

§ 1316.04

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;
- (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.

21 CFR Ch. II (4–1–98 Edition)

§ 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;