§ 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.

(3) The term ''outsourcing facility'' has the meaning given to such term in section 353b(d)(4) of this title.

(4) The term ''reinspection'' means, with respect to an outsourcing facility, 1 or more inspections conducted under section 374 of this title subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

(June 25, 1938, ch. 675, § 744J, as added Pub. L. 113–54, title I, § 102(b), Nov. 27, 2013, 127 Stat. 593.)

§ 379j–62. Authority to assess and use outsourcing facility fees

(a) Establishment and reinspection fees

(1) In general

For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

(A) an annual establishment fee from each outsourcing facility; and

(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

(2) Multiple reinspections

An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

(b) Establishment and reinspection fee setting

The Secretary shall—

(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and

(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

(c) Amount of establishment fee and reinspection fee

(1) In general

For each outsourcing facility in a fiscal year—

(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of—

(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus

(ii) the small business adjustment factor described in paragraph (3); and

(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).

(2) Inflation adjustment factor

(A) In general

For fiscal year 2015 and subsequent fiscal years, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

(i) 1;

(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; plus

(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years.

(B) Compounded basis

The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

(3) Small business adjustment factor

The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

(A) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

(4) Exception for small businesses

(A) In general

In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to \1/3\ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

(B) Application

To qualify for the exception under this paragraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.