

§ 1301.45

Any other person participating in the hearing pursuant to §1301.35(b) shall have the burden of proving any propositions of fact or law asserted by such person in the hearing.

(b) At any hearing on the granting or denial of an applicant to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall have the burden of proving that the requirements for each registration pursuant to section 303(g) of the Act (21 U.S.C. 823(g)) are satisfied.

(c) At any hearing on the granting or denial of an application to be registered to import or export any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to sections 1008(a) and (d) of the Act (21 U.S.C. 958 (a) and (d)) are satisfied. Any other person participating in the hearing pursuant to §1301.34 shall have the burden of proving any propositions of fact or law asserted by him/her in the hearings.

(d) At any other hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 or section 1008(c) and (d) of the Act (21 U.S.C. 823 or 958(c) and (d)) are not satisfied.

(e) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) or section 1008(d) of the Act (21 U.S.C. 824(a) or 958(d)) are satisfied.

[62 FR 13956, Mar. 24, 1997]

§ 1301.45 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the FEDERAL REGISTER (unless expedited pursuant to §1301.36(h)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[62 FR 13956, Mar. 24, 1997]

21 CFR Ch. II (4–1–23 Edition)

§ 1301.46 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his/her order on the granting, denial, revocation, or suspension of registration. In the event that an application for registration to import or to manufacture in bulk a basic class of any controlled substance listed in Schedule I or II is granted, or any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his/her order upon each party in the hearing.

[62 FR 13956, Mar. 24, 1997]

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

§ 1301.51 Modification in registration.

(a) Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address by submitting a written request to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Additionally, such a request may be submitted on-line at www.DEAdiversion.usdoj.gov.

(1) The request shall contain:

(i) The registrant's name, address, and registration number as printed on the certificate of registration;

(ii) The substances and/or schedules to be added to the registration or the new name or address; and

(iii) A signature in accordance with §1301.13(j).

(2) If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, the registrant shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate.

(b) Any manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy registered pursuant to this part, may apply to modify its registration to become authorized as a collector by submitting a written request to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Additionally, such request may be submitted on-line at *www.DEAdiversion.usdoj.gov*.

(1) The request shall contain:

(i) The registrant's name, address, and registration number as printed on the certificate of registration;

(ii) The method(s) of collection the registrant intends to conduct (collection receptacle and/or mail-back program); and

(iii) A signature in accordance with §1301.13(j).

(2) If a hospital/clinic with an on-site pharmacy or retail pharmacy is applying for a modification in registration to authorize such registrant to be a collector to maintain a collection receptacle at a long-term care facility in accordance with §1317.80 of this chapter, the request shall also include the name and physical location of each long-term care facility at which the hospital/clinic with an on-site pharmacy, or the retail pharmacy, intends to operate a collection receptacle.

(c) No fee shall be required for modification. The request for modification shall be handled in the same manner as an application for registration. If the modification of registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 223) to the registrant, who shall maintain it with the old certificate of registration until expiration.

[79 FR 53561, Sept. 9, 2014]

§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.

(a) Except as provided in paragraph (b) of this section, the registration of any person, and any modifications of that registration, shall terminate, without any further action by the Administration, if and when such person

dies, ceases legal existence, discontinues business or professional practice, or surrenders a registration. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact. In the case of a surrender, termination shall occur upon receipt by any employee of the Administration of a duly executed DEA form 104 or any signed writing indicating the desire to surrender a registration.

(b) No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administration may specifically designate and then only pursuant to written consent. Any person seeking authority to transfer a registration shall submit a written request, providing full details regarding the proposed transfer of registration, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(c) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his/her certificate of registration, and any unexecuted order forms in his/her possession, to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Any controlled substances in his/her possession may be disposed of in accordance with part 1317 of this chapter.

(d) Any registrant desiring to discontinue business activities altogether or with respect to controlled substance (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information: