

shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular controlled substance or substances affected by the revocation or suspension which are in his/her possession; or

(2) Place all of such substances under seal as described in sections 304(f) or 958(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(h) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under paragraph (e) of this section may request a hearing on the revocation or suspension of his/her registration at a time earlier than specified in the order to show cause pursuant to §1301.37. This request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

(i) In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

[62 FR 13955, Mar. 24, 1997]

§ 1301.37 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 and/or section 1008 of the Act (21 U.S.C. 823 and 958) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 or section 1008 of the Act (21 U.S.C. 824 and 958), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he/she desires a hearing, file a request for a hearing pursuant to §1301.43. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to §1301.41.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

[62 FR 13955, Mar. 24, 1997]

HEARINGS

§ 1301.41 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be

§ 1301.42

governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by sections 303, 304, and 1008 of the Act (21 U.S.C. 823-824 and 958), by §§1301.42-1301.46 of this part, and by the procedures for administrative hearings under the Act set forth in §§1316.41-1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

[62 FR 13956, Mar. 24, 1997]

§ 1301.42 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to import or to manufacture in bulk a basic class of controlled substance listed in Schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

[62 FR 13956, Mar. 24, 1997]

§ 1301.43 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §1301.32 or §§1301.34-1301.36 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause (or the date of publication of notice of the application for registration in the FEDERAL REGISTER in the case of §1301.34), file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any person entitled to participate in a hearing pursuant to §1301.34 or §1301.35(b) and desiring to do so shall, within 30 days of the date of publication of notice of the request for a hearing in the FEDERAL REGISTER, file with the Administrator a written notice of intent to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for

21 CFR Ch. II (4-1-20 Edition)

a hearing need not also file a notice of appearance.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to §1301.32 or §§1301.34-1301.36 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding such person's position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §1301.32 or §§1301.34-1301.36 fails to file a request for a hearing or a notice of appearance, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his/her final order pursuant to §1301.46 without a hearing.

[62 FR 13956, Mar. 24, 1997]

§ 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. 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