(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 appropriate, 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—

(1) the progress the Secretary has made, based on the performance measures, benchmarks, and other elements that measure successful recruitment, hiring, training, development, and retention activities; and

(2) whether actions taken in response to the Plan improved the capacity of the Food and Drug Administration to achieve the strategic goals and priorities described in subsection (c)(1).

(f) Additional considerations

The Food and Drug Administration Strategic Workforce Plan issued in fiscal year 2023 shall address the effect of the COVID–19 pandemic on hiring, retention, and other workforce challenges for the Food and Drug Administration, including protecting such workforce during public health emergencies.

(June 25, 1938, ch. 675, § 714B, as added Pub. L. 117–328, div. FF, title III, § 3623, Dec. 29, 2022, 136 Stat. 5878.)

§ 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.)

Editorial Notes

AMENDMENTS

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

Statutory Notes and Related Subsidiaries

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.)

Editorial Notes

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.

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