

§ 1309.51

show cause why the application for 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 of the Act (21 U.S.C. 824), 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 desires a hearing, file a request for a hearing pursuant to § 1309.54. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to § 1309.51.

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

HEARINGS

§ 1309.51 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application therefore, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by sections 303 and 304 of the Act (21 U.S.C. 823-824), by §§ 1309.52 through 1309.57, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41 through 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.

21 CFR Ch. II (4-1-03 Edition)

§ 1309.52 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. 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.

§ 1309.53 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, 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 a hearing pursuant to §§ 1309.42 and 1309.43 may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his 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.

(c) If any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 fails to file a request for a hearing, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing, unless he shows good cause for such failure.

(d) If any person entitled to a hearing waives or is deemed to waive his or her opportunity for the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1309.57 without a hearing.

[60 FR 32454, June 22, 1995. Redesignated at 62 FR 13968, Mar. 24, 1997]

§ 1309.54 Burden of proof.

(a) At any hearing for the denial of a registration, the Administration shall