

(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 the 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 2¹ 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.