

**(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;

(C) at least every 180 days, request referrals for potential members of advisory committees from a variety of stakeholders, including—

(i) product developers, patient groups, and disease advocacy organizations; and  
(ii) relevant—

(I) professional societies;

(II) medical societies;

(III) academic organizations; and

(IV) governmental organizations; and

(D) in carrying out subparagraphs (A) and (B), take into account the levels of activity (including the numbers of annual meetings) and the numbers of vacancies of the advisory committees.

**(2) Recruitment activities**

The recruitment activities under paragraph

(1) may include—

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

(B) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

(C) 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 whom the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

**(3) Expertise**

In carrying out this subsection, the Secretary shall seek to ensure that the Secretary has access to the most current expert advice.

**(c) Disclosure of determinations and certifications**

Notwithstanding section 107(a)(2) of the Ethics in Government Act of 1978, the following shall apply:

**(1) 15 or more days in advance**

As soon as practicable, but (except as provided in paragraph (2)) 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 or a written certification as referred to in section 208(b)(3) of such title, applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or 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—

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

(B) the reasons of the Secretary for such determination or certification, including, as appropriate, the public health interest in

having the expertise of the member with respect to the particular matter before the advisory committee.

**(2) 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 or a written certification as referred to in section 208(b)(3) of such title applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or 552a of title 5) on the Internet Web site of the Food and Drug Administration, the information described in subparagraphs (A) and (B) of paragraph (1) as soon as practicable after the Secretary makes such determination or certification, 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) (other than information exempted from disclosure under section 552 of title 5 and section 552a of title 5).

**(e) Annual report**

**(1) In general**

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—

(A) with respect to the fiscal year that ended on September 30 of the previous year, the number of persons nominated for participation at meetings for each advisory committee, the number of persons so nominated, and willing to serve, the number of vacancies on each advisory committee, and the number of persons contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18;

(B) with respect to such year, the number of persons contacted for services as members for each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for such participation to constitute a disqualifying financial interest under section 208 of title 18;

(C) with respect to such year, the number of members attending meetings for each advisory committee; and

(D) with respect to such year, the aggregate number of disclosures required under subsection (d) and the percentage of individuals to whom such disclosures did not apply who served on such committee.

**(2) Public availability**

Not later than 30 days after submitting any report under paragraph (1) to the committees

specified in such paragraph, the Secretary shall make each such report available to the public.

**(f) Periodic review of guidance**

Not less than once every 5 years, the Secretary shall—

(1) review guidance of the Food and Drug Administration with respect to advisory committees regarding disclosure of conflicts of interest and the application of section 208 of title 18; and

(2) update such guidance as necessary to ensure that the Food and Drug Administration receives appropriate access to needed scientific expertise, with due consideration of the requirements of such section 208.

**(g) Guidance on reported disclosed financial interest or involvement**

The Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members that are disclosed under subsection (c) but that the Secretary determines not to meet the definition of a disqualifying interest under section 208 of title 18 for the purposes of participating in a particular matter.

(June 25, 1938, ch. 675, § 712, as added Pub. L. 110-85, title VII, § 701(a), Sept. 27, 2007, 121 Stat. 900; amended Pub. L. 112-144, title XI, § 1142(a), July 9, 2012, 126 Stat. 1127.)

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.

Section 107(a)(2) of the Ethics in Government Act of 1978, referred to in subsec. (c), is section 107(a)(2) of Pub. L. 95-521, which is set out in the Appendix to Title 5, Government Organization and Employees.

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.

AMENDMENTS

2012—Subsecs. (b), (c). Pub. L. 112-144, § 1142(a)(1), added subsecs. (b) and (c) and struck out former subsecs. (b) and (c) which related to appointments to advisory committees and disclosures, prohibitions on participation, and waivers.

Subsec. (d). Pub. L. 112-144, § 1142(a)(2), substituted “subsection (c)” for “subsection (c)(3)”.

Subsec. (e). Pub. L. 112-144, § 1142(a)(3), amended subsec. (e) generally. Prior to amendment, subsec. (e) related to annual report.

Subsec. (f). Pub. L. 112-144, § 1142(a)(4), substituted “shall—” for “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.” and added pars. (1) and (2).

Subsec. (g). Pub. L. 112-144, § 1142(a)(5), added subsec. (g).

## EFFECTIVE DATE OF 2012 AMENDMENT

Pub. L. 112-144, title XI, §1142(b), July 9, 2012, 126 Stat. 1130, provided that: “The amendments made by subsection (a) [amending this section] apply beginning on October 1, 2012.”

## 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.

#### (c) Timing of submission for review

If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is directed by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

#### (d) Timing for review and clearance

The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

#### (e) Non-timely review

If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

#### (f) Effect

Nothing in this section shall be construed as affecting any restrictions on such publication or presentation provided by other provisions of law.

(June 25, 1938, ch. 675, §713, as added Pub. L. 110-85, title XI, §1101, Sept. 27, 2007, 121 Stat. 971.)

### § 379d-3. Streamlined hiring authority

#### (a) In general

In addition to any other personnel authorities under other provisions of law, the Secretary may, without regard to the provisions of title 5 governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

#### (b) Activities described

The activities described in this subsection are—

- (1) activities under this chapter related to the process for the review of device applications (as defined in section 379i(8) of this title); and
- (2) activities under this chapter related to human generic drug activities (as defined in section 379j-41 of this title).

#### (c) Objectives specified

The objectives specified in this subsection are—

- (1) with respect to the activities under subsection (b)(1), the goals referred to in section 379j-1(a)(1) of this title; and
- (2) with respect to the activities under subsection (b)(2), the goals referred to in section 379j-43(a) of this title.

#### (d) Internal controls

The Secretary shall institute appropriate internal controls for appointments under this section.

#### (e) Sunset

The authority to appoint employees under this section shall terminate on the date that is 3 years after July 9, 2012.

(June 25, 1938, ch. 675, §714, as added and amended Pub. L. 112-144, title II, §208, title III, §307, July 9, 2012, 126 Stat. 1007, 1025.)

## AMENDMENTS

2012—Subsec. (b). Pub. L. 112-144, §307(1), amended subsec. (b) generally. Prior to amendment, text read as follows: “The activities described in this subsection are activities under this chapter related to the process for the review of device applications (as defined in section 379i(8) of this title).”

Subsec. (c). Pub. L. 112-144, §307(2), amended subsec. (c) generally. Prior to amendment, text read as follows: “The objectives specified in this subsection are with respect to the activities under subsection (b), the goals referred to in section 379j-1(a)(1) of this title.”

## EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by section 307 of Pub. L. 112-144 effective Oct. 1, 2012, see section 305 of Pub. L. 112-144, set out as an Effective and Termination Dates note under section 379j-41 of this title.

## EFFECTIVE DATE

Section effective Oct. 1, 2012, see section 206 of Pub. L. 112-144, set out as an Effective Date of 2012 Amendment note under section 379i of this title.

### § 379d-4. Reporting requirements

#### (a) Generic drugs

Beginning with fiscal year 2013 and ending after fiscal year 2017, not later than 120 days