

**§ 1301.37**

registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes pursuant to part 1303 of this chapter and any import or export permits issued to the registrant for such class or classes pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant 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conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction.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

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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)(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