

the form prescribed in §1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance.

(c)(1) Any person entitled to a hearing pursuant to §1301.32 or 1301.34 through 36 who fails to file a timely request for a hearing shall be deemed to have waived their right to a hearing and to be in default, unless the registrant/applicant establishes good cause for failing to file a timely hearing request. Any person who has failed to timely request a hearing under paragraph (a) of this section may seek to be excused from the default by filing a motion with the Office of Administrative Law Judges establishing good cause to excuse the default no later than 45 days after the date of receipt of the order to show cause. Thereafter, any person who has failed to timely request a hearing under paragraph (a) of this section and seeks to be excused from the default shall file such motion with the Office of the Administrator, which shall have exclusive authority to rule on the motion.

(2) Any person who has requested a hearing pursuant to this section but who fails to timely file an answer and who fails to demonstrate good cause for failing to timely file an answer, shall be deemed to have waived their right to a hearing and to be in default. Upon motion of DEA, the presiding officer shall then enter an order terminating the proceeding.

(3) In the event DEA fails to prosecute or a person who has requested a hearing fails to plead (including by failing to file an answer) or otherwise defend, said party shall be deemed to be in default and the opposing party may move to terminate the proceeding. Upon such motion, the presiding officer shall then enter an order terminating the proceeding, absent a showing of good cause by the party deemed to be in default. Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.

(d) If any person entitled to participate in a hearing pursuant to this section fails to file a notice of appearance either as part of a hearing request or

separately, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived their opportunity to participate in the hearing, unless such person shows good cause for such failure.

(e) A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the order to show cause.

(f)(1) In the event that a registrant/applicant is deemed to be in default pursuant to paragraph (c)(1) of this section, and has not established good cause to be excused from the default, or the presiding officer has issued an order terminating the proceeding pursuant to paragraphs (c)(2) or (c)(3) of this section, DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to §1316.67 of this chapter.

(2) In the event that DEA is deemed to be in default and the presiding officer has issued an order terminating the proceeding pursuant to paragraph (c)(3) of this section, the presiding officer shall transmit the record to the Administrator for his consideration no later than five business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, DEA may seek relief only by filing a motion with the Office of the Administrator establishing good cause to excuse its default.

(3) A party held to be in default may move to set aside a default final order issued by the Administrator by filing a motion no later than 30 days from the date of issuance by the Administrator of a default final order. Any such motion shall be granted only upon a showing of good cause to excuse the default.

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§ 1301.44 Burden of proof.

(a) At any hearing on an application to manufacture 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 section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied.

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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.

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§ 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.

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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.