2010 unless the amount of the total appropriations for food safety activities at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) is equal to or greater than the amount of appropriations for food safety activities at the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year), multiplied by the adjustment factor under paragraph (3).

(2) Authority

If—

(A) the Secretary does not assess fees under subsection (a) for a portion of a fiscal year because paragraph (1) applies; and

(B) at a later date in such fiscal year, such paragraph (1) ceases to apply,

the Secretary may assess and collect such fees under subsection (a), without any modification to the rate of such fees, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(3) Adjustment factor

(A) In general

The adjustment factor described in paragraph (1) shall be the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year, but in no case shall such adjustment factor be negative.

(B) Compounded basis

The adjustment under subparagraph (A) made each fiscal year shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2009.

(4) Limitation on amount of certain fees

(A) In general

Notwithstanding any other provision of this section and subject to subparagraph (B), the Secretary may not collect fees in a fiscal year such that the amount collected—

(i) under subparagraph (B) of subsection (a)(1) exceeds $20,000,000; and

(ii) under subparagraphs (A) and (D) of subsection (a)(1) exceeds $25,000,000 combined.

(B) Exception

If a domestic facility (as defined in section 350d(b) of this title) or an importer becomes subject to a fee described in subparagraph (A), (B), or (D) of subsection (a)(1) after the maximum amount of fees has been collected by the Secretary under subparagraph (A), the Secretary may collect a fee from such facility or importer.

(d) Crediting and availability of fees

Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the operating expenses of the Food and Drug Administration employees and contractors performing activities associated with these food safety fees.

(e) Collection of fees

(1) In general

The Secretary shall specify in the Federal Register notice described in subsection (b)(1) the time and manner in which fees assessed under this section shall be collected.

(2) Collection of unpaid fees

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

(f) Annual report to Congress

Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for each such year and a summary description of the entities paying such fees and the types of business in which such entities engage.

(g) Authorization of appropriations

For fiscal year 2010 and each fiscal year thereafter, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under the other provisions of this section.

(June 25, 1938, ch. 675, §743, as added Pub. L. 111–353, title I, §107(a), Jan. 4, 2011, 124 Stat. 3906.)

CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

SUBPART 7—FEES RELATING TO GENERIC DRUGS

§ 379j–41. Definitions

For purposes of this subpart:

(1) The term ''abbreviated new drug application''—

(A) means an application submitted under section 355(j) of this title, an abbreviated application submitted under section 357 of this title (as in effect on the day before November 21, 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

(B) does not include an application for a positron emission tomography drug.

(2) The term ''active pharmaceutical ingredient'' means—

(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

(i) to be used as a component of a drug; and

(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

(3) The term ''adjustment factor'' means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

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

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

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

(5)(A) The term ''facility''—

(i) means a business or other entity—

(I) under one management, either direct or indirect; and

(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

(i) closely related to the same business enterprise;

(ii) under the supervision of the same local management; and

(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

(6) The term ''finished dosage form'' means—

(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

(7) The term ''generic drug submission'' means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

(8) The term ''human generic drug activities'' means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

(B) The issuance of—

(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The issuance of letters related to Type II active pharmaceutical drug master files which—

(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

(ii) document that no deficiencies need to be addressed.

(D) Inspections related to generic drugs.

(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

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

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

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