

Pub. L. 112-144, title III, §304(a), July 9, 2012, 126 Stat. 1024, which provided that this section and section 379j-42 of this title would cease to be effective Oct. 1, 2017, was repealed by Pub.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(a) of Pub. L. 112-144, formerly set out above, is effective Oct. 1, 2017.]

Pub. L. 112-144, title III, §305, July 9, 2012, 126 Stat. 1024, provided that: “The amendments made by this title [enacting this section and sections 379d-4, 379j-42, and 379j-43 of this title and amending sections 352 and 379d-3 of this title] shall take effect on October 1, 2012, or the date of the enactment of this title [July 9, 2012], whichever is later, except that fees under section 302 [enacting this section and sections 379j-42 and 379j-43 of this title] shall be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after October 1, 2012, regardless of the date of enactment of this title.”

SAVINGS CLAUSE

Pub. L. 117-180, div. F, title III, §3006, Sept. 30, 2022, 136 Stat. 2159, provided that: “Notwithstanding the amendments made by this title [amending sections 379j-42 and 379j-43 of this title and repealing provisions set out as notes under this section and section 379j-43 of this title], part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-41 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 abbreviated new drug applications (as defined in such part as of such day) that were received by the Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced 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 III, §307, Aug. 18, 2017, 131 Stat. 1027, provided that: “Notwithstanding the amendments made by this title [amending this section and sections 379j-42 and 379j-43 of this title and repealing provisions set out as notes under this section and section 379j-43 of this title], part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-41 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 abbreviated new drug applications (as defined in such part as of such day) that were received by the Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced 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 HUMAN GENERIC DRUGS

Pub. L. 117-180, div. F, title III, §3001(b), Sept. 30, 2022, 136 Stat. 2155, provided that: “Congress finds that the fees authorized by the amendments made by this title [amending sections 379j-42 and 379j-43 of this title and repealing provisions set out as notes under this section and section 379j-43 of this title] will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-41 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 III, §301(b), Aug. 18, 2017, 131 Stat. 1020, provided that: “The Congress finds that the fees authorized by the amendments made in this title [amending this section and sections 379j-42 and 379j-43 of this title and repealing provisions set out as notes under this section and section 379j-43 of this title] will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-41 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 III, §301(b), July 9, 2012, 126 Stat. 1008, provided that: “The Congress finds that the fees authorized by the amendments made in this title [enacting this section and sections 379d-4, 379j-42, and 379j-43 of this title and amending sections 352 and 379d-3 of this title] will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 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-42. Authority to assess and use human generic drug 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) One-time backlog fee for abbreviated new drug applications pending on October 1, 2012

(A) In general

Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

(B) Method of fee amount calculation

The amount of each one-time backlog fee shall be calculated by dividing \$50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

(C) Notice

Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

(D) Fee due date

The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

(E) Sunset

This paragraph shall cease to be effective October 1, 2022.

(2) Drug master file fee**(A) In general**

Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

(B) One-time payment

If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

(C) Notice

Not later than 60 days before the start of each of fiscal years 2023 through 2027, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

(D) Availability for reference**(i) In general**

Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

(ii) Conditions

A drug master file shall be deemed available for reference by the Secretary if—

(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

(iii) List

The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

(E) Fee due date**(i) In general**

Subject to clause (ii), a drug master file fee shall be due on the earlier of—

(I) the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file; or

(II) the date on which the drug master file holder requests the initial completeness assessment.

(ii) Limitation

No fee shall be due under subparagraph (A) for a fiscal year until the later of—

(I) 30 calendar days after publication of the notice provided for in subparagraph (C); or

(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(3) Abbreviated new drug application filing fee**(A) In general**

Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application shall be subject to a fee for each such submission in the amount established under subsection (d).

(B) Notice

Not later than 60 days before the start of each of fiscal years 2023 through 2027, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(C) Fee due date

The fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

(D) Refund of fee if abbreviated new drug application is not considered to have been received, is withdrawn prior to being received, or is no longer received**(i) Applications not considered to have been received and applications withdrawn prior to being received**

The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 355(j)(5)(A) of this title for a cause other than failure to pay fees, or that has been withdrawn prior to being received within the meaning of section 355(j)(5)(A) of this title.

(ii) Applications no longer received

The Secretary shall refund 100 percent of the fee paid under subparagraph (A) for any abbreviated new drug application if the Secretary initially receives the application under section 355(j)(5)(A) of this title and subsequently determines that an exclusivity period for a listed drug should have prevented the Secretary from receiving such application, such that the abbreviated new drug application is no longer received within the meaning of section 355(j)(5)(A) of this title.

(E) Fee for an application the Secretary considers not to have been received, or that has been withdrawn

An abbreviated new drug application that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn,

shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

(F) Additional fee for active pharmaceutical ingredient information not included by reference to Type II active pharmaceutical ingredient drug master file

An applicant that submits a generic drug submission on or after October 1, 2017, shall pay a fee, in the amount determined under subsection (d)(2), in addition to the fee required under subparagraph (A), if—

- (i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and
- (ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

(4) Generic drug facility fee and active pharmaceutical ingredient facility fee

(A) In general

Facilities identified in at least one generic drug submission that is approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

(i) Generic drug facility

Each person that owns a facility which is identified in at least one generic drug submission that is approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

(ii) Active pharmaceutical ingredient facility

Each person that owns a facility which is identified in at least one generic drug submission in which the facility is approved to produce one or more active pharmaceutical ingredients or in a Type II active pharmaceutical ingredient drug master file referenced in at least one such generic drug submission, shall be assessed an annual fee for each such facility.

(iii) Facilities producing both active pharmaceutical ingredients and finished dosage forms

Each person that owns a facility identified in at least one generic drug submission that is approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject only to the fee attributable to the manufacture of the finished dosage forms for that facility.

(B) Amount

The amount of fees established under subparagraph (A) shall be established under subsection (d).

(C) Notice

Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(D) Fee due date

For each of fiscal years 2023 through 2027, the fees under subparagraph (A) for such 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 for such year.

(5) Generic drug applicant program fee

(A) In general

A generic drug applicant program fee shall be assessed annually as described in subsection (b)(2)(E).

(B) Amount

The amount of fees established under subparagraph (A) shall be established under subsection (d).

(C) Notice

Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(D) Fee due date

For each of fiscal years 2023 through 2027, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

- (i) the first business day on or after October 1 of each such fiscal year; or
- (ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section for such fiscal year.

(6) Date of submission

For purposes of this chapter, a generic drug submission or Type II pharmaceutical master file is deemed to be “submitted” to the Food and Drug Administration—

(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

(b) Fee revenue amounts

(1) In general

(A) Fiscal year 2023

For fiscal year 2023, fees under subsection (a) shall be established to generate a total

estimated revenue amount under such subsection of \$582,500,000.

(B) Fiscal years 2024 through 2027

(i) In general

For each of the fiscal years 2024 through 2027, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to the base revenue amount for the fiscal year under clause (ii), as adjusted pursuant to subsection (c).

(ii) Base revenue amount

The base revenue amount for a fiscal year referred to in clause (i) is equal to the total revenue amount established under this paragraph for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(3).

(2) Types of fees

In establishing fees under paragraph (1) to generate the revenue amounts specified in such paragraph for a fiscal year, such fees shall be derived from the fees under paragraphs (2) through (5) of subsection (a) as follows:

(A) Five percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

(B) Thirty-three percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications).

(C) Twenty percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a contract manufacturing organization facility shall be equal to twenty-four percent of the fee for a facility that is not a contract manufacturing organization facility. The amount of the fee for a facility located outside the United States and its territories and possessions shall be \$15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.

(D) Six percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be \$15,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions.

(E)(i) Thirty-six percent shall be derived from fees under subsection (a)(5) (relating to generic drug applicant program fees). For purposes of this subparagraph, if a person has affiliates, a single program fee shall be assessed with respect to that person, including its affiliates, and may be paid by that person or any one of its affiliates. The Secretary shall determine the fees as follows:

(I) If a person (including its affiliates) owns at least one but not more than 5 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affil-

ates) shall be assessed a small business generic drug applicant program fee equal to one-tenth of the large size operation generic drug applicant program fee.

(II) If a person (including its affiliates) owns at least 6 but not more than 19 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium size operation generic drug applicant program fee equal to two-fifths of the large size operation generic drug applicant program fee.

(III) If a person (including its affiliates) owns 20 or more approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a large size operation generic drug applicant program fee.

(ii) For purposes of this subparagraph, an abbreviated new drug application shall be deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of such abbreviated new drug application by April 1 of the previous fiscal year.

(c) Adjustments

(1) Inflation adjustment

For fiscal year 2024 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, to equal the base revenue amount for the fiscal year (as specified in subsection (b)(1)(B)(ii)) multiplied by an amount equal to the sum of—

(A) one;

(B) 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 human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

(C) 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 human generic drug activities for the first 3 years of the preceding 4 fiscal years.

(2) Capacity planning adjustment

(A) In general

Beginning with fiscal year 2024, the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

(B) Capacity planning methodology

The Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

(i) be derived from the methodology and recommendations made in the report titled “Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations” announced in the Federal Register on August 3, 2020 (85 Fed. Reg. 46658); and

(ii) incorporate approaches and attributes determined appropriate by the Secretary, including approaches and attributes made in such report, except that in incorporating such approaches and attributes the workload categories used in forecasting resources shall only be the workload categories specified in section VIII.B.2.e. of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022.

(C) Limitations**(i) In general**

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 subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

(ii) Additional limitation

An adjustment under this paragraph shall not exceed 3 percent of the sum described in clause (i) for the fiscal year, except that such limitation shall be 4 percent if—

(I) for purposes of a fiscal year 2024 adjustment, the Secretary determines that during the period from April 1, 2021, through March 31, 2023—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,000; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022);

(II) for purposes of a fiscal year 2025 adjustment, the Secretary determines that during the period from April 1, 2022, through March 31, 2024—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined);

(III) for purposes of a fiscal year 2026 adjustment, the Secretary determines that during the period from April 1, 2023, through March 31, 2025—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined); and

(IV) for purposes of a fiscal year 2027 adjustment, the Secretary determines that during the period from April 1, 2024, through March 31, 2026—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined).

(D) Publication in Federal Register

The Secretary shall publish in the Federal Register notice referred to in subsection (a) the fee revenue and fees resulting from the adjustment and the methodology under this paragraph.

(3) Operating reserve adjustment**(A) In general**

For fiscal year 2024 and each subsequent fiscal year, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section for such fiscal year if such an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B) with respect to that fiscal year.

(B) Number of weeks

The number of weeks specified in this subparagraph is—

(i) 8 weeks for fiscal year 2024;

(ii) 9 weeks for fiscal year 2025; and

(iii) 10 weeks for each of fiscal year 2026 and 2027.

(C) Decrease

If the Secretary has carryover balances for human generic drug activities in excess of 12 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 12 weeks of such operating reserves.

(D) Rationale for adjustment

If an adjustment under this paragraph 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 subsection (a) publishing the fee revenue and fees for the fiscal year involved.

(d) Annual fee setting**(1) Fiscal years 2023 through 2027**

Not later than 60 days before the first day of each of fiscal years 2023 through 2027, the Secretary shall establish the fees described in paragraphs (2) through (5) of subsection (a),

based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

(2) Fee for active pharmaceutical ingredient information not included by reference to Type II active pharmaceutical ingredient drug master file

In establishing the fee under paragraph (1), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

(A) the sum of—

(i) the total number of such active pharmaceutical ingredients in such submission; and

(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

(e) Limitations

(1) In general

The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

(2) Leasing and necessary equipment

Beginning on October 1, 2023, the authorities under section 379j-41(12)(C) of this title shall include only leasing and necessary scientific equipment.

(f) Identification of facilities

(1) Required submission of facility identification

Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (3) shall submit to the Secretary the information required under this subsection each year. Such information shall, for each fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous fiscal year.

(2) Information required to be submitted

At a minimum, the submission required by paragraph (1) shall include for each such facility—

(A) identification of a facility identified in an approved or pending generic drug submission;

(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

(C) whether or not the facility is located within the United States and its territories and possessions;

(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs;

(E) whether the facility manufactures drugs that are not generic drugs; and

(F) whether the facility is a contract manufacturing organization facility.

(3) Certain sites and organizations

(A) In general

Any person that owns or operates a site or organization described in subparagraph (B)

shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

(B) Sites and organizations

A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

(i) a site in which a bioanalytical study is conducted;

(ii) a clinical research organization;

(iii) a contract analytical testing site; or

(iv) a contract repackager site.

(C) Notice

The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

(D) Inspection authority

The Secretary's inspection authority under section 374(a)(1) of this title shall extend to all such sites and organizations.

(g) Effect of failure to pay fees

(1) Generic drug backlog fee

Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on a publicly available arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 355(j)(5)(A) of this title until such outstanding fee is paid. This paragraph shall cease to be effective on October 1, 2022.

(2) Drug master file fee

(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 355(j)(5)(A) of this title unless the condition specified in clause (ii) is met.

(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active

pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 355(j)(5)(A) of this title.

(3) Abbreviated new drug application fee

Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 355(j)(5)(A) of this title until such outstanding fee is paid.

(4) Generic drug facility fee and active pharmaceutical ingredient facility fee

(A) In general

Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 355(j)(5)(A) of this title.

(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 355(j)(5)(A) of this title if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 352(aa) of this title.

(B) Application of penalties

The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

(C) Nonreceival for nonpayment

(i) Notice

If an abbreviated new drug application or supplement to an abbreviated new drug

application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

(ii) Nonreceival

If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 355(j)(5)(A) of this title.

(5) Generic drug applicant program fee

(A) In general

A person who fails to pay a fee as required under subsection (a)(5) by the date that is 20 calendar days after the due date, as specified in subparagraph (D) of such subsection, shall be subject to the following:

(i) The Secretary shall place the person on a publicly available arrears list.

(ii) Any abbreviated new drug application submitted by the generic drug applicant or an affiliate of such applicant shall not be received, within the meaning of section 355(j)(5)(A) of this title.

(iii) All drugs marketed pursuant to any abbreviated new drug application held by such applicant or an affiliate of such applicant shall be deemed misbranded under section 352(aa) of this title.

(B) Application of penalties

The penalties under subparagraph (A) shall apply until the fee required under subsection (a)(5) is paid.

(h) Limitations

(1) In general

Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 379j-41 of this title) applicable to the fiscal year involved.

(2) Authority

If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(i) Crediting and availability of fees

(1) In general

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, subject to paragraph (2). 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 human generic drug activities.

(2) Collections and appropriation Acts

(A) In general

The fees authorized by this section—

(i) subject to subparagraph (C), 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; and

(ii) shall be available—

(I) for fiscal year 2023, to defray the costs of human generic drug activities (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 activities), 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 \$97,000,000 multiplied by the adjustment factor defined in section 379j-41(3) of this title applicable to such fiscal year; and

(II) for fiscal year 2024 and each subsequent fiscal year, to defray the costs of human generic drug activities (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 activities), 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 human generic drug activities, is no less than \$97,000,000 multiplied by the adjustment factor defined in section 379j-41(3) of this title applicable to the fiscal year involved.

(B) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated as described in subclause (I) or (II) of such subparagraph, as applicable, are not more than 10 percent below the level specified in such subparagraph.

(C) 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 pro-

vided in advance in a prior year appropriations Act.

(3) Authorization of appropriations

For each of the fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

(j) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar 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.

(k) 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, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(l) Positron emission tomography drugs

(1) Exemption from fees

Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

(2) Identification requirement

Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

(m) Disputes concerning fees

To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

(n) Substantially complete applications

An abbreviated new drug application that is not considered to be received within the meaning of section 355(j)(5)(A) of this title because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been “substantially complete” on the date of its submission within the meaning of section 355(j)(5)(B)(iv)(II)(cc) of this title. An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 355(j)(5)(A) of this title as of the date such applicable fee is received.

(o) Information on abbreviated new drug applications owned by applicants and their affiliates

(1) In general

By April 1 of each year, each person that owns an abbreviated new drug application, or a designated affiliate of such person, shall submit, on behalf of the person and the affiliates of such person, to the Secretary a list of—

(A) all approved abbreviated new drug applications owned by such person; and

(B) if any affiliate of such person also owns an abbreviated new drug application, all affiliates that own any such abbreviated new drug application and all approved abbreviated new drug applications owned by any such affiliate.

(2) Format and method

The Secretary shall specify in guidance the format and method for submission of lists under this subsection.

(June 25, 1938, ch. 675, §744B, as added Pub. L. 112-144, title III, §302, July 9, 2012, 126 Stat. 1011; amended Pub. L. 112-193, §2(b)(2), (3), Oct. 5, 2012, 126 Stat. 1443; Pub. L. 115-52, title III, §303, title IX, §905(b)(3), Aug. 18, 2017, 131 Stat. 1021, 1090; Pub. L. 117-180, div. F, title III, §3002, Sept. 30, 2022, 136 Stat. 2155; Pub. L. 117-328, div. FF, title III, §3625(c), Dec. 29, 2022, 136 Stat. 5881.)

TERMINATION OF SECTION

For termination of section by section 3004(a) of Pub. L. 117-180, see Effective and Termination Dates note below.

Editorial Notes

REFERENCES IN TEXT

Section 3001(b) of the Generic Drug User Fee Amendments of 2022, referred to in subsec. (c)(2)(B)(ii), (C)(ii)(I)(bb), is section 3001(b) of title III of div. F of Pub. L. 117-180, which is set out as a note under section 379j-41 of this title.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117-180, §3002(a)(1), substituted “2023” for “2018” in introductory provisions.

Subsec. (a)(2)(C). Pub. L. 117-180, §3002(a)(2), substituted “2023 through 2027” for “2018 through 2022”.

Subsec. (a)(3)(B). Pub. L. 117-180, §3002(a)(3), substituted “2023 through 2027” for “2018 through 2022”.

Subsec. (a)(4)(D). Pub. L. 117-180, §3002(a)(4), substituted “2023 through 2027” for “2018 through 2022” in introductory provisions.

Subsec. (a)(5)(D). Pub. L. 117-180, §3002(a)(5), substituted “2023 through 2027” for “2018 through 2022” in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 117-180, §3002(b)(1)(A), substituted “2023” for “2018” in heading and “2023” for “2018” and “\$582,500,000” for “\$493,600,000” in text.

Subsec. (b)(1)(B). Pub. L. 117-180, §3002(b)(1)(B), amended subpar. (B) generally. Prior to amendment, text read as follows: “For each of the fiscal years 2019 through 2022, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to \$493,600,000, as adjusted pursuant to subsection (c).”

Subsec. (b)(2)(C). Pub. L. 117-180, §3002(b)(2)(A), substituted “twenty-four percent” for “one-third the amount”.

Subsec. (b)(2)(D). Pub. L. 117-180, §3002(b)(2)(B), substituted “Six percent” for “Seven percent”.

Subsec. (b)(2)(E)(i). Pub. L. 117-180, §3002(b)(2)(C), substituted “Thirty-six percent” for “Thirty-five percent”.

Subsec. (c)(1). Pub. L. 117-180, §3002(c)(1)(A), in introductory provisions, substituted “2024” for “2019” and “to equal the base revenue amount for the fiscal year (as specified in subsection (b)(1)(B)(ii) multiplied” for “to equal the product of the total revenues established in such notice for the prior fiscal year multiplied”.

Subsec. (c)(1)(C). Pub. L. 117-180, §3002(c)(1)(B), substituted “Washington-Arlington-Alexandria, DC-VA-MD-WV” for “Washington-Baltimore, DC-MD-VA-WV”.

Subsec. (c)(2), (3). Pub. L. 117-180, §3002(c)(2), added pars. (2) and (3) and struck out former par. (2) which provided for increases in fees in fiscal year 2022 if needed to provide for not more than 3 months of operating reserves for the first 3 months of fiscal year 2023.

Subsec. (d)(1). Pub. L. 117-180, §3002(d), substituted “2023 through 2027” for “2018 through 2022” in heading and “later than 60 days before the first day of each of fiscal years 2023 through 2027” for “more than 60 days before the first day of each of fiscal years 2018 through 2022” in text.

Subsec. (e)(2). Pub. L. 117-328, §3625(c)(1), substituted “379j-41(12)(C) of this title” for “379j-41(11)(C) of this title”.

Subsec. (g)(3). Pub. L. 117-180, §3002(e), struck out “and prior approval supplement fee” after “application fee” in heading.

Subsec. (i)(2)(A)(ii). Pub. L. 117-328, §3625(c)(2)(A), 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. (i)(2)(B). Pub. L. 117-328, §3625(c)(2)(B), substituted “as described in subclause (I) or (II) of such subparagraph, as applicable,” for “for human generic activities”.

Subsec. (i)(3). Pub. L. 117-180, §3002(f), substituted “fiscal years 2023 through 2027” for “fiscal years 2018 through 2022”.

2017—Subsec. (a). Pub. L. 115-52, §303(a)(1), substituted “fiscal year 2018” for “fiscal year 2013” in introductory provisions.

Subsec. (a)(1)(E). Pub. L. 115-52, §303(a)(2), added subpar. (E).

Subsec. (a)(2)(C). Pub. L. 115-52, §303(a)(3)(A), amended subpar. (C) generally. Prior to amendment, subpar. (C) related to publication of notice for fiscal years 2013 to 2017.

Subsec. (a)(2)(E)(i). Pub. L. 115-52, §303(a)(3)(B)(i), substituted “on the earlier of—” for “no later than”, inserted subcl. (I) designation before “the date”, substituted “; or” for period at end, and added subcl. (II).

Subsec. (a)(2)(E)(ii)(I). Pub. L. 115-52, §303(a)(3)(B)(ii), substituted “notice provided for in subparagraph (C)” for “notice provided for in clause (i) or (ii) of subparagraph (C), as applicable”.

Subsec. (a)(3). Pub. L. 115-52, §303(a)(4)(A), struck out “and prior approval supplement” after “application” in heading.

Subsec. (a)(3)(A). Pub. L. 115-52, §303(a)(4)(B), struck out “or a prior approval supplement to an abbreviated new drug application” after “application”.

Subsec. (a)(3)(B), (C). Pub. L. 115-52, §303(a)(4)(C), amended subpars. (B) and (C) generally. Prior to amendment, subpars. (B) and (C) related to notice for fiscal years 2013 to 2017 and fee due dates, respectively.

Subsec. (a)(3)(D). Pub. L. 115-52, §303(a)(4)(D), inserted in heading “, is withdrawn prior to being received, or is no longer received” after “received” and in text substituted cls. (i) and (ii) for “The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 355(j)(5)(A) of this title for a cause other than failure to pay fees.”

Subsec. (a)(3)(E). Pub. L. 115-52, § 303(a)(4)(E), struck out “or prior approval supplement” after “new drug application”.

Subsec. (a)(3)(F). Pub. L. 115-52, § 303(a)(4)(F), substituted “2017” for “2012” and “subsection (d)(2)” for “subsection (d)(3)” in introductory provisions.

Subsec. (a)(4)(A). Pub. L. 115-52, § 303(a)(5)(A)(i), substituted “in at least one generic drug submission that is” for “, or intended to be identified, in at least one generic drug submission that is pending or” in introductory provisions.

Subsec. (a)(4)(A)(i). Pub. L. 115-52, § 303(a)(5)(A)(ii), substituted “in at least one generic drug submission that is” for “or intended to be identified in at least one generic drug submission that is pending or”.

Subsec. (a)(4)(A)(ii). Pub. L. 115-52, § 303(a)(5)(A)(iii), substituted “is identified in at least one generic drug submission in which the facility is approved to produce one or more active pharmaceutical ingredients or in a Type II active pharmaceutical ingredient drug master file referenced in at least one such” for “produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a”.

Subsec. (a)(4)(A)(iii). Pub. L. 115-52, § 303(a)(5)(A)(i), (iv), substituted “in at least one generic drug submission that is” for “, or intended to be identified, in at least one generic drug submission that is pending or” and “only to the fee attributable to the manufacture of the finished dosage forms” for “to fees under both such clauses”.

Subsec. (a)(4)(C), (D). Pub. L. 115-52, § 303(a)(5)(B), amended subpars. (C) and (D) generally. Prior to amendment, subpars. (C) and (D) related to notice and fee due date for fiscal years 2013 to 2017, respectively.

Subsec. (a)(5), (6). Pub. L. 115-52, § 303(a)(6), (7), added par. (5) and redesignated former par. (5) as (6).

Subsec. (b)(1)(A). Pub. L. 115-52, § 303(b)(1)(A), substituted “2018” for “2013” in heading and “2018” for “2013” and “\$493,600,000” for “\$299,000,000” in text and struck out at end “Of that amount—

“(i) \$50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

“(ii) \$249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).”

Subsec. (b)(1)(B). Pub. L. 115-52, § 303(b)(1)(B), substituted “2019 through 2022” for “2014 through 2017” in heading and “2019 through 2022” for “2014 through 2017”, “paragraphs (2) through (5)” for “paragraphs (2) through (4)”, and “\$493,600,000” for “\$299,000,000” in text.

Subsec. (b)(2). Pub. L. 115-52, § 303(b)(2)(A), substituted “such paragraph for a fiscal year” for “paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017” and “through (5)” for “through (4)” in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 115-52, § 303(b)(2)(B), substituted “Five percent” for “Six percent”.

Subsec. (b)(2)(B), (C). Pub. L. 115-52, § 303(b)(2)(C), amended subpars. (B) and (C) generally. Prior to amendment, subpars. (B) and (C) read as follows:

“(B) Twenty-four percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

“(C) Fifty-six percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than \$15,000 and not more than \$30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between

inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.”

Subsec. (b)(2)(D). Pub. L. 115-52, § 303(b)(2)(D), substituted “Seven percent” for “Fourteen percent”, “\$15,000” for “not less than \$15,000 and not more than \$30,000”, and “possessions.” for “possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.”

Subsec. (b)(2)(E). Pub. L. 115-52, § 303(b)(2)(E), added subpar. (E).

Subsec. (c)(1). Pub. L. 115-52, § 303(c)(1), substituted “2019” for “2014” and inserted “to equal the product of the total revenues established in such notice for the prior fiscal year multiplied” after “a fiscal year,” in introductory provisions and struck out concluding provisions which read as follows: “The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.”

Subsec. (c)(2). Pub. L. 115-52, § 303(c)(2), substituted “2022” for “2017” in two places, substituted “the first 3 months of fiscal year 2023” for “the first 3 months of fiscal year 2018”, and struck out “Such fees may only be used in fiscal year 2018.” before “If such an adjustment”.

Subsec. (d)(1). Pub. L. 115-52, § 303(d)(1), added par. (1) and struck out former par. (1) which related to setting fees for fiscal year 2013.

Subsec. (d)(2), (3). Pub. L. 115-52, § 303(d), redesignated par. (3) as (2), substituted “fee under paragraph (1)” for “fees under paragraphs (1) and (2)” in introductory provisions, and struck out former par. (2) which related to setting fees for fiscal years 2014 through 2017.

Subsec. (e). Pub. L. 115-52, § 905(b)(3), substituted “Limitations” for “Limit” in heading, designated existing provisions as par. (1) and inserted heading, and added par. (2).

Subsec. (f)(1). Pub. L. 115-52, § 303(e)(3), substituted “paragraph (3)” for “paragraph (4)” and “Such information shall, for each fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous fiscal year.” for “Such information shall—

“(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

“(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous year.”

Pub. L. 115-52, § 303(e)(1), (2), redesignated par. (2) as (1) and struck out former par. (1). Prior to amendment, text of par. (1) read as follows: “Not later than October 1, 2012, the Secretary shall publish in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph (4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.”

Subsec. (f)(2). Pub. L. 115-52, § 303(e)(4)(A), (B), substituted “Information required to be submitted” for “Contents of notice” in heading and “paragraph (1)” for “paragraph (2)” in introductory provisions.

Pub. L. 115-52, § 303(e)(2), redesignated par. (3) as (2). Former par. (2) redesignated (1).

Subsec. (f)(2)(A). Pub. L. 115-52, § 303(e)(4)(C), struck out “or intended to be identified” after “facility identified”.

Subsec. (f)(2)(F). Pub. L. 115-52, § 303(e)(4)(D)–(F), added subpar. (F).

Subsec. (f)(3), (4). Pub. L. 115-52, § 303(e)(2), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (g)(1). Pub. L. 115-52, § 303(f)(1), inserted at end “This paragraph shall cease to be effective on October 1, 2022.”

Subsec. (g)(2)(C)(ii). Pub. L. 115-52, §303(f)(2), substituted “of section 355(j)(5)(A)” for “of 355(j)(5)(A)”.

Subsec. (g)(5). Pub. L. 115-52, §303(f)(3), added par. (5).

Subsec. (h)(2). Pub. L. 115-52, §303(g), struck out “for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities” after “in the rate.”

Subsec. (i)(2)(A)(i). Pub. L. 115-52, §303(h)(1)(A), substituted “subparagraph (C)” for “subparagraphs (C) and (D)”.

Subsec. (i)(2)(C). Pub. L. 115-52, §303(h)(1)(B), (D), redesignated subpar. (D) as (C) and struck out former subpar. (C). Prior to amendment, text of subpar. (C) 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. (i)(2)(D). Pub. L. 115-52, §303(h)(1)(D), redesignated subpar. (D) as (C).

Pub. L. 115-52, §303(h)(1)(C), struck out “in subsequent years” after “payments” in heading and “(after fiscal year 2013)” after “fiscal year” in text.

Subsec. (i)(3). Pub. L. 115-52, §303(h)(2), substituted “fiscal years 2018 through 2022” for “fiscal years 2013 through 2017”.

Subsec. (o). Pub. L. 115-52, §303(i), added subsec. (o).

2012—Subsec. (a). Pub. L. 112-193, §2(b)(2), inserted “for such year” after “obligation of fees” wherever appearing.

Subsec. (i)(2)(C). Pub. L. 112-193, §2(b)(3), inserted comma after “September 30, 2013” and struck out comma after “for fiscal year 2013”.

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 303 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

Section ceases to be effective Oct. 1, 2027, see section 3004(a) of Pub. L. 117-180, set out as a note under section 379j-41 of this title.

Section effective Oct. 1, 2012, with fees under this section and section 379j-41 of this title to be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after Oct. 1, 2012, see section 305 of Pub. L. 112-144, set out as a note under section 379j-41 of this title.

FEES AUTHORIZED FOR FISCAL YEAR 2013

Pub. L. 112-193, §2(c), Oct. 5, 2012, 126 Stat. 1443, provided that:

“(1) Notwithstanding section 744B(a)(2)(E)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-42(a)(2)(E)(ii)), the fee authorized under section 744B(a)(2) of such Act for fiscal year 2013 shall be due 30 calendar days after publication of the notice provided for in section 744B(a)(2)(C)(i) of such Act.

“(2) Notwithstanding section 744B(a)(3)(C)(ii) of such Act, the fee authorized under section 744B(a)(3) of such Act for fiscal year 2013 shall be due on the later of—

“(A) the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies; or

“(B) 30 calendar days after publication of the notice referred to in section 744B(a)(3)(B)(i) of such Act.

“(3) Notwithstanding section 744B(a)(4)(D)(i) of such Act, the fee authorized under section 744B(a)(4) of such Act for fiscal year 2013 shall be due not later than 45 days after the publication of the notice under section 744B(a)(4)(C)(i) of such Act.”

§ 379j-43. 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 301(b)¹ of the Generic Drug User Fee Amendments of 2022 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(2) 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) 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 human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b)¹ of the Generic Drug User Fee Amendments of 2022.

(ii) The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b)¹ of the Generic Drug User Fee Amendments of 2022.

(3) Rationale for GDUFA program changes

The Secretary shall include in the annual report under paragraph (1)—

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 379j-42 of this title, and the number of full time equivalents funded by

¹ See References in Text note below.