 77 FR 15248, Mar. 15, 2012; 79 FR 53560, Sept. 9, 2014; 85 FR 44732, July 24, 2020; 85 FR 61601, Sept. 30, 2020; 85 FR 67278, Oct. 22, 2020; 86 FR 33883, June 28, 2021; 87 FR 21022, Apr. 11, 2022; 90 FR 47563, Oct. 2, 2025]