''(1) October 1, 2012; or

''(2) the date of the enactment of this title [July 9, 2012].

''(b) EXCEPTION.—Fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], as added by this title, shall be assessed for all biosimilar biological product applications received on or after October 1, 2012, regardless of the date of the enactment of this title.''

FINDING

Pub. L. 112–144, title IV, §401(b), July 9, 2012, 126 Stat. 1026, provided that: ''The Congress finds that the fees authorized by the amendments made in this title [enacting this section and sections 379j–52 and 379j–53 of this title and amending sections 379d–4 and 379g of this title] will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], 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.''

§ 379j–52. Authority to assess and use biosimilar biological product fees

(a) Types of fees

Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Biosimilar development program fees

(A) Initial biosimilar biological product development fee

(i) In general

Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (b)(1)(A).

(ii) Meeting request

The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

(iii) Clinical protocol for IND

A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 355(i) of this title, including any regulations promulgated under section 355(i) of this title, (referred to in this section as ''investigational new drug application'') describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

(iv) Due date

The initial biosimilar biological product development fee shall be due by the earlier of the following:

(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

(v) Transition rule

Each person that has submitted an investigational new drug application prior to July 9, 2012, shall pay the initial biosimilar biological product development fee by the earlier of the following:

(I) Not later than 60 days after July 9, 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(B) Annual biosimilar biological product development fee

(i) In general

A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (b)(1)(B) for biosimilar biological product development (referred to in this section as ''annual biosimilar biological product development fee'').

(ii) Due date

The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

(I) the first business day on or after October 1 of each such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(iii) Exception

The annual biosimilar development program fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

(I) submitted a marketing application for the biological product that was accepted for filing; or

(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

(C) Discontinuation of fee obligation

A person may discontinue participation in the biosimilar biological product development program for a product effective October 1 of a fiscal year by, not later than August 1 of the preceding fiscal year—

(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the

product as a biosimilar biological product; or

(ii) if an investigational new drug application concerning the product has been submitted, withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

(D) Reactivation fee

(i) In general

A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) shall pay a fee (referred to in this section as ''reactivation fee'') by the earlier of the following:

(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

(II) Upon the date of submission (after the date on which such participation was discontinued) of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

(ii) Application of annual fee

A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

(E) Effect of failure to pay biosimilar development program fees

(i) No biosimilar biological product development meetings

If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

(ii) No receipt of investigational new drug applications

Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 355(i)(2) of this title if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) Financial hold

Notwithstanding section 355(i)(2) of this title, except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

(iv) No acceptance of biosimilar biological product applications or supplements

If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(F) Limits regarding biosimilar development program fees

(i) No refunds

The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

(ii) No waivers, exemptions, or reductions

The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

(2) Biosimilar biological product application and supplement fee

(A) In general

Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to the following fees:

(i) A fee for a biosimilar biological product application that is equal to—

(I) the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval; minus

(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to—

(I) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

(B) Reduction in fees

Notwithstanding section 404 of the Biosimilars[1] User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

(C) Payment due date

Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

(D) Exception for previously filed application or supplement

If a biosimilar biological product application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(E) Refund of application fee if application refused for filing or withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

(F) Fees for applications previously refused for filing or withdrawn before filing

A biosimilar biological product application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (c).

(3) Biosimilar biological product establishment fee

(A) In general

Except as provided in subparagraph (E), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in such application.

(B) Assessment in fiscal years

The establishment fee shall be assessed in each fiscal year for which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

(C) Due date

The establishment fee for a fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of such fiscal year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.

(D) Application to establishment

(i) Each biosimilar biological product establishment shall be assessed only one fee per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to clause (ii).

(ii) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

(E) Exception for new products

If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun,

the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

(4) Biosimilar biological product fee

(A) In general

Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar bio-

[1] So in original. Probably should be ''Biosimilar''.

logical product the annual fee established under subsection (b)(1)(F).

(B) Due date

The biosimilar biological product fee for a fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(C) One fee per product per year

The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

(b) Fee setting and amounts

(1) In general

Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

(A) Initial biosimilar biological product development fee

The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 379h(c)(4) of this title for a human drug application described in section 379h(a)(1)(A)(i) of this title for that fiscal year.

(B) Annual biosimilar biological product development fee

The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 379h(c)(4) of this title for a human drug application described in section 379h(a)(1)(A)(i) of this title for that fiscal year.

(C) Reactivation fee

The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20 percent of the amount of the fee established under section 379h(c)(4) of this title for a human drug application described in section 379h(a)(1)(A)(i) of this title for that fiscal year.

(D) Biosimilar biological product application fee

The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 379h(c)(4) of this title for a human drug application described in section 379h(a)(1)(A)(i) of this title for that fiscal year.

(E) Biosimilar biological product establishment fee

The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 379h(c)(4) of this title for a prescription drug establishment for that fiscal year.

(F) Biosimilar biological product fee

The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 379h(c)(4) of this title for a prescription drug product for that fiscal year.

(2) Limit

The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

(c) Application fee waiver for small business

(1) Waiver of application fee

The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

(A) application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business; and

(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

(2) Considerations

In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) Small business defined

In this subsection, the term ''small business'' means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 379g of this title) or a biosimilar biological product application (as defined in section 379j–51(4) of this title) and introduced or delivered for introduction into interstate commerce.

(d) Effect of failure to pay fees

A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

(e) Crediting and availability of fees

(1) In general

Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and

in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

(2) Collections and appropriation Acts

(A) In general

Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

(B) Use of fees and limitation

The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

(C) Fee collection during first program year

Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

(D) Provision for early payments in subsequent years

Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) Authorization of appropriations

For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

(f) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(g) Written requests for waivers and refunds

To qualify for consideration for a waiver under subsection (c), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

(h) Construction

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(June 25, 1938, ch. 675, § 744H, as added Pub. L. 112–144, title IV, § 402, July 9, 2012, 126 Stat. 1029.)

TERMINATION OF SECTION

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

REFERENCES IN TEXT

July 9, 2012, referred to in subsec. (a)(1)(A)(v), was in the original ''the date of the enactment of the Biosimilars User Fee Act of 2012'', which was translated as meaning the date of enactment of the Biosimilar User Fee Act of 2012, title IV of Pub. L. 112–144, to reflect the probable intent of Congress.

Section 404 of the Biosimilar User Fee Act of 2012, referred to in subsec. (a)(2)(B), is section 404 of title IV of Pub. L. 112–144, July 9, 2012, 126 Stat. 1038. Section 404(a) is set out as a note under section 379j–51 of this title, and section 404(b) is set out as a note under section 379j–53 of this title.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2017, see section 404(a) of Pub. L. 112–144, set out as a note under section 379j–51 of this title.

Section effective Oct. 1, 2012, with fees under this subpart to be assessed for all biosimilar biological product applications received on or after Oct. 1, 2012, see section 405 of Pub. L. 112–144, set out as a note under section 379j–51 of this title.

§ 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