

REFERENCES IN TEXT

The Federal Trade Commission Act, referred to in subsecs. (b) and (d), is act Sept. 26, 1914, ch. 311, 38 Stat. 717, as amended, which is classified generally to subchapter I (§41 et seq.) of chapter 2 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see section 58 of Title 15 and Tables.

§ 379. Confidential information**(a) Contractors**

The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this chapter, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

(b) Ability to receive and protect confidential information obtained from foreign governments**(1) In general**

The Secretary shall not be required to disclose under section 552 of title 5 (commonly referred to as the "Freedom of Information Act"), or any other provision of law, any information relating to drugs obtained from a foreign government agency, if—

(A) the information concerns the inspection of a facility, is part of an investigation, alerts the United States to the potential need for an investigation, or concerns a drug that has a reasonable probability of causing serious adverse health consequences or death to humans or animals;

(B) the information is provided or made available to the United States Government voluntarily on the condition that it not be released to the public; and

(C) the information is covered by, and subject to, a written agreement between the Secretary and the foreign government.

(2) Time limitations

The written agreement described in paragraph (1)(C) shall specify the time period for which paragraph (1) shall apply to the voluntarily disclosed information. Paragraph (1) shall not apply with respect to such information after the date specified in such agreement, but all other applicable legal protections, including the provisions of section 552 of title 5 and section 247d-7e(e)(1) of title 42, as applicable, shall continue to apply to such information. If no date is specified in the written agreement, paragraph (1) shall not apply with respect to such information for a period of more than 36 months.

(3) Disclosures not affected

Nothing in this section authorizes any official to withhold, or to authorize the withhold-

ing of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States.

(4) Relation to other law

For purposes of section 552 of title 5, this subsection shall be considered a statute described in subsection (b)(3)(B) of such section 552.

(c) Authority to enter into memoranda of understanding for purposes of information exchange

The Secretary may enter into written agreements to provide information referenced in section 331(j) of this title to foreign governments subject to the following criteria:

(1) Certification

The Secretary may enter into a written agreement to provide information under this subsection to a foreign government only if the Secretary has certified such government as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner of Food and Drugs.

(2) Written agreement

The written agreement to provide information to the foreign government under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 247d of title 42 that is relevant to the information.

(3) Information exchange

The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 331(j) of this title in only the following circumstances:

(A) Information concerning the inspection of a facility may be provided to a foreign government if—

(i) the Secretary reasonably believes, or the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

(4) Effect of subsection

Nothing in this subsection affects the ability of the Secretary to enter into any written

agreement authorized by other provisions of law to share confidential information.

(June 25, 1938, ch. 675, §708, as added Pub. L. 94-295, §8, May 28, 1976, 90 Stat. 582; amended Pub. L. 112-144, title VII, §710, July 9, 2012, 126 Stat. 1070.)

AMENDMENTS

2012—Pub. L. 112-144 designated existing provisions as subsec. (a), inserted heading, and added subsecs. (b) and (c).

§ 379a. Presumption of existence of jurisdiction

In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

(June 25, 1938, ch. 675, §709, as added Pub. L. 94-295, §8, May 28, 1976, 90 Stat. 583; amended Pub. L. 105-115, title IV, §419, Nov. 21, 1997, 111 Stat. 2379; Pub. L. 111-31, div. A, title I, §103(k), June 22, 2009, 123 Stat. 1837.)

AMENDMENTS

2009—Pub. L. 111-31 inserted “tobacco product,” after “device.”

1997—Pub. L. 105-115 substituted “a device, food, drug, or cosmetic” for “a device”.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

§ 379b. Consolidated administrative and laboratory facility

(a) Authority

The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

(b) Awarding of contract

The Secretary shall solicit contract proposals under subsection (a) of this section from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

(c) Donations

In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the Food and Drug Administration gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section \$100,000,000 for fiscal year 1991, and such sums as may be necessary for each of the subsequent fiscal years, to remain available until expended.

(June 25, 1938, ch. 675, §710, as added Pub. L. 101-635, title I, §101, Nov. 28, 1990, 104 Stat. 4583.)

§ 379c. Transferred

CODIFICATION

Section, act June 25, 1938, ch. 675, §711, as added Nov. 28, 1990, Pub. L. 101-635, title II, §201, 104 Stat. 4584, which related to recovery and retention of fees for freedom of information requests, was renumbered section 731 of act June 25, 1938, by Pub. L. 102-571, title I, §106(6), Oct. 29, 1992, 106 Stat. 4499, and transferred to section 379f of this title.

§ 379d. Automation of Food and Drug Administration

(a) In general

The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this chapter.

(b) Authorization of appropriations

There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, §711, formerly §712, as added Pub. L. 101-635, title IV, §401, Nov. 28, 1990, 104 Stat. 4585; renumbered §711, Pub. L. 102-571, title I, §106(3), Oct. 29, 1992, 106 Stat. 4498.)

PRIOR PROVISIONS

A prior section 711 of act June 25, 1938, was renumbered section 731 by Pub. L. 102-571 and is classified to section 379f of this title.

§ 379d-1. Conflicts of interest

(a) Definitions

For purposes of this section:

(1) Advisory committee

The term “advisory committee” means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

(2) Financial interest

The term “financial interest” means a financial interest under section 208(a) of title 18.

(b) Recruitment for advisory committees

(1) In general

The Secretary shall—

(A) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

(B) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities;