§ 379j–53. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 401(b) of the Biosimilar User Fee Act of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort.

(b) Fiscal report

Not later than 120 days after the end of fiscal year 2013 and each subsequent fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) Study

(1) In general

The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

(2) Interim results

Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

(3) Final results

Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

(e) Reauthorization

(1) Consultation

In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(3) Transmittal of recommendations

Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(June 25, 1938, ch. 675, § 744I, as added Pub. L. 112–144, title IV, § 403, July 9, 2012, 126 Stat. 1037.)

TERMINATION OF SECTION

For termination of section by section 404(b) of Pub. L. 112–144, see Effective and Termination Dates note set out below.

REFERENCES IN TEXT

Section 401(b) of the Biosimilar User Fee Act of 2012, referred to in subsec. (a), is section 401(b) of Pub. L. 112–144, which is set out as a note under section 379j–51 of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 112–144, title IV, § 404(b), July 9, 2012, 126 Stat. 1038, provided that: ''Section 744I of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–53], as added by section 403 of this Act, shall cease to be effective January 31, 2018.''

Section effective Oct. 1, 2012, see section 405 of Pub. L. 112–144, set out as a note under section 379j–51 of this title.

SUBPART 9—FEES RELATING TO OUTSOURCING FACILITIES

§ 379j–61. Definitions

In this subpart:

(1) The term ''affiliate'' has the meaning given such term in section 379g(11) of this title.

(2) The term ''gross annual sales'' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.