§ 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).