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;

(iv) recruitment using targeted direct hiring authorities; and

(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

(2) Recommendations

The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.

(June 25, 1938, ch. 675, § 714A, as added Pub. L. 114–255, div. A, title III, § 3072(a), Dec. 13, 2016, 130 Stat. 1134.)

§ 379d–4. Reporting requirements

(a) Generic drugs

Beginning with fiscal year 2013 and ending after fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under subpart 7 of part C, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications for approval of a generic drug under section 355(j) of this title, amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year—

(1) the number of such applications that met the goals identified for purposes of subpart 7 of part C, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;

(2) the average total time to decision by the Secretary for applications for approval of a generic drug under section 355(j) of this title, amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter;

(3) the total number of applications under section 355(j) of this title, amendments to such applications, and prior approval supplements with respect to such applications that were pending with the Secretary for more than 10 months on July 9, 2012; and

(4) the number of applications described in paragraph (3) on which the Food and Drug Administration took final regulatory action in the previous fiscal year.

(b) Biosimilar biological products

(1) In general

Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under subpart 8 of part C, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

(A) the number of applications for approval filed under section 262(k) of title 42; and

(B) the percentage of applications described in subparagraph (A) that were approved by the Secretary.

(2) Additional information

As part of the performance report described in paragraph (1), the Secretary shall include an explanation of how the Food and Drug Administration is managing the biological product review program to ensure that the user fees collected under subpart 2[1] are not used to review an application under section 262(k) of title 42.

(June 25, 1938, ch. 675, § 715, as added and amended Pub. L. 112–144, title III, § 308, title IV, § 408, July 9, 2012, 126 Stat. 1025, 1039.)

AMENDMENTS

2012—Subsec. (b). Pub. L. 112–144, § 408, added subsec. (b).

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by section 408 of Pub. L. 112–144 effective Oct. 1, 2012, see section 405 of Pub. L. 112–144, set out as an Effective and Termination Dates note under section 379j–51 of this title.

EFFECTIVE DATE

Section 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.

§ 379d–5. Guidance document regarding product promotion using the Internet

Not later than 2 years after July 9, 2012, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

(Pub. L. 112–144, title XI, § 1121, July 9, 2012, 126 Stat. 1112.)

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

PART B—COLORS

§ 379e. Listing and certification of color additives for foods, drugs, devices, and cosmetics

(a) Unsafe color additives

A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 342(c), 351(a)(4), or 361(e) of this title, as the case may be, unless—

[1] So in original. Probably means subpart 2 of part C.