

§ 1316.11

(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

21 CFR Ch. II (4–1–01 Edition)

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