section 301 of this title], part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–51 et seq.], as in effect on the day before the date of the enactment of this title [Aug. 18, 2017], shall continue to be in effect with respect to biosimilar biological product applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2012, but before October 1, 2017, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2018.''

CONGRESSIONAL FINDINGS CONCERNING FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Pub. L. 117–180, div. F, title IV, § 4001(b), Sept. 30, 2022, 136 Stat. 2160, provided that: ''Congress finds that the fees authorized by the amendments made by this title [see section 4001(a) of Pub. L. 117–180, set out as a Short Title of 2022 Amendment note under section 301 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 (21 U.S.C. 379j–51 et seq.), 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.''

Pub. L. 115–52, title IV, § 401(b), Aug. 18, 2017, 131 Stat. 1028, provided that: ''The Congress finds that the fees authorized by the amendments made in this title [see section 401(a) of Pub. L. 115–52, set out as a Short Title of 2017 Amendment note under section 301 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 [21 U.S.C. 379j–51 et seq.], 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.''

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 2023, the Secretary shall assess and collect fees in accordance with this section as follows:

**(1) Biosimilar biological product 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 (c)(5).

**(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 7 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 7 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 (c)(5) for the biosimilar biological product development program (referred to in this section as ''annual biosimilar biological product development fee''), except that, in the case that such product (including, where applicable, ownership of the rel-

evant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.

**(ii) Due date**

The annual biosimilar biological product development 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 biological product development 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;

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

(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).

**(iv) Refund**

If a person submits a marketing application for a biosimilar biological product before October 1 of a fiscal year and such application is subsequently accepted for filing, the person may request a refund equal to the annual biosimilar biological product development fee paid by the person for the product for such fiscal year. To qualify for consideration for a refund under this clause, a person shall submit to the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.

**(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), or who has been administratively removed from such program for a product under subparagraph (E)(v), shall, if the person seeks to resume participation in such program, pay all annual biosimilar biological product development fees previously assessed for such product and still owed and a fee (referred to in this section as ''reactivation fee'') by the earlier of the following:

(I) Not later than 7 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued or the date of administrative removal, as applicable).

(II) Upon the date of submission (after the date on which such participation was discontinued or the date of administrative removal, as applicable) by such person 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), except that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.

**(E) Effect of failure to pay 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.

**(v) Administrative removal from the biosimilar biological product development program**

If a person has failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of 2 consecutive fiscal years, the Secretary may administratively remove such person from the biosimilar biological product development program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to such person of the intended administrative removal.

**(F) Limits regarding fees**

**(i) Refunds**

Except as provided in subparagraph (B)(iv), 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 fee**

**(A) In general**

Each person that submits, on or after October 1, 2017, a biosimilar biological product application shall be subject to the following fees:

(i) A fee established under subsection (c)(5) 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.

(ii) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval. Such fee shall be equal to half of the amount of the fee described in clause (i).

**(B) Rule of applicability; treatment of certain previously paid fees**

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—

(i) be subject to any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted; and

(ii) be entitled to no reduction of such application fees based on the amount of fees paid for that product before October 1, 2017, under such subparagraph (A), (B), or (D).

**(C) Payment due date**

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

**(D) Exception for previously filed application**

If a biosimilar biological product application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn prior to approval (without a waiver), the submission of a biosimilar biological product application 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 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 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 (d).

**(3) Biosimilar biological product program fee**

**(A) In general**

Each person who is named as the applicant in a biosimilar biological product application shall pay the annual biosimilar biologi-

cal product program fee established for a fiscal year under subsection (c)(5) for each biosimilar biological product that—

(i) is identified in such a biosimilar biological product application approved as of October 1 of such fiscal year;

(ii) may be dispensed only under prescription pursuant to section 353(b) of this title; and

(iii) as of October 1 of such fiscal year, does not appear on a list, developed and maintained by the Secretary, of discontinued biosimilar biological products.

**(B) Due date**

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

**(D) Limitation**

A person who is named as the applicant in a biosimilar biological product application shall not be assessed more than 5 biosimilar biological product program fees for a fiscal year for biosimilar biological products identified in such biosimilar biological product application.

**(E) Movement to discontinued list**

**(i) Date of inclusion**

If a written request to place a product on the list referenced in subparagraph (A) of discontinued biosimilar biological products is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, withdrawn from sale, then for purposes of assessing the biosimilar biological product program fee, the Secretary shall consider such product to have been included on such list on the later of—

(I) the date such request was received; or

(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

**(ii) Treatment as withdrawn from sale**

For purposes of clause (i), a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

**(iii) Special rule for products removed from discontinued list**

If a biosimilar biological product that is identified in a biosimilar biological product application approved as of October 1 of a fiscal year appears, as of October 1 of such fiscal year, on the list referenced in subparagraph (A) of discontinued biosimilar biological products, and on any subsequent day during such fiscal year the biosimilar biological product does not appear on such list, except as provided in subparagraph (D), each person who is named as the applicant in a biosimilar biological product application with respect to such product shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for such biosimilar biological product. Notwithstanding subparagraph (B), such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for each fiscal year.

**(b) Fee revenue amounts**

**(1) In general**

For each of the fiscal years 2023 through 2027, fees under subsection (a) shall, except as provided in subsection (c), be established to generate a total revenue amount equal to the sum of—

(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the strategic hiring and retention adjustment (as determined under subsection (c)(2));

(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

(F) for fiscal year 2023 an additional amount of $4,428,886; and

(G) for fiscal year 2024 an additional amount of $320,569.

**(2) Allocation of revenue amount among fees**

**(A) Allocation**

The Secretary shall determine the percentage of the total revenue amount for a fiscal year to be derived from, respectively—

(i) initial and annual biosimilar biological product development fees and reactivation fees under subsection (a)(1);

(ii) biosimilar biological product application fees under subsection (a)(2); and

(iii) biosimilar biological product program fees under subsection (a)(3).

**(B) Biosimilar biological product development fees**

The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.

**(C) Reactivation fee**

The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to

twice the amount of the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.

**(3) Annual base revenue**

For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

(A) for fiscal year 2023, $43,376,922; and

(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(4).

**(c) Adjustments; annual fee setting**

**(1) Inflation adjustment**

**(A) In general**

For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

(i) such annual base revenue for the fiscal year under subsection (b)(1)(A); and

(ii) the inflation adjustment percentage under subparagraph (B).

**(B) Inflation adjustment percentage**

The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—

(i) 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 the process for the review of biosimilar biological product applications (as defined in section 379j–51(13) of this title) for the first 3 years of the preceding 4 fiscal years; and

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; 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 the process for the review of biosimilar biological product applications (as defined in section 379j–51(13) of this title) for the first 3 years of the preceding 4 fiscal years.

**(2) Strategic hiring and retention adjustment**

For each fiscal year, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by $150,000.

**(3) Capacity planning adjustment**

**(A) In general**

For each fiscal year, the Secretary shall, in addition to the adjustments under paragraphs (1) and (2), further adjust the fee revenue and fees under this section for a fiscal year to reflect changes in the resource capacity needs of the Secretary for the process for the review of biosimilar biological product applications.

**(B) Methodology**

For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled ''Biosimilar User Fee Rates for Fiscal Year 2021'' published in the Federal Register on August 4, 2020 (85 Fed. Reg. 47220). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

**(C) Limitations**

Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment).

**(D) Publication in Federal Register**

The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

**(4) Operating reserve adjustment**

**(A) Increase**

For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

**(B) Decrease**

**(i) Fiscal year 2023**

For fiscal year 2023, if the Secretary has carryover balances for such process in excess of 33 weeks of such operating reserves, the Secretary shall decrease such fee rev-

enue and fees to provide for not more than 33 weeks of such operating reserves.

**(ii) Fiscal year 2024**

For fiscal year 2024, if the Secretary has carryover balances for such process in excess of 27 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 27 weeks of such operating reserves.

**(iii) Fiscal year 2025 and subsequent fiscal years**

For fiscal year 2025 and subsequent fiscal years, if the Secretary has carryover balances for such process in excess of 21 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves.

**(C) Federal Register notice**

If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5)(B) establishing fee revenue and fees for the fiscal year involved.

**(5) Annual fee setting**

For fiscal year 2023 and each subsequent fiscal year, the Secretary shall, not later than 60 days before the start of each such fiscal year—

(A) establish, for the fiscal year, initial and annual biosimilar biological product development fees and reactivation fees under subsection (a)(1), biosimilar biological product application fees under subsection (a)(2), and biosimilar biological product program fees under subsection (a)(3), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(B) publish such fee revenue and fees in the Federal Register.

**(6) Limit**

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

**(d) 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 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.

**(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.

**(e) 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 such fees owed by such person have been paid.

**(f) 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 limitations**

**(i) In general**

The fees authorized by this section shall be available—

(I) for fiscal year 2023, 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 such fiscal year; and

(II) for fiscal year 2024 and each subsequent fiscal year, 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 sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with the process for the review of biosimilar biological product applications, is no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

**(ii) Leasing and necessary equipment**

Beginning on October 1, 2023, the authorities under section 379j–51(9)(C) of this title shall include only leasing and necessary scientific equipment.

**(C) Compliance**

The Secretary shall be considered to have met the requirements of subparagraph (B)(i) in any fiscal year if the costs allocated as described in subclause (I) or (II) of such subparagraph, as applicable, are not more than 15 percent below the level specified in such subparagraph.

**(D) Provision for early payments**

Payment of fees authorized under this section for a fiscal year, 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 2023 through 2027, 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.

**(g) 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.

**(h) Written requests for waivers and returns; disputes concerning fees**

To qualify for consideration for a waiver under subsection (d), or for the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such waiver or return and, except as otherwise specified in this section, such written request shall be submitted to the Secretary not later than 180 days after such fee is due. A request submitted under this paragraph shall include any legal authorities under which the request is made.

**(i) 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; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(V), Dec. 13, 2016, 130 Stat. 1155; Pub. L. 115–52, title IV, §403, title IX, §905(b)(4), Aug. 18, 2017, 131 Stat. 1028, 1090; Pub. L. 116–136, div. A, title III, §3856(b)(1), Mar. 27, 2020, 134 Stat. 458; Pub. L. 117–180, div. F, title IV, §4003, Sept. 30, 2022, 136 Stat. 2160; Pub. L. 117–328, div. FF, title III, §3625(b), Dec. 29, 2022, 136 Stat. 5880.)

TERMINATION OF SECTION

*For termination of section by section 4005(a) of Pub. L. 117–180, see Effective and Termination Dates note set out below.*

**Editorial Notes**

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–180, §4003(a)(1), substituted ''fiscal year 2023'' for ''fiscal year 2018'' in introductory provisions.

Subsec. (a)(1)(A)(iv)(I), (v)(II). Pub. L. 117–180, §4003(a)(2), substituted ''7 days'' for ''5 days''.

Subsec. (a)(1)(B)(i). Pub. L. 117–180, §4003(a)(3)(A), inserted before period at end '', except that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee''.

Subsec. (a)(1)(B)(iii)(III). Pub. L. 117–180, §4003(a)(3)(B), added subcl. (III).

Subsec. (a)(1)(B)(iv). Pub. L. 117–180, §4003(a)(3)(C), substituted ''is subsequently accepted for filing'' for ''is accepted for filing on or after October 1 of such fiscal year''.

Subsec. (a)(1)(D). Pub. L. 117–180, §4003(a)(4), amended subpar. (D) generally. Prior to amendment, subpar. (D) related to payment of a reactivation fee for resuming participation in the biosimilar biological product development program and application of annual biosimilar biological product development fee for a person paying a reactivation fee.

Subsec. (a)(1)(E)(v). Pub. L. 117–180, §4003(a)(5), added cl. (v).

Subsec. (a)(2)(D). Pub. L. 117–180, §4003(a)(6), inserted ''prior to approval'' after ''or was withdrawn''.

Subsec. (a)(3)(A)(ii), (iii). Pub. L. 117–180, §4003(a)(7)(A), added cl. (ii) and redesignated former cl. (ii) as (iii).

Subsec. (a)(3)(E). Pub. L. 117–180, §4003(a)(7)(B), added subpar. (E).

Subsec. (a)(4). Pub. L. 117–180, §4003(a)(8), struck out par. (4) which related to the annual fee for each biosimilar biological product in a biosimilar biological product application.

Subsec. (b)(1). Pub. L. 117–180, §4003(b)(2), (3), redesignated par. (2) as (1) and amended it generally. Prior to amendment, par. related to fee revenue amounts for fiscal years 2019 through 2022. Former par. (1) struck out.

Pub. L. 117–180, §4003(b)(1), struck out par. (1) which related to fee revenue amounts for fiscal year 2018.

Subsec. (b)(2). Pub. L. 117–180, §4003(b)(2), (4)(A), redesignated par. (3) as (2) and struck out ''; limitations on fee amounts'' after ''among fees'' in heading. Former par. (2) redesignated (1).

Subsec. (b)(2)(B) to (D). Pub. L. 117–180, § 4003(b)(4)(B), (C), redesignated subpars. (C) and (D) as (B) and (C), respectively, and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: ''Until the first fiscal year for which the capacity planning adjustment under subsection (c)(2) is effective, the amount of any fee under subsection (a) for a fiscal year after fiscal year 2018 shall not exceed 125 percent of the amount of such fee for fiscal year 2018.''

Subsec. (b)(3), (4). Pub. L. 117–180, § 4003(b)(2), (5), redesignated par. (4) as (3) and amended it generally. Prior to amendment, text read as follows: ''For purposes of paragraph (2), the dollar amount of the annual base revenue for a fiscal year shall be the dollar amount of the total revenue amount for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(3).'' Former par. (3) redesignated (2).

Subsec. (c)(1)(A). Pub. L. 117–180, § 4003(c)(1)(A)(i), substituted ''subsection (b)(1)(B)'' for ''subsection (b)(2)(B)'' in introductory provisions.

Subsec. (c)(1)(A)(i). Pub. L. 117–180, § 4003(c)(1)(A)(ii), substituted ''subsection (b)(1)(A)'' for ''subsection (b)''.

Subsec. (c)(1)(B)(ii). Pub. L. 117–180, § 4003(c)(1)(B), substituted ''Washington-Arlington-Alexandria, DC–VA–MD–WV'' for ''Washington-Baltimore, DC–MD–VA–WV''.

Subsec. (c)(2) to (4). Pub. L. 117–180, § 4003(c)(2), added pars. (2) to (4) and struck out former pars. (2) to (4) which related to application and methodology of capacity planning adjustment, operating reserve adjustment, and fiscal year 2018 adjustment, respectively.

Subsec. (c)(5). Pub. L. 117–180, § 4003(c)(3), substituted ''2023'' for ''2018'' in introductory provisions.

Subsec. (f)(2)(B)(i). Pub. L. 117–328, § 3625(b)(1), substituted ''available—'' for ''available for a fiscal year beginning after fiscal year 2012'', designated remainder of existing provisions as subcl. (I), inserted ''for fiscal year 2023,'' before ''to defray the costs'', substituted ''such fiscal year; and'' for ''the fiscal year involved.'', and added subcl. (II).

Subsec. (f)(2)(C). Pub. L. 117–328, § 3625(b)(2), substituted ''subparagraph (B)(i) in any fiscal year if the costs allocated as described in subclause (I) or (II) of such subparagraph, as applicable,'' for ''subparagraph (B) in any fiscal year if the costs described in such subparagraph''.

Subsec. (f)(3). Pub. L. 117–180, § 4003(d), substituted ''2023 through 2027'' for ''2018 through 2022''.

Subsec. (h). Pub. L. 117–180, § 4003(e), amended subsec. (h) generally. Prior to amendment, text read as follows: ''To qualify for consideration for a waiver under subsection (d), 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.''

2020—Subsec. (f)(2)(B). Pub. L. 116–136, § 3856(b)(1), amended Pub. L. 115–52, § 905(b)(4). See 2017 Amendment note below.

2017—Subsec. (a). Pub. L. 115–52, § 403(a)(1), substituted ''fiscal year 2018'' for ''fiscal year 2013'' in introductory provisions.

Subsec. (a)(1). Pub. L. 115–52, § 403(a)(2), substituted ''Biosimilar biological product'' for ''Biosimilar'' in heading.

Subsec. (a)(1)(A)(i). Pub. L. 115–52, § 403(a)(3), substituted ''(c)(5)'' for ''(b)(1)(A)''.

Subsec. (a)(1)(B)(i). Pub. L. 115–52, § 403(a)(4), substituted ''(c)(5) for the biosimilar biological product development program'' for ''(b)(1)(B) for biosimilar biological product development''.

Subsec. (a)(1)(B)(ii). Pub. L. 115–52, § 403(a)(5), substituted ''annual biosimilar biological product development fee'' for ''annual biosimilar biological product development program fee'' in introductory provisions.

Subsec. (a)(1)(B)(iii). Pub. L. 115–52, § 403(a)(6), substituted ''annual biosimilar biological product development fee'' for ''annual biosimilar development program fee''.

Subsec. (a)(1)(B)(iv). Pub. L. 115–52, § 403(a)(7), added cl. (iv).

Subsec. (a)(1)(C). Pub. L. 115–52, § 403(a)(8), substituted ''for a product, effective October 1 of a fiscal year, by,'' for ''for a product effective October 1 of a fiscal year by,'' in introductory provisions.

Subsec. (a)(1)(D)(i). Pub. L. 115–52, § 403(a)(9)(A), inserted '', if the person seeks to resume participation in such program,'' before ''pay a fee'' in introductory provisions.

Subsec. (a)(1)(D)(i)(I). Pub. L. 115–52, § 403(a)(9)(B), inserted ''by such person'' after ''grants a request''.

Subsec. (a)(1)(D)(i)(II). Pub. L. 115–52, § 403(a)(9)(C), inserted ''by such person'' after ''discontinued)''.

Subsec. (a)(1)(E). Pub. L. 115–52, § 403(a)(10), struck out ''biosimilar development program'' after ''pay'' in heading.

Subsec. (a)(1)(F). Pub. L. 115–52, § 403(a)(11)(A), struck out ''biosimilar development program'' after ''regarding'' in heading.

Subsec. (a)(1)(F)(i). Pub. L. 115–52, § 403(a)(11)(B), amended cl. (i) generally. Prior to amendment, text read as follows: ''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).''

Subsec. (a)(2). Pub. L. 115–52, § 403(a)(12)(A), struck out ''and supplement'' after ''application'' in heading.

Subsec. (a)(2)(A), (B). Pub. L. 115–52, § 403(a)(12)(B), amended subpars. (A) and (B) generally. Prior to amendment, subpars. (A) and (B) related to the fee for a biosimilar biological product application or a supplement submitted on or after Oct. 1, 2012, and to a reduction in certain fees, respectively.

Subsec. (a)(2)(C). Pub. L. 115–52, § 403(a)(12)(D), struck out ''or supplement'' after ''application''.

Subsec. (a)(2)(D). Pub. L. 115–52, § 403(a)(12)(C)–(E), in heading, struck out ''or supplement'' after ''application'' and in text, substituted ''application was submitted'' for ''application or supplement was submitted'', ''application, was accepted'' for ''application or supplement, was accepted'', and ''application for the same product'' for ''application or a supplement for the same product''.

Subsec. (a)(2)(E). Pub. L. 115–52, § 403(a)(12)(D), struck out ''or supplement'' after ''application''.

Subsec. (a)(2)(F). Pub. L. 115–52, § 403(c)(2), substituted ''subsection (d)'' for ''subsection (c)''.

Pub. L. 115–52, § 403(a)(12)(D), struck out ''or supplement'' after ''application''.

Subsec. (a)(3). Pub. L. 115–52, § 403(a)(13), amended par. (3) generally. Prior to amendment, par. (3) consisted of subpars. (A) to (E) which related to biosimilar biological product establishment fee, assessment, due date, assessment and division of fee for a biosimilar biological product establishment that manufactures for multiple applicants, and exception for new products, respectively.

Subsec. (a)(4)(A). Pub. L. 115–52, § 403(c)(3), substituted ''subsection (c)(5)'' for ''subsection (b)(1)(F)''.

Subsec. (b). Pub. L. 115–52, § 403(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) consisted of pars. (1) and (2) which related to fee amounts and limit to total amount of fees, respectively.

Subsec. (c). Pub. L. 115–52, § 403(c)(4), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 115–52, § 403(c)(1), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (d)(1). Pub. L. 115–52, § 403(d), substituted ''affiliate shall pay'' for ''affiliate shall pay—'' and ''not a small business.'' for ''not a small business; and'', struck out subpar. (A) designation before ''application fees for all'', and struck out subpar. (B) which read as follows: ''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.''

Subsec. (e). Pub. L. 115–52, § 403(e), substituted ''all such fees'' for ''all fees''.

Pub. L. 115–52, § 403(c)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 115–52, § 403(c)(1), redesignated subsec. (e) as (f). Former subsec. (f) redesignated (g).

Subsec. (f)(2)(B). Pub. L. 115–52, § 905(b)(4), as amended by Pub. L. 116–136, § 3856(b)(1), substituted ''limitations'' for ''limitation'' in heading, designated existing provisions as cl. (i) and inserted heading, and added cl. (ii).

Subsec. (f)(2)(C). Pub. L. 115–52, § 403(f)(1)(A), added subpar. (C) and struck out former subpar. (C). Prior to amendment, text read as follows: ''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.''

Subsec. (f)(2)(D). Pub. L. 115–52, § 403(f)(1)(B), struck out ''in subsequent years'' after ''payments'' in heading and ''(after fiscal year 2013)'' after ''fiscal year'' in text.

Subsec. (f)(3). Pub. L. 115–52, § 403(f)(2), substituted ''2018 through 2022'' for ''2013 through 2017''.

Subsec. (g). Pub. L. 115–52, § 403(c)(1), redesignated subsec. (f) as (g). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 115–52, § 403(c)(2), substituted ''subsection (d)'' for ''subsection (c)''.

Pub. L. 115–52, § 403(c)(1), redesignated subsec. (g) as (h). Former subsec. (h) redesignated (i).

Subsec. (i). Pub. L. 115–52, § 403(c)(1), redesignated subsec. (h) as (i).

2016—Subsec. (a)(1)(A)(v). Pub. L. 114–255, § 3101(a)(2)(V)(i), which directed technical amendment in paragraph (1)(A)(v) to reference in original act which appears in text as reference to July 9, 2012, was executed by making the amendment in introductory provisions and in subcl. (I), to reflect the probable intent of Congress.

Subsec. (a)(2)(B). Pub. L. 114–255, § 3101(a)(2)(V)(ii), substituted ''Biosimilar User Fee Act of 2012'' for ''Biosimilars User Fee Act of 2012''.

**Statutory Notes and Related Subsidiaries**

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–180 effective Oct. 1, 2022, with fees under this subpart to be assessed for all biosimilar biological product applications received on or after Oct. 1, 2022, see section 4006 of Pub. L. 117–180, set out as a note under section 379j–51 of this title.

EFFECTIVE DATE OF 2020 AMENDMENT

Pub. L. 116–136, div. A, title III, § 3856(b)(2), Mar. 27, 2020, 134 Stat. 458, provided that: ''The amendment made by paragraph (1) [amending Pub. L. 115–52 which amended this section] shall take effect as of the enactment of the FDA Reauthorization Act of 2017 (Public Law 115–52).''

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 403 of Pub. L. 115–52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all biosimilar biological product applications received on or after Oct. 1, 2017, see section 406 of Pub. L. 115–52, set out as a note under section 379j–51 of this title.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2027, see section 4005(a) of Pub. L. 117–180, 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

#### (1) General requirements

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)[1] of the Biosimilar User Fee Amendments of 2022 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.

#### (2) Additional information

The report under this subsection shall include the progress of the Food and Drug Administration in achieving the goals, and future plans for meeting the goals, including—

(A) 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) the number of original biosimilar biological product applications filed per fiscal year, and the number of approvals issued by the agency for such applications; and

(C) the number of resubmitted original biosimilar biological product applications filed per fiscal year and the number of approvals[2] letters issued by the agency for such applications.

#### (3) Real time reporting

##### (A) In general

Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subpart, the Secretary shall post the data described in subparagraph (B) for such quarter and on a cumulative basis for the fiscal year on the internet website of the Food and Drug Administration, and may remove duplicative data from the annual report under this subsection.

##### (B) Data

The Secretary shall post the following data in accordance with subparagraph (A):

(i) The number and titles of draft and final guidance on topics related to the process for the review of biosimilars, and whether such guidances were required by statute or pursuant to a commitment under the letters described in section 401(b)[1] of the Biosimilar User Fee Amendments of 2022.

(ii) The number and titles of public meetings held on topics related to the process for the review of biosimilars, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 401(b)[1] of the Biosimilar User Fee Amendments of 2022.

[1] See References in Text note below.

[2] So in original.