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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.

§ 1301.12 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 in which he or she practices) 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 recordkeeping 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.

- (c) As provided in 21 U.S.C. 822(e)(2), a registrant who is a veterinarian may transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice without obtaining a separate registration so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

[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; 89 FR 8539, Feb. 8, 2024]