

(d)(1) *When to File: Hearing Request.* A party that wishes to request a hearing in response to an order to show cause must file with the Office of the Administrative Law Judges and serve on DEA such request no later than 30 days following the date of receipt of the order to show cause. Service of the request on DEA shall be accomplished by sending it to the address, or email address, provided in the order to show cause.

(2) *When to File: Answer.* A party requesting a hearing shall also file with the Office of the Administrative Law Judges and serve on DEA an answer to the order to show cause no later than 30 days following the date of receipt of the order to show cause. A party shall also serve its answer on DEA at the address, or the email address, provided in the order to show cause. The presiding officer may, upon a showing of good cause by the party, consider an answer that has been filed out of time.

(3) *Contents of Answer; Effect of Failure to Deny.* For each factual allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have and is unable to obtain sufficient information to admit or deny the allegation. When a party intends in good faith to deny only a part of an allegation, the party shall specify so much of it as is true and shall deny only the remainder. A statement of a lack of information shall have the effect of a denial. Any factual allegation not denied shall be deemed admitted.

(4) *Amendments.* Prior to the issuance of the prehearing ruling, a party may as a matter of right amend its answer one time. Subsequent to the issuance of the prehearing ruling, a party may amend its answer only with leave of the presiding officer. Leave shall be freely granted when justice so requires.

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

[62 FR 13955, Mar. 24, 1997; 87 FR 68044, Nov. 14, 2022]

HEARINGS

§ 1301.41 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any reg-

istration or application therefor, 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, 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; default.

(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

§ 1301.44

21 CFR Ch. II (4–1–25 Edition)

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.

[62 FR 13956, Mar. 24, 1997, as amended at 87 FR 68044, Nov. 14, 2022]

§ 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.