

(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.)

Editorial Notes**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.”

Statutory Notes and Related Subsidiaries**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, including cross-cutting operational positions, that support the development, review, and regulation of medical products and the regulation of food and cosmetics. 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 29, 2022, 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 includes—

(A) an updated 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;

(B) an analysis of how the Secretary has used the authorities provided under this section, and a plan for how the Secretary will use the authority under this section, and other applicable hiring authorities, for employees of the Food and Drug Administration; and

(C) an updated 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; amended Pub. L. 117–328, div. FF, title III, § 3624, Dec. 29, 2022, 136 Stat. 5879.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, § 3624(1), inserted “, including cross-cutting operational positions,” after “professional positions” and “and the regulation of food and cosmetics” after “medical products”.

Subsec. (d)(1). Pub. L. 117–328, § 3624(2)(A), in introductory provisions, substituted “December 29, 2022” for “December 13, 2016” and “that includes” for “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”.

Subsec. (d)(1)(A). Pub. L. 117–328, § 3624(2)(B), inserted “updated” before “analysis” and substituted semicolon for “; and”.

Subsec. (d)(1)(B). Pub. L. 117–328, § 3624(2)(D), added subpar. (B). Former subpar. (B) redesignated (C).

Subsec. (d)(1)(C). Pub. L. 117–328, § 3624(2)(C), (E), redesignated subpar. (B) as (C) and substituted “an updated recruitment” for “a recruitment” in introductory provisions.

§ 379d–3b. Strategic Workforce Plan and report

(a) In general

Not later than September 30, 2023, and at least every 4 years thereafter, the Secretary shall develop, begin implementation of, and submit to the appropriate committees of Congress and post on the website of the Food and Drug Administration, a coordinated strategy and report to provide direction for the activities and programs of the Secretary to recruit, hire, train, develop, and retain the workforce needed to fulfill the public health mission of the Food and Drug Administration, including to facilitate collaboration across centers, to keep pace with new biomedical, technological, and scientific advancements, and support the development, review, and regulation of medical products. Each such report shall be known as the “Food and Drug Administration Strategic Workforce Plan”.

(b) Use of the Food and Drug Administration Strategic Workforce Plan

Each center within the Food and Drug Administration shall develop and update, as appro-

priate, a strategic plan that will be informed by the Food and Drug Administration Strategic Workforce Plans developed under subsection (a).

(c) Contents of the Food and Drug Administration Strategic Workforce Plan

Each Food and Drug Administration Strategic Workforce Plan under subsection (a) shall—

(1) include agency-wide human capital strategic goals and priorities for recruiting, hiring, training, developing, and retaining a qualified workforce for the Food and Drug Administration;

(2) establish specific actions the Secretary will take to achieve such strategic goals and priorities and address the workforce needs of the Food and Drug Administration in the forthcoming fiscal years;

(3) identify challenges and risks the Secretary will face in meeting its strategic goals and priorities, and the actions the Secretary will take to overcome those challenges and mitigate those risks;

(4) establish performance measures, benchmarks, or other elements that the Secretary will use to measure and evaluate progress in achieving such strategic goals and priorities and the effectiveness of such strategic goals and priorities; and

(5) define functions, capabilities, and gaps in such workforce and identify strategies to recruit, hire, train, develop, and retain such workforce.

(d) Considerations

In developing each Food and Drug Administration Strategic Workforce Plan under subsection (a), the Secretary shall consider—

(1) the number of employees (including senior leadership and non-senior leadership employees) eligible for retirement, the expertise of such employees, and the employing center of such employees;

(2) the vacancy and turnover rates for employees with different types of expertise and from different centers, including any changes or trends related to such rates;

(3) the results of the Federal Employee Viewpoint Survey for employees of the Food and Drug Administration, including any changes or trends related to such results;

(4) rates of pay for different types of positions, including rates for different types of expertise within the same field (such as differences in pay between different medical specialists), and how such rates of pay impact the ability of the Secretary to achieve the strategic goals and priorities described in subsection (c);

(5) the statutory hiring authorities used to hire Food and Drug Administration employees, and the time to hire across different hiring authorities; and

(6) any other timely and relevant information, as the Secretary determines appropriate.

(e) Evaluation of progress

Each Food and Drug Administration Strategic Workforce Plan issued pursuant to subsection (a), with the exception of the first such Food and Drug Administration Strategic Workforce Plan, shall include an evaluation of—