AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

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. The 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.

(e) If any person entitled to a hearing under §1315.52 or entitled to participate in a hearing under paragraph (c) of this section fails to file a request for a hearing or notice of appearance or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing unless he shows good cause for such failure.

(f) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order under §1315.62 without a hearing.

§1315.58 Burden of proof.

(a) At any hearing regarding the determination or adjustment of an assessment of annual needs each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension, or denial of a procurement, import, or individual manufacturing quota, the Administration shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

§1315.60 Time and place of hearing.

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement, import, or individual manufacturing quota under §1315.54, the Administrator shall hold a hearing.

(b) Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(c) The hearing shall commence at the place and time designated in the notice given under paragraph (b) of this section or in the notice of hearing published in the FEDERAL REGISTER pursuant to §1315.11(c) or §1315.13(c), but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement by the presiding officer at the hearing.

§1315.62 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the determination or adjustment of the assessment of annual needs or on the issuance, adjustment, suspension, or denial of the procurement, import, or individual manufacturing quota, as the case may be. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his order upon each party in the hearing.

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subpart A—Administrative Inspections

Sec.

1316.01 Scope of subpart A.
1316.02 Definitions.
1316.03 Authority to make inspections.
1316.04 Exclusion from inspection.
1316.05 Entry.
1316.06 Notice of inspection.
1316.07 Requirement for administrative inspection warrant; exceptions.
1316.08 Consent to inspection.
1316.09 Application for administrative inspection warrant.
1316.10 Administrative probable cause.
1316.11 Execution of warrants.
1316.12 Refusal to allow inspection with an administrative warrant.
1316.13 Frequency of administrative inspections.

Subpart B—Protection of Researchers and Research Subjects

1316.21 Definitions.
1316.22 Exemption.
1316.23 Confidentiality of identity of research subjects.
1316.24 Exemption from prosecution for researchers.

Subpart C—Enforcement Proceedings

1316.31 Authority for enforcement proceeding.
1316.32 Notice of proceeding; time and place.
1316.33 Conduct of proceeding.
1316.34 Records of proceeding.

Subpart D—Administrative Hearings

1316.41 Scope of subpart D.
1316.42 Definitions.
1316.43 Information; special instructions.
1316.44 Waiver or modification of rules.
1316.45 Filings; address; hours.
1316.46 Inspection of record.
1316.47 Request for hearing.
1316.48 Notice of appearance.
1316.49 Waiver of hearing.
1316.50 Appearance; representation; authorization.
1316.51 Conduct of hearing and parties; ex parte communications.
1316.52 Presiding officer.
1316.53 Time and place of hearing.
1316.54 Prehearing conference.
1316.55 Prehearing ruling.
1316.56 Burden of proof.
1316.57 Submission of documentary evidence and affidavits and identification of witnesses subsequent to prehearing conference.
1316.58 Summary of testimony; affidavits.
1316.59 Submission and receipt of evidence.
1316.60 Objections; offer of proof.
1316.61 Exceptions to rulings.
1316.62 Interlocutory appeals from rulings of the presiding officer.
1316.63 Official transcript; index; corrections.
1316.64 Proposed findings of fact and conclusions of law.
1316.65 Report and record.
1316.66 Exceptions.
1316.67 Final order.
1316.68 Copies of petitions for judicial review.

SOURCE: 36 FR 7820, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Subpart A—Administrative Inspections

AUTHORITY: 21 U.S.C. 822(f), 830(a), 871(b), 880, 958(f), 965.

§ 1316.01 Scope of subpart A.

Procedures regarding administrative inspections and warrants pursuant to sections 302(f), 510, 1008(d), and 1015 of the Act (21 U.S.C. 822(f), 880, 958(d), and 965) are governed generally by those sections and specifically by the sections of this subpart.

§ 1316.02 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 *Administration* means the Drug Enforcement Administration.

(c) The term *controlled premises* means—

(1) Places where original or other records or documents required under the Act are kept or required to be kept, and

(2) Places, including factories, warehouses, or other establishments and conveyances, where persons registered under the Act or exempted from registration under the Act, or regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.

(d) 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).

(e) The term *inspector* means an officer or employee of the Administration authorized by the Administrator to make inspections under the Act.

(f) The term *register* and *registration* refer to registration required and permitted by sections 303 and 1008 of the Act (21 U.S.C. 823 and 958).

(g) 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. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 60 FR 32465, June 22, 1995; 60 FR 36334, July 14, 1995; 62 FR 13969, Mar. 24, 1997]

§ 1316.03 Authority to make inspections.

In carrying out his functions under the Act, the Administrator, through his inspectors, is authorized in accordance with sections 510 and 1015 of the Act (21 U.S.C. 880 and 965) to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to part 1304 of this chapter, order form records required to be kept pursuant to part 1305 of this chapter, prescription and distribution records required to be kept pursuant to part 1306 of this chapter, records of listed chemicals, tableting machines, and encapsulating machines required to be kept pursuant to part 1310 of this chapter, import/export records of listed chemicals required to be kept pursuant to part 1313 of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage.

(b) Inspecting within reasonable limits and to a reasonable manner all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances and listed chemicals on-hand at the premises;

(d) Collecting samples of controlled substances or listed chemicals (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 400 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances or listed chemicals by the registrant or regulated person (*i.e.*, has the distribution of controlled substances or listed chemicals increased markedly within the past year, and if so why);

(f) Except as provided in § 1316.04, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 55 FR 50827, Dec. 11, 1990; 60 FR 32465, June 22, 1995; 77 FR 4238, Jan. 27, 2012]

§ 1316.04 Exclusion from inspection.

(a) Unless the owner, operator or agent in charge of the controlled premises so consents in writing, no inspection authorized by these regulations shall extend to:

(1) Financial data:

(2) Sales data other than shipping data; or

(3) Pricing data.

(b) [Reserved]

§ 1316.05 Entry.

An inspection shall be carried out by an inspector. Any such inspector, upon (a) stating his purpose and (b) presenting to the owner, operator or agent in charge of the premises to be inspected (1) appropriate credentials, and (2) written notice of his inspection authority under § 1316.06 of this chapter, and (c) receiving informed consent under § 1316.08 or through the use of administrative warrant issued under §§ 1316.09–1316.13, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

[36 FR 7820, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973; 62 FR 13970, Mar. 24, 1997]

§ 1316.06 Notice of inspection.

The notice of inspection (DEA (or DNB) Form 82) shall contain:

(a) The name and title of the owner, operator, or agent in charge of the controlled premises;

(b) The controlled premises name;

(c) The address of the controlled premises to be inspected;

(d) The date and time of the inspection;

(e) A statement that a notice of inspection is given pursuant to section 510 of the Act (21 U.S.C. 880);

(f) A reproduction of the pertinent parts of section 510 of the Act; and

(g) The signature of the inspector.

§ 1316.07 Requirement for administrative inspection warrant; exceptions.

In all cases where an inspection is contemplated, an administrative inspection warrant is required pursuant to section 510 of the Act (21 U.S.C. 880), except that such warrant shall not be required for establishments applying for initial registration under the Act, for the inspection of books and records pursuant to an administrative subpoena issued in accordance with section 506 of the Act (21 U.S.C. 876) nor for entries in administrative inspections (including seizures of property):

(a) With the consent of the owner, operator, or agent in charge of the controlled premises as set forth in §1316.08;

(b) In situations presenting imminent danger to health or safety;

(c) In situations involving inspection of conveyances where there is reasonable cause to obtain a warrant;

(d) In any other exceptional or emergency circumstance or time or opportunity to apply for a warrant is lacking; or

(e) In any other situations where a warrant is not constitutionally required.

§ 1316.08 Consent to inspection.

(a) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected.

(b) Wherever possible, informed consent shall consist of a written statement signed by the owner, operator, or agent in charge of the premises to be inspected and witnessed by two persons. The written consent shall contain the following information:

(1) That he (the owner, operator, or agent in charge of the premises) has been informed of his constitutional right not to have an administrative inspection made without an administrative inspection warrant;

(2) That he has right to refuse to consent to such an inspection;

(3) That anything of an incriminating nature which may be found may be seized and used against him in a criminal prosecution;

(4) That he has been presented with a notice of inspection as set forth in §1316.06;

(5) That the consent is given by him is voluntary and without threats of any kind; and

(6) That he may withdraw his consent at any time during the course of inspection.

(c) The written consent shall be produced in duplicate and be distributed as follows:

(1) The original will be retained by the inspector; and

(2) The duplicate will be given to the person inspected.

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

§ 1316.09 Application for administrative inspection warrant.

(a) An administrative inspection warrant application shall be submitted to any judge of the United States or of a State court of record, or any United States magistrate and shall contain the following information:

(1) The name and address of the controlled premises to be inspected;

(2) A statement of statutory authority for the administrative inspection warrant, and that the fact that the particular inspection in question is designed to insure compliance with the Act and the regulations promulgated thereunder;

(3) A statement relating to the nature and extent of the administrative inspection, including, where necessary, a request to seize specified items and/or to collect samples of finished or unfinished controlled substances or listed chemicals;

(4) A statement that the establishment either:

(i) Has not been previously inspected, or

(ii) Was last inspected on a particular date.

(b) The application shall be submitted under oath to an appropriate judge or magistrate.

[36 FR 7820, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973; 60 FR 32466, June 22, 1995]

§ 1316.10 Administrative probable cause.

If the judge or magistrate is satisfied that ''administrative probable cause,'' as defined in section 510(d)(1) of the Act (21 U.S.C. 880(d)(1)) exists, he shall issue an administrative warrant. Administrative probable cause shall not mean criminal probable cause as defined by Federal statute or case law.

§ 1316.11 Execution of warrants.

An administrative inspection warrant shall be executed and returned as required by, and any inventory or seizure made shall comply with the requirements of, section 510(d)(3) of the Act (21 U.S.C. 880(d)(3)). The inspection shall begin as soon as is practicable after the issuance of the administrative inspection warrant and shall be completed with reasonable promptness. The inspection shall be conducted during regular business hours and shall be completed in a reasonable manner.

§ 1316.12 Refusal to allow inspection with an administrative warrant.

If a registrant or any person subject to the Act refuses to permit execution of an administrative warrant or impedes the inspector in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of section 402(a)(6) of the Act (21 U.S.C. 842(a)(6)). If he persists and the circumstances warrant, he shall be arrested and the inspection shall commence or continue.

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

§ 1316.13 Frequency of administrative inspections.

Except where circumstances otherwise dictate, it is the intent of the Administration to inspect all manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I once each year. Distributors of controlled substances listed in Schedules II through V and manufacturers of controlled substances listed in Schedules III through V shall be inspected as circumstances may require, based in part on the registrant's history of compliance with the requirements of this chapter and maintenance of effective controls and procedures to guard against the diversion of controlled substances.

[62 FR 13969, Mar. 24, 1997]

Subpart B—Protection of Researchers and Research Subjects

AUTHORITY: 21 U.S.C. 830, 871(b).

§ 1316.21 Definitions.

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

(a) The term *investigative personnel* includes managers, Diversion Investigators, attorneys, analysts and support personnel employed by the Drug Enforcement Administration who are involved in the processing, reviewing and analyzing of declarations and other relevant documents or data relative to regulated transactions or are involved in conducting investigations initiated pursuant to the receipt of such declarations, documents or data.

(b) The term *law enforcement personnel* means Special Agents employed by the Drug Enforcement Administration who, in the course of their official duties, gain knowledge of information which is confidential under such section.

[54 FR 31670, Aug. 1, 1989]

§ 1316.22 Exemption.

(a) Any person who is aggrieved by a disclosure of information in violation of subsection (c)(1) of Section 310 of the Controlled Substances Act (21 U.S.C. 830) may bring a civil action against the violator for appropriate relief.

(b) Notwithstanding the provision of paragraph (a), a civil action may not be brought under such paragraph against

investigative or law enforcement personnel of the Drug Enforcement Administration.

[54 FR 31670, Aug. 1, 1989]

§ 1316.23 Confidentiality of identity of research subjects.

(a) Any person conducting a bona fide research project directly related to the enforcement of the laws under the jurisdiction of the Attorney General concerning drugs or other substances which are or may be subject to control under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) who intends to maintain the confidentiality of the identity of those persons who are the subjects of such research may petition the Administrator of the Drug Enforcement Administration for a grant of confidentiality: *Providing*, That:

(1) The Attorney General is authorized to carry out such research under the provisions of Section 502(a) (2–6) of the Controlled Substances Act of 1970 (21 U.S.C. 872(a) (2–6)); and the research is being conducted with funds provided in whole or part by the Department of Justice; or

(2) The research is of a nature that the Attorney General would be authorized to carry out under the provisions of Section 502(a) (2–6) of the Controlled Substances Act (21 U.S.C. 872(a) (2–6), and is being conducted with funds provided from sources outside the Department of Justice.

(b) All petitions for Grants of Confidentiality shall be addressed to the Administrator, Drug Enforcement Administration (see the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address):

(1) A statement as to whether the research protocol requires the manufacture, production, import, export, distribution, dispensing, administration, or possession of controlled substances, and if so the researcher's registration number or a statement that an application for such registration has been submitted to DEA;

(2) The location of the research project;

(3) The qualifications of the principal investigator;

(4) A general description of the research or a copy of the research protocol;

(5) The source of funding for the research project;

(6) A statement as to the risks posed to the research subjects by the research procedures and what protection will be afforded to the research subjects;

(7) A statement as to the risks posed to society in general by the research procedures and what measures will be taken to protect the interests of society;

(8) A specific request to withhold the names and/or any other identifying characteristics of the research subjects; and

(9) Statements establishing that a grant of confidentiality is necessary to the successful completion of the research project.

(c) The grant of confidentiality of identity of research subjects shall consist of a letter issued by the Administrator, which shall include:

(1) The researcher's name and address.

(2) The researcher's registration number, if applicable.

(3) The title and purpose of the research.

(4) The location of the research project.

(5) An authorization for all persons engaged in the research to withhold the names and identifying characteristics of persons who are the subjects of such research, stating that persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of such research for which this authorization was obtained.

(6) The limits of this authorization, if any.

(7) A statement to the effect that the grant of confidentiality of identity of research subjects shall be perpetual but shall pertain only to the subjects of the research described in the research protocol, the description of the research submitted to DEA, or as otherwise established by DEA.

(d) 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 (c) of this section and stating the starting and finishing dates of the research for which the confidentiality of identity of research subjects was granted; upon receipt of this letter, the research 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; 75 FR 10685, Mar. 9, 2010]

§ 1316.24 Exemption from prosecution for researchers.

(a) Upon registration of an individual to engage in research in controlled substances under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801), the Administrator of the Drug Enforcement Administration, on his own motion or upon request in writing from the Secretary or from the researcher or researching practitioner, may exempt the registrant when acting within the scope of his registration, from prosecution under Federal, State, or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301).

(b) All petitions for Grants of Exemption from Prosecution for the Researcher shall be addressed to the Administrator, Drug Enforcement Administration, (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address) and shall contain the following:

(1) The researcher's registration number if any, for the project;

(2) The location of the research project;

(3) The qualifications of the principal investigator;

(4) A general description of the research or a copy of the research protocol;

(5) The source of funding for the research project;

(6) A statement as to the risks posed to the research subjects by the research procedures and what protection will be afforded to the research subjects;

(7) A statement as to the risks posed to society in general by the research procedures and what measures will be taken to protect the interests of society;

(8) A specific request for exemption from prosecution by Federal, State, or local authorities for offenses related to the possession, distribution, and dispensing of controlled substances in accord with the procedures described in the research protocol;

(9) A statement establishing that a grant of exemption from prosecution is necessary to the successful completion of the research project.

(c) Any researcher or practitioner proposing to engage in research requesting both exemption from prosecution and confidentiality of identity of research subjects may submit a single petition incorporating the information required in §§ 1316.23(b) and 1316.24(b).

(d) The exemption shall consist of a letter issued by the Administrator, which shall include:

(1) The researcher's name and address;

(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; 75 FR 10685, Mar. 9, 2010]

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, 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, §§ 1313.51–1313.57, or §§ 1315.50–1315.62) apply.

[73 FR 73556, Dec. 3, 2008]

§ 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 rulemaking 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

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 rulemaking, 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.).

(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]

§ 1316.51 Conduct of hearing and parties; ex parte communications.

(a) Hearings shall be conducted in an informal but orderly manner in accordance with law and the directions of the presiding officer.

(b) Participants in any hearing and their representatives, whether or not members of the bar, shall conduct themselves in accordance with judicial standards of practice and ethics and the directions of the presiding officer. Refusal to comply with this section shall constitute grounds for immediate exclusion from any hearing.

(c) If any official of the Administration is contacted by any individual in private or public life concerning any substantive matter which is the subject of any hearing, at any time after the date on which the proceedings commence, the official who is contacted shall prepare a memorandum setting forth the substance of the conversation and shall file this memorandum in the appropriate public docket file. The presiding officer and employees of the Administration shall comply with the requirements of 5 U.S.C. 554(d) regarding ex parte communications and participation in any hearing.

§ 1316.52 Presiding officer.

A presiding officer, designated by the Administrator, shall preside over all hearings. The functions of the presiding officer shall commence upon his designation and terminate upon the certification of the record to the Administrator. The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He shall have all powers necessary to these ends, including (but not limited to) the power to:

(a) Arrange and change the date, time, and place of hearings (other than the time and place prescribed in §1301.56) and prehearing conferences and issue notice thereof.

(b) Hold conferences to settle, simplify, or determine the issues in a hearing, or to consider other matters that may aid in the expeditious disposition of the hearing.

(c) Require parties to state their position in writing with respect to the various issues in the hearing and to exchange such statements with all other parties.

(d) Sign and issue subpoenas to compel the attendance of witnesses and the production of documents and materials to the extent necessary to conduct administrative hearings pending before him.

(e) Examine witnesses and direct witnesses to testify.

(f) Receive, rule on, exclude, or limit evidence.

(g) Rule on procedural items pending before him.

(h) Take any action permitted to the presiding officer as authorized by this part or by the provisions of the Administrative Procedure Act (5 U.S.C. 551–559).

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 42 FR 57457, Nov. 3, 1977; 62 FR 13970, Mar. 24, 1997]

§ 1316.53 Time and place of hearing.

The hearing will commence at the place and time designated in the notice of hearing published in the FEDERAL REGISTER but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1316.54 Prehearing conference.

The presiding officer on his own motion, or on the motion of any party for good cause shown, may direct all parties to appear at a specified time and place for a conference for:

(a) The simplification of the issues.

(b) The possibility of obtaining stipulations, admission of facts, and documents.

(c) The possibility of limiting the number of expert witnesses.

(d) The identification and, if practicable, the scheduling of all witnesses to be called.

(e) The advance submission at the prehearing conference of all documentary evidence and affidavits to be marked for identification.

(f) Such other matters as may aid in the expeditious disposition of the hearing.

§ 1316.55 Prehearing ruling.

The presiding officer may have the prehearing conference reported verbatim and shall make a ruling reciting the action taken at the conference, the agreements made by the parties, the schedule of witnesses, and a statement of the issues for hearing. Such ruling shall control the subsequent course of the hearing unless modified by a subsequent ruling.

§ 1316.56 Burden of proof.

At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.

§ 1316.57 Submission of documentary evidence and affidavits and identification of witnesses subsequent to prehearing conference.

All documentary evidence and affidavits not submitted and all witnesses not identified at the prehearing conference shall be submitted or identified to the presiding officer as soon as possible, with a showing that the offering party had good cause for failing to so submit or identify at the prehearing conference. If the presiding officer determines that good cause does exist, the documents or affidavits shall be submitted or witnesses identified to all parties sufficiently in advance of the offer of such documents or affidavits or witnesses at the hearing to avoid prejudice or surprise to the other parties. If the presiding officer determines that good cause does not exist, he may refuse to admit as evidence such documents or affidavits or the testimony of such witnesses.

§ 1316.58 Summary of testimony; affidavits.

(a) The presiding officer may direct that summaries of the direct testimony of witnesses be prepared in writing and served on all parties in advance of the hearing. Witnesses will not be permitted to read summaries of their testimony into the record and all witnesses shall be available for cross-examination. Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) Affidavits submitted at the prehearing conference or pursuant to §1316.57 with good cause may be examined by all parties and opposing affidavits may be submitted to the presiding officer within a period of time fixed by him. Affidavits admitted into evidence shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to statements made therein.

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

§ 1316.59 Submission and receipt of evidence.

(a) The presiding officer shall admit only evidence that is competent, relevant, material and not unduly repetitious.

(b) Opinion testimony shall be admitted when the presiding officer is satisfied that the witness is properly qualified.

(c) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the presiding officer, except that a party will be permitted to challenge such authenticity at a later time upon a showing of good cause for failure to have filed such written objection.

(d) Samples, if otherwise admissible into evidence, may be displayed at the hearing and may be described for purposes of the record, or may be admitted in evidence as exhibits.

(e) Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded opportunity to controvert such fact.

(f) The presiding officer shall file as exhibits copies of the following documents:

(1) The order to show cause or notice of hearing;

(2) Any notice of waiver or modification of rules made pursuant to §1316.44 or otherwise;

(3) Any waiver of hearing (together with any statement filed therewith) filed pursuant to §1316.49 or otherwise;

(4) The prehearing ruling, if any, made pursuant to §1316.55;

(5) Any other document necessary to show the basis for the hearing.

§ 1316.60 Objections; offer of proof.

If any party in the hearing objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection without extended argument or debate thereon except as permitted by the presiding officer. A ruling of the presiding officer on any such objection shall be a part of the transcript together with such offer of proof as has been made if a proper foundation has been laid for its admission. An offer of proof made in connection with an objection taken to any ruling of the presiding officer rejecting or excluding proffered oral testimony shall consist of a statement of the substance of the evidence which the party contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in documentary or written form a copy of such evidence shall be marked for identification and shall accompany the records as the offer of proof.

§ 1316.61 Exceptions to rulings.

Exceptions to rulings of the presiding officer are unnecessary. It is sufficient that a party, at the time the ruling of the presiding officer is sought, makes known the action that he desires the presiding officer to take, or his objection to an action taken, and his grounds therefor.

§ 1316.62 Interlocutory appeals from rulings of the presiding officer.

Rulings of the presiding officer may not be appealed to the Administrator prior to his consideration of the entire hearing without first requesting the consent of the presiding officer. Within ten (10) business days of receipt of a party's request for such consent, the presiding officer shall certify on the record or in writing his determination of whether the allowance of an interlocutory appeal is clearly necessary to prevent exceptional delay, expense or prejudice to any party, or substantial detriment to the public interest. If the presiding officer denies an interlocutory appeal, he shall, within three (3) business days, transmit his determination and the parties' filings related to the interlocutory appeal to the Administrator for the Administrator's discretionary review. If an interlocutory appeal is allowed by the presiding officer or if the Administrator determines that an appeal is warranted under this section, any party to the hearing may file a brief in quintuplicate with the Administrator within such period that the Administrator directs. No oral argument will be heard unless the Administrator directs otherwise.

[84 FR 18140, Apr. 30, 2019]

§ 1316.63 Official transcript; index; corrections.

(a) Testimony given at a hearing shall be reported verbatim. The Administration will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purpose.

(b) At the close of the hearing, the presiding officer shall afford the parties and witnesses time (not longer than 30 days, except in unusual cases) in which to submit written proposed corrections of the transcript, pointing out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony.

[36 FR 7820, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 2046, Jan. 15, 1985]

§ 1316.64 Proposed findings of fact and conclusions of law.

Any party in the hearing may file in quintuplicate proposed findings of fact and conclusions of law within the time fixed by the presiding officer. Any party so filing shall also serve one copy of his proposed findings and conclusion upon each other party in the hearing. The party shall include a statement of supporting reasons for the proposed findings and conclusions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of authorities relied upon.

§ 1316.65 Report and record.

(a) As soon as practicable after the time for the parties to file proposed

findings of fact and conclusions of law has expired, the presiding officer shall prepare a report containing the following:

(1) His recommended rulings on the proposed findings of fact and conclusions of law;

(2) His recommended findings of fact and conclusions of law, with the reasons therefore; and

(3) His recommended decision.

(b) The presiding officer shall serve a copy of his report upon each party in the hearing. The report shall be considered to have been served when it is mailed to such party or its attorney of record.

(c) Not less than twenty-five days after the date on which he caused copies of his report to be served upon the parties, the presiding officer shall certify to the Administrator the record, which shall contain the transcript of testimony, exhibits, the findings of fact and conclusions of law proposed by the parties, the presiding officer's report, and any exceptions thereto which may have been filed by the parties.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 44 FR 55332, Sept. 26, 1979]

§ 1316.66 Exceptions.

(a) Within twenty days after the date upon which a party is served a copy of the report of the presiding officer, such party may file with the Hearing Clerk, Office of the Administrative Law Judge, exceptions to the recommended decision, findings of fact and conclusions of law contained in the report. The party shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.

(b) The Hearing Clerk shall cause such filings to become part of the record of the proceeding.

(c) The Administrative Law Judge may, upon the request of any party to a proceeding, grant time beyond the twenty days provided in paragraph (a) of this section for the filing of a response to the exceptions filed by another party if he determines that no party in the hearing will be unduly prejudiced and that the ends of justice will be served thereby. Provided however, that each party shall be entitled to only one filing under this section; that is, either a set of exceptions or a response thereto.

[44 FR 55332, Sept. 26, 1979]

§ 1316.67 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the FEDERAL REGISTER his final order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which date shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Administrator finds that the public interest in the matter necessitates an earlier effective date, in which event the Administrator shall specify in the order his findings as to the conditions which led him to conclude that an earlier effective date was required.

[44 FR 42179, July 19, 1979, as amended at 44 FR 55332, Sept. 26, 1979]

§ 1316.68 Copies of petitions for judicial review.

Copies of petitions for judicial review, filed pursuant to section 507 of the Act (21 U.S.C. 877) shall be delivered to and served upon the Administrator in quintuplicate. The Administrator shall certify the record of the hearing and shall file the certified record in the appropriate U.S. Court of Appeals.

[36 FR 7820, Apr. 24, 1971. Redesignated at 44 FR 42179, July 19, 1979]

PART 1317—DISPOSAL

Sec.

1317.01 Scope.

Subpart A—Disposal of Controlled Substances by Registrants

1317.05 Registrant disposal.

1317.10 Registrant return or recall.