

§ 1316.03

§ 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

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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:

- (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;

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(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.