

§ 1316.31

(2) The researcher's registration number for the research project;

(3) The location of the research project;

(4) A concise statement of the scope of the researcher's registration;

(5) Any limits of the exemption; and

(6) A statement that the exemption shall apply to all acts done in the scope of the exemption while the exemption is in effect. The exemption shall remain in effect until completion of the research project or until the registration of the researcher is either revoked or suspended or his renewal of registration is denied. However, the protection afforded by the grant of exemption from prosecution during the research period shall be perpetual.

(e) Within 30 days of the date of completion of the research project, the researcher shall so notify the Administrator. The Administrator shall issue another letter including the information required in paragraph (d) of this section and stating the date of which the period of exemption concluded; upon receipt of this letter the researcher shall return the original letter of exemption.

[42 FR 54946, Oct. 12, 1977. Redesignated at 54 FR 31670, Aug. 1, 1989, as amended at 62 FR 13970, Mar. 24, 1997]

Subpart C—Enforcement Proceedings

AUTHORITY: 21 U.S.C. 871(b), 883.

§ 1316.31 Authority for enforcement proceeding.

A hearing may be ordered or granted by any Special Agent in Charge of the Drug Enforcement Administration, at his discretion, to permit any person against whom criminal and/or civil action is contemplated under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951) an opportunity to present his views and his proposals for bringing his alleged violations into compliance with the law. Such hearing will also permit him to show cause why prosecution should not be instituted,

21 CFR Ch. II (4–1–03 Edition)

or to present his views on the contemplated proceeding.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

§ 1316.32 Notice of proceeding; time and place.

Appropriate notice designating the time and place for the hearing shall be given to the person. Upon request, timely and properly made, by the person to whom notice has been given, the time or place of the hearing, or both, may be changed if the request states reasonable grounds for such change. Such request shall be addressed to the Special Agent in Charge who issued the notice.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

§ 1316.33 Conduct of proceeding.

Presentation of views at a hearing under this subpart shall be private and informal. The views presented shall be confined to matters relevant to bringing violations into compliance with the Act or to other contemplated proceedings under the Act. These views may be presented orally or in writing by the person to whom the notice was given, or by his authorized representative.

§ 1316.34 Records of proceeding.

A formal record, either verbatim or summarized, of the hearing may be made at the discretion of the Special Agent in Charge. If a verbatim record is to be made, the person attending the hearing will be so advised prior to the start of the hearing.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

Subpart D—Administrative Hearings

AUTHORITY: 21 U.S.C. 811, 812, 871(b), 875, 958(d), 965.

§ 1316.41 Scope of subpart D.

Procedures in any administrative hearing held under the Act are governed generally by the rule making

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