

and/or adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by the procedures set forth in this subpart, except where more specific regulations (set forth in §§ 1301.51-1301.57, §§ 1303.31-1303.37, §§ 1308.41-1308.51, §§ 1311.51-1311.53, §§ 1312.41-1312.47, or §§ 1313.51-1313.57) apply.

[36 FR 7820, Apr. 24, 1971, as amended at 37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13970, Mar. 24, 1997]

#### § 1316.42 Definitions.

As used in this subpart, the following terms shall have the meanings specified:

(a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term *Administrator* means the Administrator of the Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(c) The term *hearing* means any hearing held pursuant to the Act.

(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]

#### § 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, Department of Justice, Washington, DC 20537. 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.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 55 FR 27464, July 3, 1990]

#### § 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, Department of Justice, Washington, DC 20537.

(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

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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]

**§ 1316.47 Request for hearing.**

(a) Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing in the following form:

\_\_\_\_\_  
(Date)  
Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative.

DEAR SIR: The undersigned \_\_\_\_\_ (Name of person) hereby requests a hearing 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.)

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

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

\_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Street address)

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(City and State)

Respectfully yours,

\_\_\_\_\_  
(Signature of person)

(b) The Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of the time allowed for response to an Order to Show Cause.

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

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1316.47, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

**§ 1316.48 Notice of appearance.**

Any person entitled to a hearing and desiring to appear in any hearing, shall, if he 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 form:

\_\_\_\_\_  
(Date)  
Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative.

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.)

(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,