

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 withholding 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 do-