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21 CFR Ch. II (4-1-23 Edition)

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; 81 FR 97019, Dec. 30, 2016]

§ 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

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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". 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 pre-clinical 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.
(iii) Reverse distributing.	Schedules I-V	New—225 Renewal— 225a.	1,850	1	

SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS—Continued

Business activity	Controlled substances	DEA application forms	Application fee (\$)	Registration period (years)	Coincident activities allowed
(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 manufacture 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 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.

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SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS—Continued

Business activity	Controlled substances	DEA application forms	Application fee (\$)	Registration period (years)	Coincident activities allowed
(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 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	

SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS—Continued

Business activity	Controlled substances	DEA application forms	Application fee (\$)	Registration period (years)	Coincident activities allowed
(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 § 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]

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

(a) All applications for registration shall be submitted for filing online using the secure application portal at *www.DEAdiversion.usdoj.gov*.

(b) Application submitted for filing are dated by the system 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 be rejected by the system, with the applicant receiving error messages at the time of application.

(c) 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; 87 FR 21022, Apr. 11, 2022]

§ 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