Subsec. (a)(1). Pub. L. 117–180, §3003(1), substituted ''Not later'' for ''Beginning with fiscal year 2018, not later''.

Subsec. (a)(2). Pub. L. 117–180, §3003(3), substituted ''Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subpart'' for ''Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter''.

Subsec. (a)(3). Pub. L. 117–180, §3003(4), substituted ''The Secretary'' for ''Beginning with fiscal year 2020, the Secretary'' in introductory provisions.

Subsec. (a)(3)(A). Pub. L. 117–328, §3626(c)(1)(A), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022 and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;''.

Subsec. (a)(3)(B). Pub. L. 117–328, §3626(c)(1)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including identifying drivers of such changes; and''.

Subsec. (a)(3)(D). Pub. L. 117–328, §3626(c)(1)(C), (D), added subpar. (D).

Subsec. (b). Pub. L. 117–180, §3003(5), substituted ''Not later'' for ''Beginning with fiscal year 2018, not later''.

Subsec. (c). Pub. L. 117–180, §3003(6), substituted ''For each'' for ''Beginning with fiscal year 2018, for each'' in introductory provisions.

Subsec. (f)(1). Pub. L. 117–180, §3003(7)(A), substituted ''fiscal year 2027'' for ''fiscal year 2022'' in introductory provisions.

Subsec. (f)(4). Pub. L. 117–328, §3626(c)(2)(B), added par. (4). Former par. (4) redesignated (5).

Subsec. (f)(5). Pub. L. 117–328, §3626(c)(2)(A), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 117–180, §3003(7)(B), substituted ''January 15, 2027'' for ''January 15, 2022''.

Subsec. (f)(6), (7). Pub. L. 117–328, §3626(c)(2)(A), redesignated pars. (5) and (6) as (6) and (7), respectively.

Subsec. (f)(7)(A). Pub. L. 117–328, §3626(c)(2)(C)(i), substituted ''The'' for ''Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the'' and inserted '', not later than 30 days after each such negotiation meeting'' before period at end.

Subsec. (f)(7)(B). Pub. L. 117–328, §3626(c)(2)(C)(ii), inserted '', in sufficient detail,'' after ''shall summarize''.

2017—Subsec. (a). Pub. L. 115–52, §903(c), designated existing provisions as par. (1), inserted heading, and added pars. (2) and (3).

Pub. L. 115–52, §304(1), substituted ''2018'' for ''2013'' and ''Generic Drug User Fee Amendments of 2017'' for ''Generic Drug User Fee Amendments of 2012''.

Subsec. (a)(4). Pub. L. 115–52, §904(c)(1), added par. (4).

Subsec. (b). Pub. L. 115–52, §304(2), substituted ''2018'' for ''2013''.

Subsecs. (c) to (e). Pub. L. 115–52, §904(c)(2), added subsecs. (c) and (d) and redesignated former subsec. (c) as (e). Former subsec. (d) redesignated (f).

Subsec. (f). Pub. L. 115–52, §904(c)(2)(A), redesignated subsec. (d) as (f).

Pub. L. 115–52, §304(3), which directed amendment of subsec. (d), effective Oct. 1, 2017, by substituting ''2022'' for ''2017'' wherever appearing, was executed by making the substitution in subsec. (f) to reflect the probable intent of Congress and the redesignation of subsec. (d) as (f), effective Aug. 18, 2017, by Pub. L. 115–52, §904(c)(2). See Amendment note above.

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 abbreviated new drug applications received on or after Oct. 1, 2022, see section 3005 of Pub. L. 117–180, set out as a note under section 379j–41 of this title.

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 304 of Pub. L. 115–52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all abbreviated new drug applications received on or after Oct. 1, 2017, see section 306 of Pub. L. 115–52, set out as a note under section 379j–41 of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 117–180, div. F, title III, §3004(b), Sept. 30, 2022, 136 Stat. 2159, provided that: ''Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) shall cease to be effective January 31, 2028.''

Pub. L. 115–52, title III, §305(b), Aug. 18, 2017, 131 Stat. 1027, which provided that this section would cease to be effective Jan. 31, 2023, was repealed by Pub. L. 117–180, div. F, title III, §3004(c), Sept. 30, 2022, 136 Stat. 2159.

[Pub. L. 117–180, div. F, title III, §3004(c), Sept. 30, 2022, 136 Stat. 2159, provided that the repeal of section 305(b) of Pub. L. 115–52, formerly set out above, is effective Oct. 1, 2022.]

Pub. L. 112–144, title III, §304(b), July 9, 2012, 126 Stat. 1024, which provided that this section would cease to be effective Jan. 31, 2018, was repealed by Pub. L. 115–52, title III, §305(c)(1), Aug. 18, 2017, 131 Stat. 1027.

[Pub. L. 115–52, title III, §305(c)(1), Aug. 18, 2017, 131 Stat. 1027, provided that the repeal of section 304(b) of Pub. L. 112–144, formerly set out above, is effective Oct. 1, 2017.]

Section effective Oct. 1, 2012, see section 305 of Pub. L. 112–144, set out as a note under section 379j–41 of this title.

SUBPART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

§ 379j–51. Definitions

For purposes of this subpart:

(1) The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items) for September of the preceding fiscal year divided by such Index for September 2011.

(2) The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(3) The term ''biosimilar biological product'' means a specific strength of a biological product in final dosage form for which a biosimilar biological product application has been approved.

(4)(A) Subject to subparagraph (B), the term ''biosimilar biological product application'' means an application for licensure of a biological product under section 262(k) of title 42.

(B) Such term does not include—

(i) a supplement to such an application;

(ii) an application filed under section 262(k) of title 42 that cites as the reference

product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

(iii) an application filed under section 262(k) of title 42 with respect to—

(I) whole blood or a blood component for transfusion;

(II) an in vitro diagnostic biological product; or

(III) a biological product for further manufacturing use only; or

(iv) an application for licensure under section 262(k) of title 42 that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

(5) The term ''biosimilar biological product development meeting'' means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

(6) The term ''biosimilar biological product development program'' means the program under this subpart for expediting the process for the review of submissions in connection with biosimilar biological product development.

(7)(A) The term ''biosimilar biological product establishment'' means a foreign or domestic place of business—

(i) that is at one general physical location consisting of one or more buildings, all of which are within 5 miles of each other; and

(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

(B) For purposes of subparagraph (A)(ii), the term ''manufactured'' does not include packaging.

(8) The term ''biosimilar initial advisory meeting''—

(A) means a meeting, if requested, that is limited to—

(i) a general discussion regarding whether licensure under section 262(k) of title 42 may be feasible for a particular product; and

(ii) if so, general advice on the expected content of the development program; and

(B) does not include any meeting that involves substantive review of summary data or full study reports.

(9) The term ''costs of resources allocated for the process for the review of biosimilar biological product applications'' means the expenses in connection with the process for the review of biosimilar biological product applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers employees and committees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under section 379j–52 of this title and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(10) The term ''final dosage form'' means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

(11) The term ''financial hold''—

(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 379j–52(a)(1) of this title; and

(B) does not mean that any of the bases for a ''clinical hold'' under section 355(i)(3) of this title have been determined by the Secretary to exist concerning the investigation.

(12) The term ''person'' includes an affiliate of such person.

(13) The term ''process for the review of biosimilar biological product applications'' means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

(D) Activities necessary for the release of lots of biosimilar biological products under section 262(k) of title 42.

(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 355(*o*) of this title (relating to postapproval studies and clinical trials and labeling changes) and section 355(p) of this title (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 355(k)(5) of this title (relating to adverse-event reports and postmarket safety activities).

(14) The term ''supplement'' means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 262(k)(4) of title 42.

(June 25, 1938, ch. 675, § 744G, as added Pub. L. 112–144, title IV, § 402, July 9, 2012, 126 Stat. 1026; amended Pub. L. 115–52, title IV, § 402, Aug. 18, 2017, 131 Stat. 1028; Pub. L. 117–180, div. F, title IV, § 4002, Sept. 30, 2022, 136 Stat. 2160.)

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—Par. (1). Pub. L. 117–180, § 4002(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) for October of the preceding fiscal year divided by such Index for October 2011.''

Par. (4)(B)(iii)(II) to (IV). Pub. L. 117–180, § 4002(b), redesignated subcls. (III) and (IV) as (II) and (III), respectively, and struck out former subcl. (II) which read as follows: ''an allergenic extract product;''.

2017—Par. (1). Pub. L. 115–52, § 402(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''The term 'adjustment factor' applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.''

Par. (3). Pub. L. 115–52, § 402(b), substituted ''means a specific strength of a biological product in final dosage form'' for ''means a product''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117–180, div. F, title IV, § 4006, Sept. 30, 2022, 136 Stat. 2166, provided that: ''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] shall take effect on October 1, 2022, or the date of the enactment of this Act [Sept. 30, 2022], whichever is later, except that fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be assessed for all biosimilar biological product applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.''

EFFECTIVE DATE OF 2017 AMENDMENT

Pub. L. 115–52, title IV, § 406, Aug. 18, 2017, 131 Stat. 1035, provided that: ''The amendments made by 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] shall take effect on October 1, 2017, or the date of the enactment of this Act [Aug. 18, 2017], whichever is later, except that fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–51 et seq.] shall be assessed for all biosimilar biological product applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.''

EFFECTIVE AND TERMINATION DATES

Pub. L. 117–180, div. F, title IV, § 4005(a), Sept. 30, 2022, 136 Stat. 2166, provided that: ''Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51, 379j–52) shall cease to be effective October 1, 2027.''

Pub. L. 115–52, title IV, § 405(a), Aug. 18, 2017, 131 Stat. 1035, which provided that this section and section 379j–52 of this title would cease to be effective Oct. 1, 2022, was repealed by Pub. L. 117–180, div. F, title IV, § 4005(c), Sept. 30, 2022, 136 Stat. 2166.

[Pub. L. 117–180, div. F, title IV, § 4005(c), Sept. 30, 2022, 136 Stat. 2166, provided that the repeal of section 405(a) of Pub. L. 115–52, formerly set out above, is effective Oct. 1, 2022.]

Pub. L. 112–144, title IV, § 404(a), July 9, 2012, 126 Stat. 1038, which provided that this section and section 379j–52 of this title would cease to be effective Oct. 1, 2017, was repealed by Pub. L. 115–52, title IV, § 405(c)(1), Aug. 18, 2017, 131 Stat. 1035.

[Pub. L. 115–52, title III, § 405(c)(1), Aug. 18, 2017, 131 Stat. 1035, provided that the repeal of section 404(a) of Pub. L. 112–144, formerly set out above, is effective Oct. 1, 2017.]

Pub. L. 112–144, title IV, § 405, July 9, 2012, 126 Stat. 1039, provided that:

''(a) IN GENERAL.—Except as provided under subsection (b), the amendments made by 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] shall take effect on the later of—

''(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.''

SAVINGS

Pub. L. 117–180, div. F, title IV, § 4007, Sept. 30, 2022, 136 Stat. 2167, provided that: ''Notwithstanding 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], 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 [Sept. 30, 2022], 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, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.''

Pub. L. 115–52, title IV, § 407, Aug. 18, 2017, 131 Stat. 1035, provided that: ''Notwithstanding the amendments made by 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], 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-