

(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) insofar as those activities relate to abbreviated new drug applications.

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

(G) Regulatory science activities related to generic drugs.

(9) The term “positron emission tomography drug” has the meaning given to the term “compounded positron emission tomography drug” in section 321(ii) of this title, except that paragraph (1)(B) of such section shall not apply.

(10) The term “prior approval supplement” means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

(11) The term “resources allocated for human generic drug activities” means the expenses 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 and employees 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 subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

(12) The term “Type II active pharmaceutical ingredient drug master file” means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

(June 25, 1938, ch. 675, §744A, as added Pub. L. 112-144, title III, §302, July 9, 2012, 126 Stat. 1008.)

TERMINATION OF SECTION

For termination of section by section 304(a) of Pub. L. 112-144, see Effective and Termination Dates note set out below.

REFERENCES IN TEXT

Section 357 of this title, referred to in par. (1)(A), was repealed by Pub. L. 105-115, title I, §125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

The Drug Price Competition and Patent Term Restoration Act of 1984, referred to in par. (1)(A), is Pub. L. 98-417, Sept. 24, 1984, 98 Stat. 1585. For complete classification of this Act to the Code, see Short Title of 1984 Amendment note set out under section 301 of this title and Tables.

EFFECTIVE AND TERMINATION DATES

Pub. L. 112-144, title III, §304(a), July 9, 2012, 126 Stat. 1024, provided that: “Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-41, 379j-42], as added by section 302 of this Act, shall cease to be effective October 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.”

FINDING

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 2013, 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).

(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

(i) Fiscal year 2013

Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

(ii) Fiscal year 2014 through 2017

Not later than 60 days before the start of each of fiscal years 2014 through 2017, 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 no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

(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 clause (i) or (ii) of subparagraph (C), as applicable; 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 and prior approval supplement filing fee

(A) In general

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

(B) Notice

(i) Fiscal year 2013

Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

(ii) Fiscal years 2014 through 2017

Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(C) Fee due date

(i) In general

Except as provided in clause (ii), 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.

(ii) Special rule for 2013

For fiscal year 2013, such fees shall be due on the later of—

(I) the date on which the fee is due under clause (i);

(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

(III) if an appropriations Act is not enacted providing for the collection and

obligation of fees for such year under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.

(D) Refund of fee if abbreviated new drug application is not considered to have been received

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.

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

An abbreviated new drug application or prior approval supplement 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, 2012, shall pay a fee, in the amount determined under subsection (d)(3), 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, or intended to be identified, in at least one generic drug submission that is pending or 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 or intended to be identified in at least one generic drug submission that is pending or 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 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 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, or intended to be identified, in at least one generic drug submission that is pending or 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 to fees under both such clauses for that facility.

(B) Amount

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

(C) Notice

(i) Fiscal year 2013

For fiscal year 2013, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

(ii) Fiscal years 2014 through 2017

Within the timeframe specified in subsection (d)(2), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(D) Fee due date

(i) Fiscal year 2013

For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

(I) not later than 45 days after the publication of the notice under subparagraph (B); or

(II) if an appropriations Act is not enacted providing for the collection and obligation of fees for such year under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

(ii) Fiscal years 2014 through 2017

For each of fiscal years 2014 through 2017, 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) 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 2013

For fiscal year 2013, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of \$299,000,000. 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).

(B) Fiscal years 2014 through 2017

For each of the fiscal years 2014 through 2017, fees under paragraphs (2) through (4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to \$299,000,000, as adjusted pursuant to subsection (c).

(2) Types of fees

In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017, such fees shall be derived from the fees under paragraphs (2) through (4) of subsection (a) as follows:

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

(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.

(D) Fourteen 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 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, including 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 and its territories and possessions and those located outside of the United States and its territories and possessions.

(c) Adjustments

(1) Inflation adjustment

For fiscal year 2014 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, 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-Baltimore, DC-MD-VA-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.

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.

(2) Final year adjustment

For fiscal year 2017, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for

the first 3 months of fiscal year 2018. Such fees may only be used in fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

(d) Annual fee setting

(1) Fiscal year 2013

For fiscal year 2013—

(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the abbreviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

(B) the Secretary shall establish, not later than 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

(2) Fiscal years 2014 through 2017

Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval supplement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

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

In establishing the fees under paragraphs (1) and (2), 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) Limit

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.

(f) Identification of facilities

(1) Publication of notice; deadline for compliance

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.

(2) 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 (4) shall submit to the Secretary the information required under this subsection each year. 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.

(3) Contents of notice

At a minimum, the submission required by paragraph (2) shall include for each such facility—

(A) identification of a facility identified or intended to be 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; and

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

(4) 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.

(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 355(j)(5)(A) of this title.

(3) Abbreviated new drug application fee and prior approval supplement 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) Nonreceipt 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) Nonreceipt

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.

(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, 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 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 subparagraphs (C) and (D), 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 for a fiscal year beginning after fiscal year 2012 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 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 for human generic activities are not more than 10 percent below the level specified in such subparagraph.

(C) Fee collection during first program year

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

(D) Provision for early payments in subsequent years

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

(3) Authorization of appropriations

For each of the fiscal years 2013 through 2017, 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 per-

son 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.

(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.)

TERMINATION OF SECTION

For termination of section by section 304(a) of Pub. L. 112-144, see Effective and Termination Dates note below.

AMENDMENTS

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”.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2017, see section 304(a) of Pub. L. 112-144, 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

Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) Fiscal report

Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

- (A) the Committee on Energy and Commerce of the House of Representatives;
- (B) the Committee on Health, Education, Labor, and Pensions of the Senate;
- (C) scientific and academic experts;
- (D) health care professionals;
- (E) representatives of patient and consumer advocacy groups; and
- (F) the generic drug industry.

(2) Prior public input

Prior to beginning negotiations with the generic drug industry on the reauthorization of this subpart, the Secretary shall—

- (A) publish a notice in the Federal Register requesting public input on the reauthorization;
- (B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and