

§ 1316.01

21 CFR Ch. II (4–1–03 Edition)

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 Appeal from ruling of 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.

Subpart E—Seizure, Forfeiture, and Disposition of Property

- 1316.71 Definitions.
- 1316.72 Officers who will make seizures.
- 1316.73 Custody and other duties.
- 1316.74 Appraisal.
- 1316.75 Advertisement.
- 1316.76 Requirements as to claim and bond.

- 1316.77 Administrative forfeiture.
- 1316.78 Judicial forfeiture.
- 1316.79 Petitions for remission or mitigation of forfeiture.
- 1316.80 Time for filing petitions.
- 1316.81 Handling of petitions.

Subpart F—Expedited Forfeiture Proceedings for Certain Property

- 1316.90 Purpose and scope.
- 1316.91 Definitions.
- 1316.92 Petition for expedited release in an administrative forfeiture action.
- 1316.93 Ruling on petition for expedited release in an administrative forfeiture action.
- 1316.94 Posting of substitute res in an administrative forfeiture action.
- 1316.95 Petition for expedited release of a conveyance in a judicial forfeiture action.
- 1316.96 Ruling on a petition for expedited release of a conveyance in a judicial forfeiture action.
- 1316.97 Initiating judicial forfeiture proceeding against a conveyance within 60 days of the filing of a claim and cost bond.
- 1316.98 Substitute res bond in a judicial forfeiture action against a conveyance.
- 1316.99 Notice provisions.

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.

Drug Enforcement Administration, Justice

§ 1316.04

(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 84 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]

§ 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: