(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; Pub. L. 114–255, div. A, title III, §3101(a)(2)(U), Dec. 13, 2016, 130 Stat. 1155.)

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

2016—Subsec. (e)(1)(B). Pub. L. 114–255 substituted ''service as members'' for ''services as members''.

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(9) 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; Pub. L. 115–52, title II, § 202(b), Aug. 18, 2017, 131 Stat. 1013.)

AMENDMENTS

2017—Subsec. (b)(1). Pub. L. 115–52 substituted ''379i(9)'' for ''379i(8)''.

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 2017 AMENDMENT

Amendment by Pub. L. 115–52 effective Oct. 1, 2017, with fees under subpart 3 of part C of this subchapter to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i 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–3a. Hiring authority for scientific, technical, and professional personnel

(a) In general

The Secretary may, notwithstanding title 5, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

(b) Compensation

(1) In general

Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and set—

(A) the annual rate of pay of any individual appointed under subsection (a); and

(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before December 13, 2016.

(2) Limitation

The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3.

(3) Public availability

The annual rate of pay provided to an individual in accordance with this section shall be publicly available information.

(c) Rule of construction

The authorities under this section shall not be construed to affect the authority provided under section 379d–3 of this title.

(d) Report on workforce planning

(1) In general

Not later than 18 months after December 13, 2016, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including—

(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

(i) recruitment through nongovernmental recruitment or placement agencies;

(ii) recruitment through academic institutions;

(iii) recruitment or hiring bonuses, if applicable;