

## Drug Enforcement Administration, Justice

## § 1316.47

(d) The term *Hearing Clerk* means the hearing clerk of the Administration.

(e) The term *person* includes an individual, corporation, government or governmental subdivision or agency, business trust, partnership, association or other legal entity.

(f) The term *presiding officer* means an administrative law judge qualified and appointed as provided in the Administrative Procedure Act (5 U.S.C. 556).

(g) The term *proceeding* means all actions involving a hearing, commencing with the publication by the Administrator of the notice of proposed rule-making or the issuance of an order to show cause.

(h) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[36 FR 7820, Apr. 24, 1971, as amended at 38 FR 757, Jan. 4, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13969, Mar. 24, 1997; 77 FR 4238, Jan. 27, 2012]

### § 1316.43 Information; special instructions.

Information regarding procedure under these rules and instructions supplementing these rules in special instances will be furnished by the Hearing Clerk upon request.

### § 1316.44 Waiver or modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this subpart by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

### § 1316.45 Filings; address; hours.

Documents required or permitted to be filed in, and correspondence relating to, hearings governed by the regulations in this chapter shall be filed with the Hearing Clerk, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. This office is open Monday

through Friday from 8:30 a.m. to 5 p.m. eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time, except on national legal holidays. Documents shall be dated and deemed filed upon receipt by the Hearing Clerk.

[75 FR 10685, Mar. 9, 2010]

### § 1316.46 Inspection of record.

(a) The record bearing on any proceeding, except for material described in subsection (b) of this section, shall be available for inspection and copying by any person entitled to participate in such proceeding, during office hours in the office of the Hearing Clerk, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) The following material shall not be available for inspection as part of the record:

(1) A research protocol filed with an application for registration to conduct research with controlled substances listed in Schedule I, pursuant to §1301.32 (a)(6) of this chapter, if the applicant requests that the protocol be kept confidential;

(2) An outline of a production or manufacturing process filed with an application for registration to manufacture a new narcotic controlled substance, pursuant to §1301.33 of this chapter, if the applicant requests that the outline be kept confidential;

(3) Any confidential or trade secret information disclosed in conjunction with an application for registration, or in reports filed while registered, or acquired in the course of an investigation, entitled to protection under subsection 402(a) (8) of the Act (21 U.S.C. 842(a) (8)) or any other law restricting public disclosure of information; and

(4) Any material contained in any investigatory report, memorandum, or file, or case report compiled by the Administration.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13970, Mar. 24, 1997; 75 FR 10645, Mar. 9, 2010]

### § 1316.47 Request for hearing; answer.

(a) Any person entitled to a hearing and desiring a hearing shall, within the

## § 1316.48

period permitted for filing, file a request for a hearing that complies with the following format (see the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address):

(Date) \_\_\_\_\_  
Drug Enforcement Administration, Attn:  
Hearing Clerk/OALJ  
(Mailing Address) \_\_\_\_\_  
Subject: Request for Hearing  
Dear Sir:

The undersigned \_\_\_\_\_ (Name of the Person) hereby requests a hearing in the matter of: \_\_\_\_\_ (Identification of the proceeding).  
(State with particularity the interest of the person in the proceeding.)

All notices to be sent pursuant to the proceeding should be addressed to:

(Name) \_\_\_\_\_  
(Street Address) \_\_\_\_\_  
(City and State) \_\_\_\_\_  
Respectfully yours,  
(Signature of Person) \_\_\_\_\_

(b) A party shall file an answer as required under §§1301.37(d) or 1309.46(d) of this chapter, as applicable. The presiding officer, upon request and a showing of good cause, may grant a reasonable extension of the time allowed for filing the answer.

[87 FR 68045, Nov. 14, 2022]

## § 1316.48 Notice of appearance.

Any person entitled to a hearing and desiring to appear in any hearing, shall, if he or she has not filed a request for hearing, file within the time specified in the notice of proposed rule-making, a written notice of appearance in the following format (see the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address):

(Date) \_\_\_\_\_  
Drug Enforcement Administration, Attn:  
Hearing Clerk/OALJ  
(Mailing Address) \_\_\_\_\_  
Subject: Notice of Appearance  
Dear Sir:

Please take notice that \_\_\_\_\_ (Name of person) will appear in the matter of: \_\_\_\_\_ (Identification of the proceeding).

(A) (State with particularity the interest of the person in the proceeding.).

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

## 21 CFR Ch. II (4–1–23 Edition)

(C) (State briefly the position of the person with regard to the particular objections or issues.).

All notices to be sent pursuant to this appearance should be addressed to:

(Name) \_\_\_\_\_  
(Street Address) \_\_\_\_\_  
(City and State) \_\_\_\_\_  
Respectfully yours,  
(Signature of Person) \_\_\_\_\_

[81 FR 97041, Dec. 30, 2016]

## § 1316.49 Waiver of hearing.

In proceedings other than those conducted under part 1301 or part 1309 of this chapter, any person entitled to a hearing may, within the period permitted for filing a request for hearing or notice of appearance, 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.

[36 FR 7820, Apr. 24, 1971, as amended at 87 FR 68045, Nov. 14, 2022]

## § 1316.50 Appearance; representation; authorization.

Any person entitled to appear in a hearing may appear in person or by a representative in any proceeding or hearing and may be heard with respect to matters relevant to the issues under consideration. A representative must either be an employee of the person or an attorney at law who is a member of the bar, in good standing, of any State, territory, or the District of Columbia, and admitted to practice before the highest court of that jurisdiction. Any representative may be required by the Administrator or the presiding officer to present a notarized power of attorney showing his authority to act in such representative capacity and/or an affidavit or certificate of admission to practice.

[36 FR 7820, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]