§ 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) Appointments to advisory committees

(1) Recruitment

(A) In general

The Secretary shall—

(i) 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;

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

(iii) take into account the advisory committees with the greatest number of vacancies.

(B) Recruitment activities

The recruitment activities under subparagraph (A) may include—

(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

(ii) making widely available, including by using existing electronic communica-

tions channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

(iii) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

(2) Evaluation and criteria

When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, a written certification as referred to in section 208(b)(3) of title 18, or a waiver as referred to in subsection (c)(2) of this section for service on the committee at a meeting of the committee.

(c) Disclosures; prohibitions on participation; waivers

(1) Disclosure of financial interest

Prior to a meeting of an advisory committee regarding a ''particular matter'' (as that term is used in section 208 of title 18), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

(2) Prohibitions and waivers on participation

(A) In general

Except as provided under subparagraph (B), a member of an advisory committee may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

(B) Waiver

If the Secretary determines it necessary to afford the advisory committee essential expertise, the Secretary may grant a waiver of the prohibition in subparagraph (A) to permit a member described in such subparagraph to—

(i) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

(ii) participate as a voting member with respect to a particular matter considered in a committee meeting.

(C) Limitation on waivers and other exceptions

(i) Definition

For purposes of this subparagraph, the term ''exception'' means each of the following with respect to members of advisory committees:

(I) A waiver under section 355(n)(4) of this title (as in effect on the day before September 27, 2007).

(II) A written determination under section 208(b) of title 18.

(III) A written certification under section 208(b)(3) of such title.

(ii) Determination of total number of members slots and member exceptions during fiscal year 2007

The Secretary shall determine—

(I)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who participated in the meeting; and

(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the ''total number of 2007 meeting slots''); and

(II)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who received an exception for the meeting; and

(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the ''total number of 2007 meeting exceptions'').

(iii) Determination of percentage regarding exceptions during fiscal year 2007

The Secretary shall determine the percentage constituted by—

(I) the total number of 2007 meeting exceptions; divided by

(II) the total number of 2007 meeting slots.

(iv) Limitation for fiscal years 2008 through 2012

The number of exceptions at the Food and Drug Administration for members of advisory committees for a fiscal year may not exceed the following:

(I) For fiscal year 2008, 95 percent of the percentage determined under clause (iii) (referred to in this clause as the ''base percentage'').

(II) For fiscal year 2009, 90 percent of the base percentage.

(III) For fiscal year 2010, 85 percent of the base percentage.

(IV) For fiscal year 2011, 80 percent of the base percentage.

(V) For fiscal year 2012, 75 percent of the base percentage.

(v) Allocation of exceptions

The exceptions authorized under clause (iv) for a fiscal year may be allocated within the centers or other organizational units of the Food and Drug Administration as determined appropriate by the Secretary.

(3) Disclosure of waiver

Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

(A) 15 or more days in advance

As soon as practicable, but (except as provided in subparagraph (B)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, a written certification as referred to in section 208(b)(3) of title 18, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5 and section 552a of title 5 (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet Web site of the Food and Drug Administration—

(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

(ii) the reasons of the Secretary for such determination, certification, or waiver.

(B) Less than 30 days in advance

In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, a written certification as referred to in section 208(b)(3) of title 18, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5 and section 552a of title 5) on the Internet Web site of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

(d) Public record

The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(3) (other than information exempted from disclosure under section 552 of title 5 and section 552a of title 5).

(e) Annual report

Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report that describes—

(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(3) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

(3) with respect to such year, the number of times the disclosures required under subsection (c)(3) occurred under subparagraph (B) of such subsection; and

(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

(f) Periodic review of guidance

Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.

(June 25, 1938, ch. 675, §712, as added Pub. L. 110–85, title VII, §701(a), Sept. 27, 2007, 121 Stat. 900.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (a)(1), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

The Ethics in Government Act of 1978, referred to in subsecs. (b)(2) and (c)(3), is Pub. L. 95–521, Oct. 26, 1978, 92 Stat. 1824. For complete classification of this Act to the Code, see Short Title note set out under section 101 of Pub. L. 95–521 in the Appendix to Title 5, Government Organization and Employees, and Tables.

The Privacy Act of 1974, referred to in subsec. (c)(3)(A), is Pub. L. 93–579, Dec. 31, 1974, 88 Stat. 1896, which enacted section 552a of Title 5, Government Organization and Employees, and provisions set out as notes under section 552a of Title 5. For complete classification of this Act to the Code, see Short Title of 1974 Amendment note set out under section 552a of Title 5 and Tables.

PRIOR PROVISIONS

A prior section 712 of act June 25, 1938, was renumbered section 711 by Pub. L. 102–571 and is classified to section 379d of this title.

EFFECTIVE DATE

Section effective Oct. 1, 2007, see section 701(c) of Pub. L. 110–85, set out as an Effective Date of 2007 Amendment note under section 355 of this title.

§ 379d–2. Policy on the review and clearance of scientific articles published by FDA employees

(a) Definition

In this section, the term ''article'' means a paper, poster, abstract, book, book chapter, or other published writing.

(b) Policies

The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.